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Medical Technologies Advisory Committee – 19 September 2024

One-piece closed bags for adults with a colostomy

The following documents are made available to the Committee:

- 1.** Final Scope
- 2.** Assessment Report Overview
- 3.** Updated External Assessment Report produced by Peninsula Technology Assessment Group, University of Exeter
- 4.** External Assessment Report consultation comments and responses
- 5.** User Preference Report
- 6.** Patient Organisation submissions

Late-stage assessment

GID-HTE10045 One-piece closed bags for adults with a colostomy

Final scope

1 Introduction

The topic has been identified for late-stage assessment (LSA) by NICE, in collaboration with the Department of Health and Social Care. LSA aims to assess technologies that are in widespread or established use in the NHS. Over time, technologies often undergo continuous or incremental innovation and adaptation. LSA will assess if the value added by incremental innovation justifies any price variation. It will ensure that patient and system benefits are maximised and support procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.

The technologies identified for this assessment are 1-piece closed bags available for prescription in primary and community care in the NHS. The evaluation will assess the clinical and economic benefits of 1-piece closed bags for people with a colostomy, as well as evaluating how product features impact outcomes and user preference.

This scope is limited to publicly available sources of information.

Population

Colostomy surgery is an operation to divert 1 or both ends of the colon through an opening in the abdomen ([NHS, 2020](#)). This opening is called a stoma. A bag (also known as a pouch or appliance) can be placed over the stoma to collect bodily waste (faeces). A colostomy may be needed to treat a variety of conditions or diseases. It is estimated that there are over 200,000 people with a stoma in the UK ([Colostomy UK, 2024](#)). [Open Prescribing](#)

reports that 1-piece closed bags were prescribed on 428,464 prescriptions in England between February 2023 to January 2024, costing the NHS £92 million.

Current management

Colostomy surgery is recommended by NICE as a potential treatment option for:

- people with colorectal cancer,
- people with diverticular perforation or complicated acute diverticulitis,
- and people with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options have been considered.

Colostomy surgery may also be needed during the treatment of other conditions including, but not limited to, anal cancer, vaginal or cervical cancer, ovarian cancer, Crohn's disease, endometriosis, Hirschsprung's disease, birth defects or trauma. A full list of related NICE guidance is listed in [Appendix A](#) of this document. Colostomy surgery may be temporary and can be reversed, or it can be permanent. People with a permanent stoma are entitled to receive prescriptions of stoma supplies for free ([Colostomy UK, 2024](#)).

A clinical nurse specialist (CNS) in stoma care will perform colostomy siting assessments before colostomy surgery to ensure the stoma is in the most appropriate location for each person. This may not always happen for emergency colostomy surgeries. A CNS in stoma care will perform further assessments after colostomy surgery to ensure that the most appropriate bag is prescribed.

Some people with a colostomy will experience complications ([Burch, 2021](#)). Common issues are bag leakage and peristomal skin complications which can be painful and difficult to manage. Other stoma-related complications include constipation, diarrhoea, infection, ischaemia, dehydration, retraction, mucocutaneous separation, parastomal hernia, prolapse, stenosis and stricture. Some bags may have specific features to help prevent or reduce the impact of stoma-related complications. For example, parastomal hernias may

be managed by the appropriate bag or with additional support wear. Occasionally people may need surgery to repair the hernia or prevent it worsening. [NICE's interventional procedures guidance recommends reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia](#) provided special arrangements are in place for clinical governance, consent, and audit or research.

Colostomy surgery and related complications can also negatively impact a person's psychological and emotional health due to changes in bodily function, body image, activity, and personal care needs. Trying to adapt to these changes could impact a person's social life, work life, personal and sexual relationships and general quality of life ([Black and Notter, 2021](#)). A Coloplast funded report ([Advancing Stoma Care Services: evidence-based proposals for a best practice pathway](#)) notes that a person's confidence in creating and maintaining a leak free seal when using their bag is key to successful management and maintaining quality of life.

Typically, when a person has undergone colostomy surgery and is discharged from hospital, a CNS in stoma care recommends the type of bag that should be used. Initial bag selection may be based on multiple factors, including the person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output and a person's manual dexterity ([Bowles et al, 2022](#)). As a person's colostomy wound heals after surgery, or if they experience issues with their colostomy, they may need to try alternative products to find a more suitable bag. In some cases, a person may be recommended supporting products (such as skin fillers, adhesive rings or belts) to make the bag more usable and secure. [The Association of Stoma Care Nurses UK National Clinical Guidelines](#) states that CNS in stoma care should select and initiate the most appropriate bag without pressure from the sponsoring company, ensuring patients have complete freedom of choice for bag and prescription options. It states that only stoma products listed in parts IXA and IXC of the Drug Tariff should be given. The guideline notes that on average, 1-piece closed bags are changed 1 to 3 times a day, and that bags

with a convex baseplate should only be used when clinically appropriate and on the recommendation of a CNS in stoma care.

The level of involvement for people with a colostomy in the decision-making process related to bag choice may vary across services ([Bowles, 2022](#)).

[NICE's guideline on shared decision-making](#) highlights that people have the right to make informed decisions about their care and should understand the choices available to them.

The CNS in stoma care also identifies a local dispensing appliance contractor (DAC) or community pharmacy as options for the collection or delivery of bags in the future. The majority of people with a colostomy get their bags from a local DAC, and only a small number of people will get bags from community pharmacies. Stock levels and bag availability is managed by the DAC or community pharmacy, and costs are only incurred by the NHS once products have been dispensed.

A CNS in stoma care will continue to provide ongoing physical and psychological support to people living with a colostomy. Periodically, or in response to stoma complications an appliance use review may be done by a community pharmacy contractor or a nurse working with a DAC. [The Association for Stoma Care Nurses stoma care nursing standards and audit tool for the newborn to elderly \(2021\)](#) says that appliance use reviews should be offered on an annual basis to support appropriate use and good prescribing practice. Regular appliance use reviews can reduce the number of people lost to follow-up, help people to ensure that they are using the most suitable bag, allow monitoring of prescription requests and reduce product waste. But, they are not conducted consistently in all areas of England.

[Advancing Stoma Care Services: evidence-based proposals for a best practice pathway](#) highlights the significant variation for the provision and funding of care, support and follow-ups in stoma care services across the country and how this impacts product use as well as quality of life for people with a stoma. The report highlights the need for a standardised, patient-centred care pathway to better meet the needs of people living with a stoma.

2 Technologies

This section describes the NHS market for 1-piece closed bags as well as information on their purpose and properties based on information provided to NICE by companies and experts, and information available in the public domain.

2.1 Current NHS market for the technologies

In community and primary care, 1-piece closed bags are supplied using an NHS prescription for technologies listed in Part IXC of the [Drug Tariff](#) under the 'colostomy bag' subgroup. In secondary care, 1-piece closed bags are purchased through NHS Supply Chain or given to hospitals free of charge by companies.

Approximately 80% of hospitals in England have a formal sponsorship agreement (awarded via an NHS tender process) in place with stoma appliance suppliers or manufacturers ([Kettle, 2019](#)). With these agreements in place, companies may provide funding for stoma care services including clinical nurse specialists (CNS) in stoma care. Hospitals without a formal sponsorship agreement may have non-formal agreements with companies which may include IT system provision, CNS in stoma care honorary contracts, service level agreements or admin support. Most dispensing appliance contractors (DACs) are linked to specific companies, and community-based nurses may also be sponsored or have relationships with specific DACs.

Currently, there are over 15 companies listed as supplying 'colostomy bags' in Part IXC of the Drug Tariff. But, the majority of the market share comes from only a small number of these companies, based on a local stoma care quality improvement report ([Kettle, 2019](#)). Some products listed may be from older ranges and only used by a small number of people who do not wish to switch to a newer bag.

Manufacturers or suppliers submit applications for each product or product range they wish to include in Part IX of the Drug Tariff using [the guidance](#)

[provided](#). Part IX of the Drug Tariff is currently undergoing consultation and the guidance for manufacturers or suppliers may be updated to reflect any changes. Technologies must meet the following criteria to be included:

- the products are safe and of good quality (companies are responsible for ensuring their technologies comply with the relevant UK legislation)
- they are appropriate for GP and, if relevant, prescribing by appropriate practitioners
- they are cost effective.

The price of the technology may be similar to the closest comparator technology listed, or an applicant may seek an alternative price with justification as to why their technology is different to other listed technologies. Reasons could include change in patient benefit or changes to overall cost or impact to NHS (such as reduced staff time or increased product durability). Once added to the tariff, companies may seek price rises for a particular product once a year or at longer intervals (with the price rise being equivalent to annual price rises). Companies should inform NHS Prescription Services of a proposed change or deletion of a product listing in Part IX of the Drug Tariff.

Prices of technologies are listed in Part IX of the Drug Tariff. The price for 1-piece closed bags with a flat baseplate ranges from £1.85 to £3.84 per bag. The price for 1-piece closed bags with a convex baseplate ranges from £2.05 to £3.61 per bag. In addition to the cost of the technologies listed, additional fees can be claimed by suppliers such as dispensing fees and customisation fees (for example, for personalisation of cut-to-fit products).

Local stoma care quality improvement programmes, such as the StoMap programme in the East of England ([Kettle, 2019](#)) have highlighted the need for reduced product price variation and a national pricing strategy for all products to ensure fair and best value pricing for both trusts and integrated care boards (ICBs). It has also been reported that a potentially effective way of reducing the cost of stoma care is finding the appropriate bag for a person, reducing wastage and the need for supporting products ([Bird, 2017](#)).

Description of the technologies

Bags for people with a colostomy are made up of a baseplate that attaches to the skin around the stoma, and a bag that collects bodily waste (faeces). Baseplates are generally made from hydrocolloids, are adhesive and can contain additives designed to promote skin health. Generally, people with a colostomy will use a closed bag which are removed and disposed of after each use and more suitable for people with formed faeces and a less frequent output. Bags can also come as 1-piece or 2-piece systems. One-piece systems have the baseplate and bag joined together, whereas 2-piece systems allow the bag to be removed while the baseplate is separate and remains around the stoma between bag changes. As the majority of people with a colostomy use 1-piece bags, these products are the focus of this assessment.

The baseplate of 1-piece closed bags can be flat, convex or concave to suit different body shapes and can be made of different materials. Convex baseplates may be beneficial for people with a retracted stoma, telescoping stoma or people experiencing leakage. Convexity depth and firmness varies, so an assessment for these bags by a CNS stoma care is needed before use. Concave baseplates may be beneficial for people with curves, bulges or hernias around their stoma. Baseplates may have different types of adhesives and come in different shapes and sizes to try and improve durability, stop leakage and reduce creasing around the stoma opening. Baseplates can also come in pre-cut or cut-to-fit versions to make sure the bag fits correctly around a person's stoma. Bags come in different sizes (including but not limited to mini, midi and maxi). Bag size may depend on the size of the person, food intake, type of output, the time of day or the type of activity being done. Different colours of bags are often available, and bags may have additional innovative features designed to suit specific needs of the user.

2.2 Technology features

Part IX of the Drug Tariff contains a list of 1-piece closed bags under the 'colostomy bag' subgroup that have been approved by NHS Prescription

Services for prescribing at NHS expense by an appropriate practitioner in primary or community care.

For this assessment NICE will consider all 1-piece closed bags that are currently available for NHS prescription under the 'colostomy bag' subgroup on Part IXC of the Drug Tariff. Although NHS Supply Chain also procure bags for secondary care, the focus of the evaluation will be prescribing for adults in primary care and community care as this is the main area of use for these technologies. Features evaluated in this assessment would be applicable to those technologies listed on NHS Supply Chain. One-piece closed bags designed specifically for newborns or young children and 2-piece ostomy systems will not be included in the assessment.

Technologies available on the drug tariff have the following basic technology requirements.

Basic technology requirements

One-piece closed bags that:

- have a range of baseplate sizes that are either pre-cut or cut-to-fit,
- have different levels of convexity, such as light, soft, flexible, deep or firm (convex bags only)
- have a filter,
- are available in a range of sizes (such as mini, midi or maxi),
- are available in either transparent or opaque,
- are available in various colours,
- and are available with or without a viewing window.

Additional features, adaptations, and potential innovations

- Baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH buffering system)
- Modified baseplate shape (e.g. flower shaped, oval shaped, tapered)
- Modified baseplate adhesive (e.g. to improve adhesion, reduce residue or improve peristomal skin condition)

- Modified bag shape (e.g. to be more discrete or allow water to drain off more easily)
- Modified filters (e.g. to improve gas release or reduce odour)
- Modified material (e.g. to be more discrete, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence)
- Flushable disposal

2.3 Technology user issues and preferences

The number and type of stoma-related complications may mean that users are restricted to or have a strong preference for a specific type of bag compared with another. For example, a person with a parastomal hernia may need to use a bag with a flexible baseplate that can be moulded around the shape of the hernia to reduce the risk of leaking. The number and type of complications may vary over time and people may need to change products multiple times over the course of their life with a colostomy. A person's body shape also changes over time (for example, due to weight loss, weight gain, pregnancy or aging). So, the suitability of a bag, including how it fits, whether it feels secure and whether it is comfortable to wear may also change over time.

Although average number of bags used for people with a colostomy is 1 to 3 per day, some people may need to use more due to their normal output quantity or due to illness. Sometimes a higher number of bag changes could indicate an issue with bag choice and people may need following up to address any underlying issues. Regular appliance use reviews can be done to assess whether the appropriate bag is being used.

If a person has had emergency colostomy surgery, there may not have been time to do a comprehensive pre-surgical assessment for the siting of the stoma. This could mean that certain bags are less suitable and a person may be more likely to try different bags to improve the fit and reduce leakage. Some people also have more than one stoma and need a bag that can fit

comfortably on their abdomen alongside another bag. This may mean that bags of certain sizes or shapes are preferred more than others.

Although companies sponsor hospitals or are linked with specific DACs, CNS in stoma care will have access to a variety of different company's bags. [NHS England's guidance for managing conflicts of interest in the NHS](#) states that sponsored post holders must not promote or favour the sponsor's specific products, and information about alternative products and suppliers should be provided. However, NHS England's commissioned report [Delivering Excellence in Stoma Care \(2020\)](#) highlights that CNS in stoma care receive training on sponsored products and may be the most familiar with bags from the sponsoring company. This can result in users being given sponsored products on discharge and continuing to use these products in the community, potentially impacting user choice.

Engagement in company run open days may also influence user choice. Companies use open days to discuss bags in more detail with users and provide free samples. Some users may also do their own research into which bags they think are most appropriate for their colostomy, increasing the likelihood of trying more bags. The company affiliation of a local DAC or limited formulary of an ICB may restrict choice away from some of the bags offered at open days or identified by users. If a person wanted to use bags that are unavailable from their DAC or local formulary, they may want to pay for the bag themselves ([Bowles, 2022](#)).

Other factors that are important to users may include ease of access, prompt delivery and access to samples to try before committing to repeat prescriptions ([Bowles, 2022](#)). People may stick with their choice of bag if they have few or limited problems such as skin irritation or leaks or may frequently try new bags until they find one which works best. Choice of bag size may be influenced by activity, such as exercise or travel, and colour may be selected to match skin tone or be discrete under clothing.

3 Decision problem

Population	Adults 18 and over with a colostomy that use 1-piece closed bags
Subgroups	If the evidence allows, the following subgroups will be considered: • People with more fragile skin that is prone to tearing such as older people or people with an underlying skin disorder • People with conditions that may impact self-care (such as issues with manual dexterity, mobility and visibility) • People with a non-complex abdominal profile or peristomal anatomy or physiology • People with a complex abdominal profile (including but not limited to a stoma close to bony prominences, abdominal dips or creasing and scarring from prior surgery) • People with complex peristomal anatomy or physiology including but not limited to people with: ○ parastomal hernia or bulging ○ retracted or sunken stoma ○ prolapsed stoma ○ stomal fistula ○ stomal stricture ○ stoma ischaemia ○ peristomal skin conditions ○ large stoma ○ thick faeces prone to pancaking ○ high output stoma ○ stoma positioned close to a wound, mucous fistula or device (such as a suprapubic catheter)
Intervention	One-piece closed bags (flat and convex or concave) with 1 or more of the following features: • baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH buffering system) • modified baseplate shape (e.g. flower shaped, oval shaped, tapered) • modified baseplate adhesive (e.g. to improve adhesion, reduce residue or improve peristomal skin condition) • modified bag shape (e.g. to be more discrete or allow water to drain off more easily) • modified filters (e.g. to improve gas release or reduce odour) • modified material (e.g. to be more discrete, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence) • flushable disposal

Comparator(s)	One-piece closed bags (flat and convex or concave) without any of the features listed in the intervention section that: • have a range of baseplate sizes that are either pre-cut or cut-to-fit, • have different levels of convexity, such as light, soft, flexible, deep or firm (convex bags only) • have a filter, • are available in a range of sizes (such as mini, midi or maxi), • are available in either transparent or opaque, • are available in various colours, • and are available with or without a viewing window.
Healthcare setting	Prescribing in primary and community care
Outcomes	Outcome measures for consideration may include but are not limited to: Intermediate outcomes • Leakage • Length of time before switching bags • Number of appointments with clinical nurse specialists in stoma care • Medicine use (e.g. topical steroids or barrier creams) • Number of or time to ballooning events • Odour control • Supporting product use for attachment and removal (e.g. adhesive removers, flange extenders, belts or underwear, irrigation appliances, skin fillers and skin protectors) • Pancaking events Clinical outcomes • Intervention-related adverse events including but not limited to: ○ Peristomal skin complications (including but not limited to skin excoriation, folliculitis, mucocutaneous separation, infection, allergic reactions, granulomas, pyoderma gangrenosum, psoriasis, erythema, papules, skin erosions, ulcers, vesicles) Patient reported outcomes • Ease of use and acceptability (e.g. bag security, durability, ease of attachment and removal, noise, pain, discomfort or itching, performance in water) • Health-related quality of life • Psychological and social impact Costs and resource use • Cost of the technology

	• Cost of supporting products (e.g. adhesive removers, flange extenders, belts or underwear, irrigation appliances, skin fillers and skin protectors) • Costs of medicines (e.g. topical steroids or barrier creams) • Cost of other resource use including: ○ Health care professional appointments or visits (primary, community and secondary care) ○ Costs associated with managing stoma-related complications, frequency of bag change, waste disposal of excess bags and prescribing and dispensation User preference will be assessed to identify and understand features of the technologies that influence decision making when selecting which technology to use. This is done alongside the assessment of the clinical and economic evidence.
Economic analysis	A health economic model will be developed, where possible, comprising a cost-comparison or cost utility analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

3.1 Potential equality issues or considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People having colorectal surgery may have an underlying condition such as cancer or inflammatory bowel disease. People who have been diagnosed with cancer or chronic diseases may be considered disabled under the Equality Act (2010).

Older people or people with underlying skin conditions may be more likely to have fragile skin that is prone to tearing. They may experience a higher rate of peristomal skin complications due to the continued removal and application of the colostomy bag baseplate. It is also reported that women experience a

higher rate of peristomal skin complications compared with men ([D'Ambrosio, 2023](#)).

Some people may need additional support or may struggle to use certain bags because of a visual or cognitive impairment, reduced manual dexterity or a learning disability. Autistic people may also find certain bags unsuitable or may need additional support. People in a wheelchair, people who are sat for long periods of time or people with excessive sweating, such as people in menopause, may struggle with the durability and security of certain bags.

Colostomy bags are mostly offered in beige, grey or clear. A small number of bags are offered in black. People may prefer choosing a bag that most closely matches their skin tone if this is available.

Age, disability, gender and race are all protected characteristics under the Equality Act (2010).

4 Stakeholders

4.1 Healthcare professional organisations

The following healthcare professional organisations have been identified as stakeholders for this evaluation:

- Association of Stoma Care Nurses
- Association of Coloproctology of Great Britain and Ireland
- British Society of Gastroenterology
- Community and District Nurses Association
- European Crohn's and Colitis Organisation
- Primary Care Society for Gastroenterology
- Royal College of General Practitioners
- Royal College of Nursing

4.2 Patient and carer organisations

NICE's [Public Involvement Programme](#) have identified the following patient and carer organisations for advice:

- Bladder and Bowel Community
- Bladder and Bowel UK
- Bowel Cancer UK
- Colostomy UK
- Crohns' and Colitis UK
- Guts UK
- IBD UK

4.3 Additional non-clinical professional organisations

The following non-clinical professional organisations have been identified as stakeholders for this evaluation:

- British Healthcare Trades Association

5 Authors

Amy Barr and Xia Li

Topic Leads

Charlotte Pelekanou

Topic Adviser

Joanne Heaney

Project Manager

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Appendix A Related NICE Guidance

- [Shared decision-making](#) (2021). NICE guideline NG197.
- [Colorectal cancer](#) (2020, updated 2021). NICE guideline NG151.
- [Diverticular disease: diagnosis and management](#) (2019). NICE guideline NG147.
- [Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent parastomal hernia](#) (2019). Interventional procedures guidance IPG654.
- [Faecal incontinence in adults: management](#) (2007). NICE clinical guideline CG49.

Appendix B Abbreviations

ICB	Integrated care board
DAC	Dispensing appliance contractor
LSA	Late-stage assessment
CNS	Clinical nurse specialist



One-piece closed bags for adults with a colostomy [GID-HTE10045]

EAG final assessment report

Produced by	Peninsula Technology Assessment Group (PenTAG) University of Exeter Medical School
Authors	Caroline Farmer ¹ Val Santo ¹ Alan Lovell ¹ Maxwell S. Barnish ¹ Ahmed Abdelsabour ¹ Jemma Perks ¹ Jenny Lowe ¹ Edward C.F. Wilson ¹ G.J. Melendez-Torres ¹ Dawn Lee ¹ ¹ Peninsula Technology Assessment Group (PenTAG), University of Exeter Medical School, Exeter
Correspondence to	Caroline Farmer 3.09 South Cloisters, St Luke's Campus, Heavitree Road, Exeter, EX1 2LU; c.farmer@exeter.ac.uk
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Author contributions

<i>Caroline Farmer</i>	Clinical evidence lead and project manager. Input into the writing of assessment documents.
<i>Val Santo</i>	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
<i>Alan Lovell</i>	Information Specialist responsible for developing and conducting evidence searches. Clinical evidence review and appraisal. Input into the writing of assessment documents
<i>Maxwell S Barnish</i>	Clinical reviewer with responsibilities for conducting the evidence review and analysis of clinical effectiveness and safety evidence. Input into the writing of assessment documents.
<i>Ahmed Abdelsabour</i>	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
<i>Jemma Perks</i>	Statistician providing support to the clinical and economic reviewers. Responsibilities included data extraction, interpretation and report writing.
<i>Jenny Lowe</i>	Document management expert with responsibilities for supporting the conduct of evidence searches. Administrative support throughout the project.
<i>Edward C.F. Wilson</i>	Health economist with responsibilities for the assessment of economic evidence and the development of the economic analysis. Input into the writing of assessment documents.
<i>G.J. Melendez-Torres</i>	Statistician and clinical evidence reviewer. Responsibilities for conducting analyses of clinical effectiveness evidence. Input into the writing of assessment documents.
<i>Dawn Lee</i>	Project director, economic evidence lead, and guarantor of the EAG assessment. Input into the writing of assessment documents.

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Confidential information

Confidential information contained within this report is shown in Table 1.

Table 1: Confidential information in this report

Brief description	AIC/CIC	Page number(s)	Source
Details and quality assessment of an [REDACTED] study submitted by a manufacturer [REDACTED]	CIC	35, 36, 37, 39, 41, 42, 43, 44, 45, 47, 50, 51, 57, 58, 63, 64, 65, 66, 67, 96, 141, 156, 158, 171, 222, 223, 240	[REDACTED]
Description of an internal company report	AIC	53, 54, 141, 146	Coloplast
Details of a [REDACTED] analysis submitted to the assessment	CIC	74	Alliance Pharmaceuticals
Data on file about the rate of switching between bags supplied by various manufacturers	CIC	91, 92	Hollister; Coloplast, Salts, Clinimed, Alliance, Convatec, Trio health, B.Braun Medical, Bullens Healthcare
Resource and cost data supplied by a manufacturer (Nørtoft 2019 subgroup analysis)	CIC	98, 99, 101, 103, 106, 107, 228, 233	Coloplast
Details of sponsorship arrangements between manufacturers and NHS England	CIC	142, 143	Hollister; Bullens; Alliance Pharmaceuticals
Information provided by NHS Scotland in confidence	CIC	144	NHS Scotland
Description of an internal company report concerning sponsorship arrangements	CIC	145	Coloplast
Description of internal clinical reports	CIC	114, 167, 242, 246, 247	Hollister
Citation of an internal clinical report	CIC	173	Coloplast
Description of a clinical report	AIC	196	Coloplast
Description of an internal clinical report	AIC	176, 242, 247, 248	B. Braun

Abbreviations: CIC, commercial in confidence

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Executive Summary

Introduction

This Late-Stage Assessment (LSA) aimed to investigate the evidence base for the features of 1-piece closed bags for adults with a colostomy to assess whether price variations were justified and whether technologies represented value for money in the NHS. The assessment [protocol](#) outlined the evaluation to be conducted by the External Assessment Group (EAG), in its role as an independent, academic group supporting NICE. This report provides a description of the assessment undertaken by the EAG and its findings.

In brief, the EAG conducted systematic evidence searches to identify and synthesise evidence that provided insight into the clinical and cost effectiveness of 1-piece closed bags for people with a colostomy using the eligibility criteria set in the review protocol. Economic analyses, including the development of a de novo economic model and additional exploratory analyses, were conducted to establish the link between the features of 1-piece closed bags and price. As part of its report, the EAG provided an overview of contextual considerations that surround the assessment of 1-piece closed bags for people with a colostomy. Finally, the implications for decision-makers and for future research are provided.

Clinical and technological evidence

The systematic review of published and unpublished evidence, including information provided by companies that produce 1-piece closed bags for people with a colostomy, identified only five studies that evaluated the clinical effectiveness of 1-piece closed bags for people with a colostomy. These five studies reported outcomes for a total of five 1-piece closed bags currently available on Part IXC of the Drug Tariff. This represented a very small minority of the total number of bags listed on the Drug Tariff. One of the included studies was a confidential, internal company evaluation that has been redacted from the published version of this report. The four other studies were sponsored by one company (Coloplast). The review identified a significant paucity in published evidence for the effectiveness of 1-piece closed bags. While four included studies were crossover randomised controlled trials (cRCTs), the overall evidence base was nevertheless of poor quality, with significant risks of bias that undermined the reliability and validity of the findings.

The combination of paucity of evidence and the methodological limitations with the evidence identified meant that it was neither feasible for the EAG to conduct a meta-analysis (to explore the effectiveness of bags) nor an intervention components analysis (to explore the relationship between bag features and scoped outcomes). The EAG consequently conducted a narrative synthesis to explore potential patterns across the evidence that could be used to draw conclusions and about the clinical effectiveness of bags or bag features. However, due to variation in study designs and a lack of consistency in the outcomes measured across studies, this process was also limited and so the findings were highly speculative.

In general, the narrative synthesis suggested that there were few clear differences in outcomes between 1-piece closed bags that shared potential innovations in the same feature category (e.g. variations in bag shape). Where differences were reported in clinical outcomes, these were not consistent across studies. Other reported differences were related to patient preferences. One study compared 1-piece closed bags that differed in several feature categories and reported some improvement in outcomes between the bags. However, due to inconsistency in the findings and poor overall study quality, these findings were also not particularly conclusive.

In order to augment the evidence base, the EAG sought advice from CNS in stoma care as to whether it would be appropriate to expand the scope for the assessment to include evidence that evaluated 1-piece closed bags in people with an ileostomy. However, due to several perceived differences between people with a colostomy and an ileostomy, feedback from CNS in stoma care was that this approach would not be useful to the assessment. The feedback from CNS in stoma care on this point is presented in Appendix E. The EAG also explored alternative sources of evidence that were not included in the original review, including (1) evidence that evaluated 2-piece closed bags in people with a colostomy, as these bags can share many of the same features as 1-piece closed bags and (2) studies comparing mixed interventions (i.e. a comparison of outcomes with a 1-piece closed bag in comparison with outcomes for a mix of different 1-piece closed bags). There was mixed feedback from CNS in stoma care about the relevance of evidence from 2-piece bags, and the EAG considered that the evidence for mixed interventions was not informative for understanding the effectiveness of potentially innovative features of 1-piece closed bags. This evidence is presented in Appendix J.

Economic evidence and analysis

As described above, the EAG reviewed current evidence and data to establish whether there was a link between potentially innovative features and price. Finding very little of either, the

EAG conducted a decision analysis to estimate the theoretical maximum price the NHS should be willing to pay to completely resolve certain complications associated with stomas and bags, based on NICE's threshold of £20,000 per quality-adjusted life year (QALY) gained. To be cost-effective it would be necessary (but not sufficient) for any bag price to be below this threshold – the sufficient condition is for the price to reflect the effectiveness of a particular bag at reducing the intended complication. Finally, the EAG compared the theoretical maximum prices with the actual prices paid, finding that in many cases these prices will not be cost-effective.

There was a substantial price difference between the cheapest and most expensive bags on the drug tariff, ranging from £1.85 to £3.84. However, there were no reliable data to quantify the cost-effectiveness of specific features or types of bags. Effectiveness data were lacking and did not demonstrate significant impacts on major complications such as peristomal skin complications (PSC) and leaks. Available health economic data were also generally from a mixed population of people with colostomy and ileostomy. The majority of studies used methods outside of the NICE reference case (i.e. vignettes or measures other than EQ-5D) or were poorly reported, with no published data on the impact of many complications on resource use or health-related quality of life (HRQoL).

In its assessment, the EAG pursued a 3-pronged strategy:

1. Assessed the correlation between drug tariff prices and claimed innovative features
2. Calculated the maximum price that would be considered cost-effective based on the NICE reference case (economically justifiable price) for bags that prevented complications impacting on HRQoL and NHS costs
3. Conducted exploratory analysis on studies showing any significant difference in a clinical outcome between bags (n=3) to determine whether price differences were supported by outcome differences.

To calculate the eJP, the EAG simply reversed the equation used to calculate an incremental cost-effectiveness ratio (ICER) in cost-effectiveness analyses, which is the staple of economic evaluation for NICE assessments. Rather than calculating the ICER with known intervention prices and comparing it to NICE's cost-effectiveness threshold, the EAG instead calculated the maximum justifiable intervention price for an intervention that provided specified benefits, converting health outcome gains to costs using the NICE cost-effectiveness threshold. This

approach can be particularly useful when, as was the case here, the cost of a particular feature was not available.

In this assessment, the eJP can be interpreted as the maximum willingness to pay to resolve a particular complication, taking into account the costs and HRQoL impact of the complication and NICE's cost-effectiveness threshold. In other words, the eJP is the maximum cost that could be added to a 'basic' bag in exchange for a bag that completely (or partially) resolves the complication to yield an ICER equal to NICE's cost-effectiveness threshold (or equivalently to yield an incremental net monetary or health benefit of zero).

The maximum eJP for a bag that for a bag which completely eliminates the chance of any one of the complications was £4.24 for a flat bag and £4.69 for a convex bag, though the EAG noted that such complete elimination was unlikely in clinical practice. For a 50% reduction in a single complication, the eJP was £2.01 to £3.00 dependent upon the complication reduced and £2.45 to £3.44 for flat and convex bags, respectively. For a 25% reduction, it was £1.90 to £2.37 and £2.35 and £2.82 for flat and convex bags, respectively. A flat or convex bag simultaneously improving all complications by 25% would be priced lower than the average 2023 bag price (£3.02) and the most expensive bag (£3.84).

The analysis made some optimistic assumptions, such as assuming that all users experienced complications with the cheapest bag, and use of more optimistic estimates for the resource use impact of PSC and leaks. The impact of multiple complications in combination was uncertain but would likely lead to an overestimation when summed. Overall, the analysis indicated that many current bag prices cannot be explained based on HRQoL and resource use impacts alone.

Key model drivers were the unit cost and frequency of healthcare professional (HCP) interactions, the cost of supporting products, and expected QALY gains (i.e. health state utilities associated with experiencing complications and their respective duration/frequency). Future research should collect better data on these key elements. The impact of PSC was the most uncertain, although this may be in part due to there being the most alternate sources of data to test the uncertainty.

The EAG attempted to explore whether the principles of Value Based Procurement¹ were being followed within the prices paid for bags. Exploratory analysis of bag price vs. the presence of features intended to deliver additional benefit showed little association between current pricing and potentially innovative features included in the NICE scope. Only the flushable disposable

feature for flat bags significantly impacted price in regression analysis. There were difficulties in determining which features were an improvement on basic standards. Pricing frameworks based on product features would need clear standards for comparison.

Finally, the analysis did not consider the impact of sponsorship and additional services from manufacturers and DACs, which might affect overall value for NHS patients and taxpayers. In Scotland, ending sponsorship of stoma nurses in 2008 led to lower mean prescription item costs but also, anecdotally, a loss of nursing staff and skills, highlighting the complexity of pricing decisions. However, subsequent advice to the EAG was that prices in Scotland were aligned to those in England in May 2023, [REDACTED].

Key points for decision-makers

The evidence did not appear to be sufficient to support price variation for any of the features considered. This was due to an absence of evidence rather than evidence of no benefit associated with the bag features. In addition, current pricing did not appear to correlate with these features. This was not to say that these features were not of benefit to people with a colostomy.

Given the number of bags purchased by the NHS each year, and the impact of complications on quality of life, the value of information yielded from research in the area could be high relative to the cost of conducting it.

Research recommendations

The EAG identified a series of priority research recommendations related to this assessment. As people with a colostomy are highly varied in their health, demographics, lifestyles and preferences, and need a 1-piece closed bag that is specific to their needs, developing evidence to evaluate the clinical and cost effectiveness of bags has complexities. This is particularly the case due to the lack of robust and validated methods for assessing outcomes important to people with a colostomy, although the NICE user preference assessment conducted as part of this late-stage assessment identified a list of outcomes that were important to people with a colostomy and should be evaluated in future evaluations. Nevertheless, the EAG considered that high quality evidence to evaluate the effectiveness of 1-piece closed bags and their features was feasible and has provided some guidance on this in this report. Evidence was also needed to inform cost effectiveness analyses of 1-piece closed bags, including: the specification of standardised definitions for bag-related complications, on which to specify health states; the

development of robust utility estimates in people with a colostomy and to represent the experience of multiple, concurrent bag-related complications; estimates of healthcare resource use; real world data to understand how 1-piece closed bags are used in clinical practice, such as rates of bag switching. Overall, the EAG considered that there was an unmet treatment need amongst people with a colostomy, in that a significant number of people may be experiencing bag-related complications that have a major impact on their physical and mental health, and their ability to engage fully with their lives. Research to improve outcomes for people with a colostomy would therefore be of significant value.

Abbreviations

Term	Definition
AE	Adverse event
AIC	Academic in confidence
BNF	British National Formulary
CASP	Critical Appraisal Skills Programme
CI	Confidence interval
CIC	Commercial in confidence
CNS	Clinical nurse specialist
CPAP	Continuous positive airway pressure
cRCT	Cluster randomised controlled trial
DAC	Dispensing Appliance Contractor
DET	Discoloration, erosion and tissue overgrowth
DHSC	Department of Health and Social Care
EAG	External Assessment Group
RFI	Request for Information
eJP	Economically justifiable price
GP	General practitioner
HCP	Healthcare professional
HRQoL	Health Related Quality of Life
Inc	Incremental
IPAA	Ileal pouch anal anastomosis
IQR	Interquartile range
LSA	Late-stage assessment
MAUDE	Manufacturer and User Facility Device Experience
MCDA	Multi-criteria decision analysis
MHRA	Medicines & Healthcare products Regulatory Agency
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE HTE	NICE health technology evaluation
NICE QS	NICE quality standard
NR	Not reported
NS	Non-significant
OST	Ostomy skin tool
PIB	Pain itching and bleeding
PICO	Population intervention comparator outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Term	Definition
PSC	Peristomal skin complication
PSSRU	Personal Social Services Research Unit
QALY	Quality-adjusted life year
QoL	Quality of life
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised controlled trial
RFI	Request for Information
RWE	Real-world evidence
SCM	Specialist committee member
SD	Standard deviation
TH	Time horizon
UK	United Kingdom

1. DECISION PROBLEM

The decision problem is described in the [scope](#)² and EAG comments are included in the [protocol](#).³ Following the initiation of the EAG assessment, the following changes and clarifications were made to the decision problem:

- **Additional features of interest included in the evaluated interventions:** Features listed in the NICE scope were not intended to be exhaustive, and as part of its assessment the EAG added an inspection window and sustainable materials to the features considered. An inspection window was considered to be very useful for people with a colostomy and their carers and clinicians to monitor their poo, particularly for people who are adjusting to their colostomy or have a change in their digestive health. The sustainability of bags was added following feedback from specialist committee members (SCMs) that this was a feature of interest to people with a colostomy, although no 1-piece closed bags were identified in the review that included this feature.
- **Removal of the word ‘modified’ from the decision problem:** In the NICE scope, several features of interest were defined as modifications from a more ‘standard’ 1-piece closed bag (e.g. modified baseplate, modified adhesive). Prior to submission of the EAG report, NICE requested that the word “modified” be removed from the features as presented in the decision problem. This was on the basis that there was variation in what might be considered to be ‘basic’ or ‘standard’ features and so it would be difficult to define which features were modifications. The EAG noted that the decision problem and the EAG’s review did not consider all baseplates, adhesives, bag shapes etc, only those that were considered to be potentially innovative and/or potentially associated with increased cost.
- **Change to the assessment comparators:** in the original decision problem, the comparators were 1-piece closed bags without any of the features listed in the intervention section of the decision problem. Following feedback from manufacturers and SCMs to the assessment that it would be challenging to definitively identify any bags as ‘standard’ bags without any potentially innovative features, this requirement was removed from the decision problem. Instead, comparison was to another bag without the feature of interest in the intervention section of the decision problem.
- **Changed understanding of the setting of care:** The setting for the original decision problem was prescribing in either primary or community care and it was noted that

prescriptions would typically be from GPs in primary care. During the assessment, the EAG spoke to several GPs who reported that they were very rarely involved in making treatment decisions for people with a colostomy (though in some areas they may be required to issue prescriptions for bags). In its assessment, the EAG considered that prescriptions for 1-piece closed bags may be issued in primary care, or outsourced to prescribing hubs, but that care for people with a colostomy was largely coordinated and delivered by a clinical nurse specialist (CNS) in stoma care in a secondary care setting or Dispensing Appliance Contractors (DACs).

2. TECHNOLOGIES

Details of the technologies evaluated in this assessment are provided in the [NICE scope](#).¹ At the time of the assessment, 1,506 1-piece closed bags were listed on the NHS Drug Tariff.⁴ As part of its assessment, the EAG sought to characterise the presence of potentially innovative features, as specified in the scope, in 1-piece closed bags available to people with a colostomy in the NHS. The EAG's findings on this were based on information provided by manufacturers or, where information was not available from companies, from information reported in materials included in the EAG's evidence review. The findings are shown in Table 2. Several companies who were invited to participate in the assessment did not engage with NICE and so no request for information (RFI) was received (Jade-Euro-Med, Marlen Healthcare, Peak Medical, Pelican Healthcare, Rocialle Direct). NICE was unable to source contact details for one company (TJ Shannon). Information about the bags manufactured by these companies was therefore taken from publicly available sources. One company (Oakmed) submitted an RFI but did not respond to the EAG's follow-up questions. No information about potentially innovative features was identified for bags manufactured by Jade-Euro-Med or TJ Shannon; while several of these bags appear on the Drug Tariff, zero or very few prescriptions for these bags have occurred within the 12-months prior to this assessment.⁵

The EAG identified the following difficulties in characterising the features of 1-piece closed bags for people with a colostomy:

- Published evidence identified by the EAG contained limited details about the features of each bag from which to make a reliable judgement about the presence or absence of specific features.
- Feedback from SCMs, including company representatives and CNS in stoma care, was that judgements about the potentially innovative nature of bag features may be influenced by several factors including the previous versions of the bag, the length of time the bag had been in use, the features of other bags available in the market, and assumptions about the effects of each feature. Comments to the EAG from one of the manufacturers during factual accuracy checks also noted that sponsorship status of the CNS in stoma care may also affect judgements. This made it challenging for the EAG or for manufacturers to make a determination about whether bag features would be considered potentially innovative and to ensure that fair decisions were made across all bags.

Perhaps reflective of the above two issues, the EAG identified conflicts between the innovative features reported by companies and in information about the bags available in the public domain. To account for this, for the purposes of the assessment, the EAG used the list of features provided by companies where these were supplied, but noted that these judgements may be subject to some uncertainty given the above.

The NICE scope for this assessment distinguished between alternative baseplate shapes that can be used to fit a person's body profile, including the need for bags to fit around a hernia in some people. The NICE scope described these as flat, convex or concave. The EAG were informed that there are products that are mouldable to a person's body, such as the Welland Medical Profile bag, which could also have a concave appearance (based on company feedback) but are not classed under concave branding. Throughout the report, for simplicity and to match the wording in the NICE scope, the EAG retains the terms convex and concave to include bags that are able to mould to these shapes as required. The EAG acknowledges that there are differences in their design as follows:

- **Convex:** A colostomy bag with a convex base means the area around the stoma bulges outward. This type is often used for people whose stoma is recessed or flush with the skin to help improve the seal and promote better drainage into the bag.
- **Concave:** A concave bag, less common, would mean that the surface of the bag base curves inward, which might help fit particular body shapes or skin contours.
- **Mouldable:** A mouldable colostomy bag has a base that can be shaped or adjusted to fit the individual contours of a person's stoma or surrounding skin.

With respect to the decision problem, the EAG noted that some of the available 1-piece closed bags are available as flat, convex or concave, but as this feature is considered to be essential for ensuring a suitable fit of a bag to a person, it was not considered to be an innovative feature for the purposes of the assessment and so was not included as a feature in the table.

The EAG discussed with its clinical experts (two CNS in stoma care) the way in which the features included in the NICE scope were intended to benefit people with a colostomy and the groups of people with a colostomy who might choose a bag with each feature. The views of these experts are shown in Table 3 and represent the opinion of the two experts, which was based on a mix of personal experience and information provided by companies about their bag features. Clinical experts stated that, in some cases, they were uncertain whether the features delivered the benefits that were intended. A comment received by the EAG from a manufacturer

during consultation noted that the addition of features can be problematic in some instances; for example, allergic reaction to baseplate additives.

Table 2: Potentially innovative features of 1-piece closed bags for adults with a colostomy

Flat bags	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Source
Opus naturFit	Y	Y	Y	N	N	Y	N	Y	Company
Confidence Supersoft	N	N	N	N	N	N	N	Y	Company
SuperFlat	N	N	Y	N	Y	N	N	N	EAG ^a
Confidence Gold	N	N	N	N	N	N	N	Y	Company
Dansac Nova 1 Closed bag	N	Y	Y	Y	N	N	N	N	Company
Emperor	N	N	N	N	Y	Y	N	Y	EAG ^a
Microskin bag	N	Y	N	N	N	N	N	N	EAG [†]
Assura inspire	N	Y	Y	Y	Y	Y	N	N	Company
UltraMax Plus	N	N	Y	Y	Y	N	N	N	EAG ^a
Assura	N	Y	Y	N	Y	Y	N	N	Company
ModermaFlex closed bag	N	Y	Y	Y	Y	Y	N	Y	Company
Softima Active	Y	Y	Y	Y	Y	Y	N	Y	Company
Protea Vital with filter	N	Y	N	N	Y	Y	N	Y	Company
Confidence Comfort	N	N	N	N	N	N	N	Y	Company
Softima closed	Y	Y	Y	Y	Y	Y	N	N (only Maxi bags currently)	Company
Primo Hydrocolloid bag	N	N	Y	N	N	N	N	N	EAG [†]
Esteem™+ bag	Y	N	N	N	N	N	N	Y	Company
Trio Genii with Sil2 silicone flange with filter	N	Y	Y	N	N	Y	N	Y	Company
Oakmed Options Alginate bag	Y	N	N	N	N	N	N	N	EAG [†]
Colomate	N	Y	Y	Y	N	N	N	N	EAG ^a
Pelican Platinum	Y	Y	Y	N	N	Y	N	N	EAG ^a
NovaLife 1	N	Y	Y	Y	Y	Y	N	Y	Company
Welland Aura Plus	Y	Y	Y	N	Y	Y	N	Y	Company
Moderma Flex with filter and CeraPlus skin barrier	Y	Y	Y	Y	Y	Y	N	Y	Company
Pelican Modavi	Y	N	N	Y	Y	Y	N	Y	EAG ^a
Confidence Natural Advance	Y	Y	Y	N	N	N	N	Y	Company
NovaLife TRE 1	Y	Y	Y	Y	Y	Y	N	Y	Company
Confidence BE bag	Y	Y	N	Y	Y	Y	N	Y	Company
Welland Aura	Y	N	Y	N	Y	Y	N	Y	Company
FreeStyle Vie	N	N	Y	N	Y	Y	N	Y	Company
Confidence Natural	Y	Y	N	N	N	N	N	Y	Company
SenSura	N	Y	Y	Y	Y	Y	N	Y	Company

One-piece closed bags for adults with a colostomy [GID-HTE10045]: EAG report

Flat bags	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Source
SenSura Mio	N	Y	Y	Y	Y	Y	N	Y	Company
UltraMax Atlas	N	N	Y	Y	Y	N	N	N	EAG ^a
Welland Aura flushable	Y	N	Y	N	Y	Y	Y	N	Company
FreeStyle Vie Flushable	N	N	Y	N	Y	Y	Y	N	Company
Convex/Concave bags	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Source
Softima convex closed bag	Y	Y	Y	Y	Y	Y	N	N	Company
Aura Convex	Y	Y	Y	N	Y	Y	N	Y	Company
Welland Aura profile	Y	Y	Y	N	Y	Y	N	Y	Company
Welland Aura Plus soft convex	Y	Y	Y	N	Y	Y	N	Y	Company
FreeStyle Vie Convex	N	N	Y	N	Y	Y	N	Y	Company
FreeStyle Vie Curvex	N	N	Y	N	Y	Y	N	Y	Company
Assura inspire seal convex	N	Y	Y	Y	Y	Y	N	N	Company
Assura colostomy seal convex bag	N	N	Y	N	Y	Y	N	N	Company
SenSura Mio concave	N	Y	Y	Y	Y	Y	N	Y	Company
SenSura Mio convex (deep/light/soft)	N	Y	Y	Y	Y	Y	N	Y	Company
Esteem™+ Soft Convex	N	N	N	Y	N	N	N	Y	Company
Esteem+ Flex convex	N	N	N	Y	N	N	N	Y	Company
Nova 1 Convex with filter	N	Y	Y	Y	N	N	N	N	Company
NovaLife 1 convex	N	Y	Y	Y	Y	Y	N	Y	Company
ModermaFlex closed convex bag	N	Y	Y	Y	Y	Y	N	Y	Company
NovaLife TRE 1 convex (soft/closed)	Y	Y	Y	Y	Y	Y	N	Y	Company
Moderma Flex convex with filter and CeraPlus skin barrier	Y	Y	Y	Y	Y	Y	N	Y	Company
Oakmed Options Alginate convex	Y	Y	Y	N	N	N	N	N	EAG [†]
Option soft convex	N	N	Y	N	N	N	N	Y	EAG [†]
Confidence BE soft convex bag	Y	Y	Y	Y	Y	Y	N	Y	EAG ^a
Confidence Natural convex bag	Y	N	Y	N	N	N	N	Y	EAG ^a
Opus naturFit convex	Y	Y	Y	N	N	Y	N	Y	EAG ^a
UltraMax Atlas convex (shallow/deep) bag	N	N	Y	Y	Y	N	N	N	EAG ^a
Colomate convex	N	Y	Y	Y	N	N	N	N	EAG ^a
Pelican Modavi convex	Y	N	N	Y	Y	Y	N	Y	EAG ^a
Pelican Platinum convex	Y	Y	Y	N	N	Y	N	N	EAG ^a
Emperor convex	N	N	N	N	Y	Y	N	Y	EAG ^a

† interpretation of RFI; ^a interpretation of publicly available data as no RFI received

Note: No column for sustainability is included as no bags were claimed to have this feature.

Table 3: The anticipated benefits of features of 1-piece closed bags for adults with a colostomy

Potentially innovative features	How are they intended to benefit adults with a colostomy?	Groups of people who may use these
Baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E)	To maintain good skin quality. To prevent skin allergies. To treat skin issues (sore, broken, excoriated skin)	Any person with sensitive skin, allergies, frail skin, skin complications, radiotherapy burns, or people with a complex stoma.
Baseplate shape (e.g. flower shaped, oval shaped, tapered)	To provide a better fit of the bag according to a person's individual body shape, and therefore prevent leakages and popping, and reduce the need for supporting products.	These are designed according to body shape. A different baseplate shape may be indicated for someone with a complex stoma, a hernia, people who are pregnant, or obese. Some people with dexterity issues may find different baseplate shapes easier to use.
Baseplate adhesive (e.g. to improve adhesion, reduce residue or improve peristomal skin condition)	Improved adhesion provides a better fit of the bag, which reduces the risk of leakage (and associated skin complications and psychological impact). However, the adhesion should still be easy to remove to avoid irritating the skin.	Any person with a colostomy may benefit from an innovative adhesive, though particularly those with additional skin needs (e.g. presence of hair, oily/dry skin, differences in skin pH, sweating), which may vary according to age, sex and ethnicity. Some people may require more security, such as during exercise and people with a complex stoma.
Bag shape (e.g. to be more discreet or allow water to drain off more easily)	A different bag shape may be more acceptable to people and thus important for psychological outcomes. Some bag shapes may also be more suitable to wear with certain types of clothes or for certain activities, such as swimming, and for showering. Bags that allow for water to drain more easily may be more comfortable to wear against the skin.	Bag shape may be driven by the preferences of the person and the activities that they do.
Filters (e.g. to improve gas release or reduce odour)	An innovative filter may have improved capability to reduce odour and reduce the incidence of ballooning or pancaking. These outcomes would have a positive impact on psychological outcomes.	This may be important for any person with a colostomy but may be particularly helpful for people with certain diets and those who have more gas (including people on CPAP or with renal issues).

Potentially innovative features	How are they intended to benefit adults with a colostomy?	Groups of people who may use these
Material (e.g. to be more discreet, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence)	Innovative materials may improve comfort and fit and may reduce noise from the bag, which would improve discreetness. The material may reduce sweating, which may exacerbate skin issues. Materials in different colours may be preferred by different people. Material that is transparent may be helpful for people who want to monitor their poo to help with management, but many people with a colostomy may prefer an opaque bag so that their poo is not visible.	Any person with a colostomy
Flushable disposal	Some people may prefer a flushable disposal as it may be easier to dispose of used bags. The mechanism of disposal can have a psychological impact for some people.	Any person with a colostomy
Inspection window	The ability to view the contents of the bag (in an otherwise opaque bag) may be helpful for people who want to monitor their own poo, or for CNS in stoma care to inspect someone's poo, to help with management.	Any person with a colostomy but particularly those adjusting to their colostomy. Inspection window can be paramount when suffering erratic poo episodes, such as infection, diarrhoea, or when in hospital for inpatient treatment.
Sustainable material	Biodegradable materials may appeal to people who are conscious of the impact of waste on the environment.	Any person with a colostomy

Abbreviations: CPAP, continuous positive airway pressure

3. CLINICAL CONTEXT

The clinical care pathway is presented in the protocol. As part of its assessment, the EAG highlighted the following considerations that provide context to understanding the effectiveness of 1-piece closed bags for people with a colostomy:

- **Adjustment period after surgery.** Following stoma surgery, people with a colostomy require time to get used to having a stoma. This includes the practicalities of getting used to using and changing bags as well as beginning to deal with the psychological impacts on work and social life of having a stoma. This could be considered as an adjustment period and the length of time this takes can vary across people with a colostomy. Adjustment may be particularly difficult for people who received an emergency colostomy and do not have time in advance of surgery to prepare for how life will change. CNS in stoma care play a crucial role in facilitating adjustment.⁶ Some factors may delay adjustment, including a person's ability to manage their bag (e.g. dexterity), difficulties finding an appropriate bag for their needs (e.g. for people with a complex peristomal anatomy or particular lifestyle needs), changing digestive health, and psychological factors (e.g. anxiety and acceptance of their stoma). A survey⁷ of people with a stoma (of whom 51% had a colostomy) revealed that there were significant psychological implications for people during the adjustment period and that peer support and support from CNS was important to help people adjust. Feedback from CNS in stoma care was that many people with a colostomy may initially receive a clear drainable bag that will help them to manage the person's stoma, as initially a person's poo can be more variable and more liquid. Then, the majority of people with a colostomy move onto closed bags when poo becomes more formed and more consistent, typically after discharge.
- **Engagement with health services.** The EAG was aware of a group of people referred to as 'the lost ostomates' who are people with a stoma who are not in regular contact with health services and for whom outcomes with their bags are unknown. There is suspicion amongst CNS in stoma care that this group includes people who are using a bag that is not meeting their needs, and therefore may be experiencing negative consequences from this but are not seeking help from CNS in stoma care. The EAG was unclear how large a group this may be but acknowledged that this may represent an unmet treatment need amongst people with a colostomy. However, comments from a manufacturer pointed out that patients may bypass their CNS in stoma care and seek help from their (DAC) instead.

- **Complications.** Results from an interim survey submitted by Colostomy UK indicated that 53% of the 3,742 participants (including people with a colostomy, ileostomy and urostomy) reported that they were impacted by leakage, 48% by pancaking, 44% by skin irritation, 39% by ballooning, and 28% by odour. The EAG considered these data to suggest that many people with a stoma may be experiencing poor outcomes with their stoma and that there is an unmet need to improve bag options for this people.
- **Heterogeneous population.** People have colostomies for different reasons (such as colonic cancer, Crohn's disease and diverticulitis) and each person's journey to receiving their colostomy will vary, meaning that both their health and attitudes towards their colostomy may be very different. For example, where a colostomy improves a person's overall quality of life, they may feel more positively about their colostomy than someone who had few symptoms beforehand (such as with someone with colon cancer). About 1 in 335 people in the UK have a stoma. No population epidemiology study profiling the age distribution of people with a colostomy could be identified however the EAG heard that people with a colostomy are typically older people but can be any age.⁸ One factor underlying this is likely that colonic cancer, one of the major causes of colostomy, is more common in older people.⁹ As the population of people with a colostomy has a broad age range, health and personal circumstances can vary widely. Irrespective of age, a person's needs and outcomes for using a 1-piece closed bag can be influenced by their lifestyle and personal preferences.
- **Choice of bag.** There are many bags (1506 as of March 2024) listed as "colostomy bags" in the Drug Tariff⁴) and the EAG received feedback from SCMs, including CNS in stoma care and people with lived experience, that the number of options can be overwhelming for some people, while others may be unaware of the level of choice available to them. Ensuring that people have the best bag to meet their needs may have a big impact on their physical and mental health and may reduce costs to the NHS through a reduction in healthcare resource use, such as appointments or use of supporting products. SCMs, including CNS in stoma care and people with lived experience, suggested that there were psychological benefits for people in having choice over the bag that they use. Interim results from a survey submitted by Colostomy UK reported that a third of people with a stoma did not feel that they were actively involved in the choice of their bag, suggesting that there is a need for increased consultation with people with a colostomy. This echoes a survey⁷ in England that showed that 55% of respondents did not feel they were offered a

choice of where to obtain their stoma products and 53% did not feel they were offered a choice of product. CNS in stoma care suggested that people who have recently had their colostomy may be particularly unaware of the choice of bags available. Comment received by the EAG (from a manufacturer during factual accuracy checks) also suggested that the choice of bag may also be heavily influenced by the sponsorship status of the CNS in stoma care. While it may be beneficial to not overwhelm people with a new stoma with the wide choice of bags available, it may be important to ensure that people are informed and involved with the choice of bags they use throughout their lives.

- **Complex and changing individual needs for adults using 1-piece closed bags.** The choice of which bag a person uses is based on multiple criteria, including the nature of the stoma, the person's body shape, a person's skin, digestive health and broader health and treatment needs, the activities that a person will likely engage in, and the person's own preferences. Therefore, on occasion, there may be few suitable bags available for the person. Each person may be changing between multiple different bags at any one point in time, according to their needs (for example, they may use a different bag for sporting activities or certain social occasions). The bag that a person uses may also change over a person's lifetime as their needs and preferences change. An SCM also noted that people with multiple stomas may need to choose bags that fit comfortably alongside each other without overcrowding.
- **Importance of CNS in stoma care.** The EAG considered that the involvement of CNS in stoma care in the care of people with a colostomy was imperative for ensuring that people would be prescribed the appropriate bag for their needs. The choice of bag is selected according to the complex and changing needs of each person, as described above. Appropriate decision-making in bag choice may therefore require meaningful consultations between CNS in stoma care and the person with a colostomy.⁶ This may not be feasible within the time and specialist knowledge available to, for example, GPs. The extensive knowledge held by CNS in stoma care about the vast number of available bags, and their understanding of the complex needs of people with a colostomy, was considered to be essential for ensuring that bags are prescribed and used appropriately, thus achieving the best possible outcomes. Achieving the best outcomes from 1-piece closed bags was also considered more likely if people with a colostomy adjust to their stoma and engage with health services, which the EAG considered was also more likely through the involvement of CNS in stoma care. Comments received from a manufacturer highlighted that some

patients may receive the support they need from their DAC rather than or in addition to the CNS in stoma care.

- **Consequences of an inappropriate bag.** Feedback from SCMs, including CNS in stoma care and people with lived experience, was that the consequences of using a bag that does not work effectively for a person or does not meet their needs could have a major impact on a person's physical and mental health. Negative outcomes that cause embarrassment for people with a colostomy, such as leakages or a lack of discreetness, may have a profound impact on a person's psychological wellbeing and their confidence to socialise with others and engage in their usual activities, including struggling to work due to bag leaks or sore skin. Skin complications arising from leakages may also cause pain and discomfort in the short-term and may be challenging to resolve, meaning that these may continue to impact on people in the medium and long-term. Such complications may also lead to an increase in NHS costs, due to the need for more frequent bag changes and treatments for health complications. People with lived experience suggested that changing bags may be a worrying period for people with a colostomy, as they need to adjust to using a new bag with some uncertainty about whether it will suit their needs.
- **Supporting products.** Some people use supporting products (such as adhesive remover sprays or wipes, barrier sprays or wipes, and flange extenders) to provide additional security and to help to secure or remove the baseplate of their bag. In some areas of the NHS, the prescription of supporting products is guided by local formularies, for example to guide where there are cheaper alternatives, to suggest appropriate quantities, and to guide where some products are now considered redundant due to advances in bag technology. SCMs with lived experience described how the use of supporting products varies between people with a colostomy, but that some people with a colostomy consider these to be essential to achieve an acceptable outcome from their bag. CNS in stoma care said that some people may not need supporting products but that other people, for example people changing their bags more regularly or those with skin complications, may be more likely to need products like adhesive removers. CNS in stoma care also said that they would typically choose to change the bag a person was using before considering supporting products. The evaluation of the effectiveness of supporting products and indications for their use was beyond the scope of this assessment, however as the use of supporting products may affect bag outcomes and costs, the EAG considered this issue relevant to this assessment.

- **Variation in care across UK.** Some people have access to more options and more frequent assessments with CNSs in stoma care who can advise on bag choice. This may not be universal across the NHS. For example, in some areas, assessments are driven by people with a colostomy, meaning that this is dependent on the person recognising that their bag is not suitable for them and having the ability to seek support (e.g. language requirements, confidence, and awareness of the variety of options available). Feedback from CNS in stoma care and published evidence suggests that many people with a colostomy may not always seek help with bag-related complications, which means that they will not receive support to change to a bag that better meets their needs. For example, a study of 202 individuals found that 80% of people who were diagnosed with PSC did not seek professional help.¹⁰
- **Sponsorship arrangements.** As noted in the NICE scope for this assessment, in England, it is common for manufacturers of stoma bags and appliances to provide sponsorship of stoma care services, wards or stoma nurses and pharmacists, as well as to require use of their own preferred Dispensing Appliance Contractors (DACs). Manufacturers may also provide training, education, and patient advice to assist in product selection, IT support, telephone helplines, post-discharge care and additional services for people with a colostomy. DACs often provide additional services such as cutting services for those who prefer not to or cannot cut bag openings to size. The EAG heard from stakeholders that manufacturers were instrumental in driving innovation for people with a colostomy and that their support had been valuable to delivering high quality care. However, the EAG also received mixed feedback from SCMs (CNS in stoma care and people with lived experience) about whether service sponsorship affected the range of bags available to people with a colostomy in that service: while in some cases, sponsorship was stated to not affect patient choice, in other instances it was said that it did, meaning that people with a colostomy may not have equal access to all bags available to them. Bowles et al.⁷ found that 55% of people with a stoma surveyed did not feel they had a choice whether to obtain products from a DAC or from a pharmacy and 53% felt that upon discharge they were not offered a choice of which bag to use. An overview of sponsorship arrangements currently in place is provided in Section 7.4.
- **Impact on carers.** People with a colostomy may be receiving varying levels of care and support from carers in their lives. The impact on carers may be particularly profound where a person with a colostomy has greater difficulties in managing their own stoma (e.g.

dexterity issues, visual impairment, sensory challenges, dementia) and where a person experiences more negative outcomes from their stoma or their bag. Outcomes for carers related to 1-piece closed bags for people with a colostomy were beyond the scope of this assessment, however the EAG noted that carer outcomes were not reported in any of the studies included in the evidence review.

4. EQUALITY ISSUES

The EAG identified the following equality issues in this assessment:

- Colostomies are most common in older adults, who may have broader health needs and issues with dexterity and accessing services.
- There are additional considerations for supporting a person with a colostomy who has dementia or mental health issues to manage their own bag, where this is possible. It may also be more challenging for healthcare professionals to manage the bag of someone with dementia or mental health issues.
- People with a colostomy who have manual dexterity issues or a visual impairment may have greater difficulty in managing their bags, and they may have fewer options for bags. However, in these cases the person may be more likely to use a 2-piece bag. There may also be specific considerations for people with a colostomy who use a wheelchair.
- People with a colostomy who have learning difficulties may require additional support in understanding the range of available products as well as in accessing services.
- People with a colostomy who are hypersensitive, either due to sensory processing difficulties or skin conditions, such as psoriasis and eczema, may have greater difficulty in managing their bags that may affect the choice of bag and whether a supporting product (e.g. adhesive remover) is used.
- People receiving various treatments, including radiotherapy, chemotherapy, or certain medications may have an increased risk of certain bag-related complications.
- People for whom English is not their first language may have greater challenges in communicating their needs and accessing support from health care professionals.
- There are an unknown number of people with a stoma who are considered to be 'lost ostomates'; people who have little or no contact with CNSs in stoma care about their colostomy, and for whom outcomes are unknown. CNSs told the EAG that there are concerns that this group may include many people with a colostomy who are not using a bag that meets their needs, and so may be experiencing poor outcomes for their physical

and mental health. Perceptions of stigma towards people with a stoma can prevent people with colostomy seeking support or guidance from health care professionals.

5. CLINICAL AND TECHNOLOGICAL EVIDENCE REVIEW

The EAG conducted the evidence review consistent with the decision problem, allowing for the additional considerations described in Section 1, and the review methods outlined in the review protocol.³ A couple of minor protocol deviations were allowed, due to the paucity of evidence identified by the evidence review. These are described in Section 5.2.

Following completion of the evidence search and study selection process, the EAG considered whether to broaden the review inclusion and exclusion criteria to include evidence for the clinical effectiveness of 1-piece closed bags conducted with people with an ileostomy. Feedback from CNS in stoma care was sought and a decision was taken not to broaden the evidence base in this way. A description of the feedback from CNSs in stoma care and the rationale for this decision is provided in Appendix E.

Due to the paucity of evidence that evaluated 1-piece closed bags for people with a colostomy, the EAG explored additional evidence that was indirect to the NICE scope and/or EAG evidence review, including: (1) evidence for the clinical effectiveness of 2-piece closed bags for people with a colostomy and (2) evidence for the clinical effectiveness of 1- and 2-piece closed bags for people with a colostomy where the comparator did not meet the review inclusion criteria (specifically, where the comparator included a mix of bags that were unknown or including multiple variations of bag features). As the decision to include this evidence was taken after preparation of the draft EAG report, for pragmatic reasons this evidence is included in Appendix J.

5.1. Evidence search strategies and study selection

The clinical evidence searches sought to identify reports of the effectiveness and safety of the features of 1-piece closed bags for adults with a colostomy. Database searches were performed in Medline, Embase, Cochrane CENTRAL, Cochrane Database of Systematic Reviews, British Nursing Index, and CINAHL. Trial protocols were identified from searches in ClinicalTrials.gov, the International Clinical Trials Registry Platform (ICTRP), and Cochrane Protocols. Association of Stoma Care Nurses (ASCN) UK conference abstracts were hand-searched, for the years they were available. All evidence sources submitted by companies during the RFI process were assessed against the inclusion criteria – those that met these criteria were added to the screening process. Real world data (primarily Clinical Practice Research Datalink [CPRD]) was considered for this evaluation. However, due to variability in how care is delivered such as

through CNSs in stoma care working predominantly in a secondary care setting, varying involvement of GPs in prescribing, the outsourcing of care to prescribing hubs, and the relevance of the outcomes available within primary care data, it was deemed that CPRD data would not contain the information required to inform the economic model.

The search is fully described in the published protocol³ – no amendments to the planned search were made. Details of the search approach, including lists of databases, search strategies and outcomes, can be found in Appendix A.

Screening took place in Rayyan and was performed using the inclusion and exclusion criteria described in the published protocol.³ As a paucity of evidence was identified in the evidence review, all studies included at full-text were included in the evidence review; i.e. the study prioritisation process described in the review protocol, for selecting the evidence most pertinent to decision-making, was not conducted.

Overall, the EAG included studies in adults with a colostomy that used 1-piece closed bags in which outcomes associated with an included bag or bag feature were reported. Studies in mixed populations, such as ileostomy and colostomy (of which there were many) were excluded, unless results were reported separately for people with a colostomy or 80% or more of participants had a colostomy. Many studies were also identified that compared outcomes with a bag in comparison with outcomes for participants using a variety of different bags (each with their own unique features). Unless results were reported separately in comparison with a specific bag or the presence/absence of a specific bag feature, these studies were excluded during full-text screening, as effect estimates could not be meaningfully associated with the effectiveness of a bag or bag feature. These studies were subsequently included in the expanded evidence base, presented in Appendix J. The EAG also excluded a number of publications that evaluated 1-piece closed bags in people without a stoma (e.g. healthy members of the public wore the bag and provided feedback on its performance) and evaluations of 1-piece bags and/or their features that were conducted within a laboratory (e.g. using laboratory measures to assess performance of a bag filter). These studies were excluded as they did not meet the evidence review criteria. Moreover, SCMs who had lived experience of having a colostomy, commented that only studies that evaluated bags in people with a colostomy should be included to ensure that their needs and preferences were captured.

As part of its assessment, the EAG contacted companies to request additional information or data. This included questions that were used to guide inclusion and exclusion decisions (e.g. to

confirm whether un-identifiable bags evaluated in publications were a bag listed on the current NHS Drug Tariff) and to identify additional relevant data (e.g. to request subgroup data that would allow an otherwise excluded publication to be included, such as outcomes specific to people with a colostomy).

5.2. Included and excluded studies

A total of 4,363 records were retrieved by the database searches, 362 from the trial protocol registry searches, and 3 from the hand-search of the ACSN UK Conference abstracts. Of these, 1281 records were removed as duplicates, leaving 3447 to be screened at title and abstract, after which 119 were identified for full text retrieval. All 119 full texts were successfully retrieved. Alongside this process, 21 records were added from the company RFI, and 4 more identified via citation searching.

Three full text articles, one confidential internal company report, and one record from clinicaltrials.gov (that reported results and where no other publication was identified) were included in the review. A PRISMA diagram of the search and screen process is provided in Appendix B. A list of studies excluded at full text along with their reason for exclusion is provided in Appendix C.

Due to the paucity of evidence meeting the review inclusion criteria, two minor protocol deviations were made to include additional evidence, as follows:

[REDACTED]

- The review protocol specified that outcomes reported on scaled outcome measures, such as quality of life outcomes and participant-reported attitudes towards the bag and its benefits, would only be included if these had undergone some psychometric validation to

determine whether the results were reliable and valid (i.e. whether participants consistently interpreted the question asked in the way intended and results were an accurate representation of their views). Such validation would also ideally provide information about how to interpret the results of these types of measures (e.g., whether a change of 1 point on a scale of 1 to 10 would have minimal or meaningful benefits for a person with a colostomy in real life). Many outcomes reported in the included studies used participant-reported scales and do not appear to have been psychometrically validated and no information was available to guide the interpretation of the findings. Again, due to the paucity of evidence, the EAG included the evidence from these studies although considered the limitations of these outcomes in its interpretation.

Table 4 is a ‘landscape map’ showing the evidence that was available for each feature of interest. Table 5 summarises the characteristics of the included studies. Four¹¹⁻¹⁴ of the studies were randomised (all of which were crossover trials). One of the trials was in Germany, two in Denmark, and one in Denmark and France – all studies had fewer than 100 participants. ■

Four of the included studies were sponsored by Coloplast and evaluated SenSura or SenSura Mio, with the comparators including each other, Nova 1 or Moderma Flex.

[REDACTED]. Three studies were published over 10 years ago, although they evaluated bags that were still in use in the NHS.

Quality appraisal of the included studies is described in Section 5.3. Results and synthesis are presented in Section 5.4.

Table 4: Landscape map of in-scope clinical studies identified for each feature

Feature	Randomised trial evidence	Non-randomised study evidence
Baseplate additive	No evidence	No evidence
Baseplate shape	Teniere 2007 (<i>Coloplast, SenSura; Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura; Hollister & Dansac, Nova 1</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██
Baseplate adhesive	Teniere 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Nova 1</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██
Bag shape	Teniere 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Nova 1</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██
Filter	Teniere 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██
Material	Teniere 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██
Flushable disposal	No evidence	No evidence
Inspection window	Teniere 2007 (<i>Coloplast, SenSura, Hollister & Dansac, Moderma Flex</i>) Voergaard 2007 (<i>Coloplast, SenSura</i>) NCT01243294 2011 (<i>Coloplast, ██████████ Coloplast, SenSura</i>) Virgin-Elliston 2023 (<i>Coloplast, SenSura Mio</i>)	██ ██

Table 5: Included studies with clinical and technological evidence

Study name, design and location	Intervention(s) and comparator	Participants and setting length of follow-up	Relevant outcomes and key results	EAG comments
Teniere, 2007 ¹² RCT (crossover) Germany Published article	Intervention: SenSura (Coloplast) closed bag with double layer adhesive (crossover) Comparator: Moderma Flex (Hollister) closed bag with single layer adhesive (crossover)	Participants: 69 men and women with a colostomy who normally use a (non-convex) 1-piece closed bag, were able to apply, remove and empty bags themselves, were not pregnant or breastfeeding, had not received chemo- or radiation therapy during the study or within two months before study start, and did not have bleeding or broken skin around the stoma. Setting: NR Follow-up: NS	Primary outcome: • Bag preference (test vs reference) Secondary outcomes: • Odour control • Ballooning • Ballooning at night • Perceived bag security • Filter leakage • Filter dysfunction • Tack • Adhesion • Flexibility • Ease of removal • Discretion	This is a relatively small RCT in a German context using a crossover design. The PICO is relevant to the decision problem. However, the EAG had concerns regarding risk of bias, in particular detection bias, due to use of non-validated outcome scales.
Voergaard, 2007 ¹⁴ RCT (crossover) Denmark Published article	Intervention: SenSura (Coloplast) closed bag with double layer adhesive (crossover) Comparator: Nova 1 (Dansac) bag (crossover)	Participants: 68 men and women with a colostomy who used a (non-convex) 1-piece bag, were able to apply and remove bags themselves, were not pregnant or breastfeeding, were not irrigating, were not treated with chemo- or radiation therapy during the study or the 2 months beforehand and did not	Primary outcome: • Preference for test vs reference bag Secondary outcomes: • Filter leakage • Wearing time • Odour • Frequency of pancaking • Ballooning • Peristomal skin complications • Overall evaluation • Comfort	This is a relatively small RCT in a Danish context using a crossover design. The PICO is relevant to the decision problem. However, the EAG had concerns regarding risk of bias, in particular detection bias, due to use of non-validated outcome scales.

Study name, design and location	Intervention(s) and comparator	Participants and setting length of follow-up	Relevant outcomes and key results	EAG comments
		have bleeding or broken skin around the stoma. Setting: NR Follow-up: Maximum 7 days	• Ease of removal • Flexibility • Perceived bag security • Adhesion	
██████████ ██████████ ██████████ ██████████	Intervention: ██████████ ██████████ Comparator: ██████████ ██████████	Participants: ██████████ Setting: ██████████ ██████████ Follow-up: ██████████ ██████████ ██████████	Primary outcome: ██████████ Secondary outcomes: ██████████ ██████████ ██████████ ██████████ ██████████ • ██████████	██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████
NCT01243294 ¹¹ RCT (crossover) Denmark and France Clinical trial registration	Intervention: ██████████ (Coloplast; crossover) Comparator: SenSura (Coloplast; crossover)	Participants: 56 Setting: NR Follow-up: 10 +-2 days in each arm	Primary outcome: • Leakage Secondary outcomes: • Wear time • Security • Handling • Comfort • All-cause non-serious AEs • All-cause serious AEs	This study was completed in 2011 and the only available results are from a clinical trial registration. Information to evaluate this study is limited. Risk of bias assessment was not feasible. The study PICO appears relevant to the decision problem.
Virgin-Elliston ¹³ RCT (crossover) Denmark Published article	Intervention: SenSura Mio (Coloplast) Full Circle Filter (crossover) Comparator:	Participants: 20 men and women who had a colostomy for ≥6 months, experienced ≥1 ballooning event per week, were able to use a	Primary outcome: • Ballooning issues Secondary outcomes: • Wear time • Pancaking issues • Odour issues	The paper, published in 2023, describes two crossover RCTs: one in a colostomy population (extracted here) and one in an ileostomy population.

Study name, design and location	Intervention(s) and comparator	Participants and setting length of follow-up	Relevant outcomes and key results	EAG comments
	SenSura (Coloplast; crossover)	bag with a flat baseplate without assistance, had a <60 mm stoma, who did not irrigate their stoma, did not have bleeding or broken skin, were not receiving radio- and/or chemotherapy, and were not pregnant or breastfeeding. Setting: NR Follow-up: 14 days in each arm	• Ease of use and acceptability • All-cause non-serious AEs • All-cause serious AEs	Both trials were very small – just 10 participants in each arm – with a follow up of 14 days for each product.

Abbreviations: AE, Adverse event; EAG, External Assessment Group; NR, not reported; PICO, population intervention comparator outcome; RCT, randomised controlled trial; RWE, real-world data; UK, United Kingdom

5.2.1. Study populations

In general, population characteristics for the study sample were not consistently reported across the evidence base. Only three studies reported the length of time since participants had their stoma surgery. In these studies, the mean length of time since stoma surgery ranged between 3.0 and 5.4 years, which suggests that participants may have on average adjusted to their stoma and were accustomed to using a 1-piece closed bag at the start of the studies. Only two studies reported any information about the complexity of participants' stoma, and in both cases this was to report that the majority of participants had flat skin around their stoma, and that a minority (22%¹² or 29%¹⁴) had a hernia. Studies either excluded people who had a PSC at baseline or did not report how many participants had a PSC at baseline. Only two studies reported the types of bag that participants were using at baseline. In both cases, most participants were using a Coloplast bag. One study,¹³ which aimed to evaluate the effectiveness of two filter types in different bags for reducing ballooning, specifically recruited people who were experiencing regular ballooning in their lives (at least once per week).

Overall, the EAG considered that there was a lack of information reported in the studies to get a view on the representatives of the overall evidence base for people with a colostomy in the NHS. Given the complex needs of people with a colostomy that determines the appropriateness of a particular bag to them, the EAG noted that feedback from CNSs in stoma care may be useful to determine whether the study populations appear representative of the populations that would use the evaluated bags in the NHS or whether the studies excluded some populations. As all included studies were sponsored by Coloplast, and the two studies that reported previous bag use stated that most participants used Coloplast bags, the EAG considered that the included evidence may plausibly better represent a population of people with a colostomy that would choose to use a Coloplast bag. The EAG was unsure to what extent this may affect the generalisability of results from the studies to the target population.

5.2.2. Technologies evaluated

Four studies evaluated outcomes associated with the SenSura 1-piece closed bag (Coloplast). The three studies compared outcomes with different comparators. One study compared the SenSura closed bag with the Moderma Flex closed bag (Hollister).¹² One study compared the SenSura closed bag with the Nova 1 bag (Dansac).¹⁴ [REDACTED]

[REDACTED]

[REDACTED]

██████████. The features of each of the evaluated bags are shown in Table 6. The Nova1 bag contained fewer potentially innovative features than the other evaluated bags, all of which included different approaches to the same feature categories (e.g. different baseplate adhesives):

Nova 1: baseplate, baseplate adhesive and an innovative bag shape

SenSura, SenSura Mio, Moderma Flex, ██████████: baseplate, baseplate adhesive, bag shape, filter, material, and an inspection window.

Table 6: Features of bags evaluated in the included evidence base

Company	Bag name	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window
Coloplast	SenSura Mio	N	Y	Y	Y	Y	Y	N	Y
	SenSura	N	Y	Y	Y	Y	Y	N	Y
Hollister & Dansac	Hollister Moderma Flex piece closed bags*	N	Y	Y	Y	Y	Y	N	Y
	Dansac Nova 1 closed bag	N	Y	Y	Y	N	N	N	N

Note:

5.2.3. Outcomes of the included studies

The outcomes evaluated in the included studies are shown in Table 7. One study¹² did not report the length of follow-up used to assess outcomes, while three used a similar timeframe (7 days, 10 ±2 days, and 14 days). [REDACTED] Where follow-up was not reported, the EAG considered it likely that a similarly short follow-up was used, given the topic area and the crossover in funder, however noted the uncertainty. Two SCMs commented on the draft report to say that a seven-to-ten-day follow-up was probably too short for evaluating the technology, given the time it may take people to adjust to using a new bag. The EAG interpreted this to mean that outcomes within this time-period may not be reflective of the long-term outcomes associated with the technology. The EAG also noted that some outcomes, such as PSC, may need time to develop and so only mild complications may be observed during a short timeframe. However, it was also noted by one of the SCMs that a period of two weeks may be used by people with a colostomy to continue or discontinue with a bag, and so the EAG considered that the timeframe of the studies may nevertheless be meaningful to bag choice for people with a colostomy.

Table 7: Outcomes reported in the included studies

	Voergaard 2007 F/up: 1 week	Teniere 2007 F/up: NR	[REDACTED] [REDACTED]	NCT01243294 F/up: 1 week	Virgin- Elliston F/up: 2 weeks
Length of time before changing bags	Y	N	█	Y	Y
PSC	Y	N	█	N	N
Leakage	Y	Y	█	Y	N
Pancaking	Y	N	█	N	Y
Ballooning	Y	Y	█	N	Y
Odour	Y	Y	█	N	Y
Ease of use and acceptability	Y	Y	█	Y	Y
Psychological and social impact	N	N	█	N	N
Intervention-related adverse events	Y	Y	█	Y	Y

Abbreviations: F/up, follow-up; PSC, peristomal skin complications

5.3. Quality appraisal of studies

A formal quality appraisal was conducted to assess the quality of the included evidence for four out of five included studies. Consistent with the review protocol, quality appraisal was not conducted for one study¹¹ for which there was only a clinical trial registry record, as insufficient detail was reported to result in a meaningful assessment of study quality. For the other four studies, the NICE risk of bias tool¹⁶ was used for RCTs and the [REDACTED]. The full results of the quality appraisal are reported in Appendix F. Overall, the quality assessment identified concerns that would suggest the included evidence was of low quality. All of the included cRCTs¹²⁻¹⁴ were considered to have a high or unclear risk of bias in at least one domain of the checklist, and in more than one domain for certain outcomes. Additional concerns were identified for all three cRCTs due to uncertainties with the appropriateness of the crossover design to evaluate 1-piece closed bags for people with a colostomy.

Two major potential sources of bias across the included studies were the risk of performance and detection bias. Due to the nature of the technology, it would not be possible to blind participants to the intervention received in each arm of the study. The EAG did not consider the lack of blinding to be an important consideration for some of the clinical measures, such as rates of leakage or PSC, however subjective outcomes are known to be impacted by participants knowledge of the intervention that they are receiving. The EAG considered it plausible that participants' expectations for the performance of the bag they were using in each arm may influence subjective outcomes such as their perceptions of odour control, security, and discreetness. Participants expectation may be affected by their prior attitudes towards the bags under evaluation, for example if they were previously using one of the bags or have tried one of the bags in the past. Participants may also have pre-existing views about the companies producing the evaluated bags, even if they have no direct knowledge of the specific bag being evaluated. Not all studies reported the bag that participants were using prior to the study, although when reported, it appeared that most of the participants were using a bag produced by the study sponsor and so may have greater familiarity where these bags were compared with bags produced by other companies.

The EAG was also concerned about the lack of psychometric validation of scaled measures used in the included studies, which measured patient-reported attitudes towards the bags as well as ratings of the frequency and severity of clinical outcomes, such as ballooning and leakage.

[REDACTED]

As discussed elsewhere in this report, where outcomes on scales have not been validated, it is not certain that results will be reliable or will accurately represent participants' views. The EAG was also concerned at the short follow-up duration in the studies, which did not exceed 14 days. The EAG considered that this length of time may be sufficient to allow people with a colostomy to make initial adjustments to using the bag and to make a judgement about whether they would choose to continue using this, however it may not be long enough to assess whether certain bag-related complications would occur (e.g. PSC, use of supporting products).

The EAG had limited details about the populations included in the studies to make a judgement about the risk of selection bias in the studies. While all cRCTs were assumed to have used appropriate methods for randomisation, and one reported adequate allocation concealment, the samples were generally small and limited populations details were provided to judge whether the groups were truly comparable at baseline. In crossover trials, this may have less impact on the results, given that all participants receive both interventions. However, as the EAG was uncertain whether carry-over effects would have influenced outcomes in the second evaluated study (for example, the EAG assumed elsewhere in its assessment that complications such as PSC would take several weeks to resolve, which was not allowed for within the study designs), any imbalance in randomisation at baseline may have influenced results.

The EAG also had some concerns regarding the representativeness of the study populations and whether outcomes would represent those that would be experienced by people with a colostomy in the NHS. As people with a colostomy vary widely in their needs and preferences, and the outcomes of each bag would be expected to vary according to whether a bag was suitable for the person using it, the EAG considered that understanding the participants included in the studies was essential for interpreting the reported results. In all studies, it was explicitly stated, or the EAG assumed to be the case, that participants were eligible for the study only if they were considered to be suitable candidates for the bags under evaluation. The EAG considered that this was highly appropriate to ensure that people who would never be prescribed the evaluated bags in clinical practice were not included in the studies. However, the criteria for making these decisions was not provided and the EAG was not aware of any standardised criteria for identifying appropriate bags according to key characteristics of a person with a colostomy. The EAG considered that there was a risk that different criteria would be used to guide these decisions across the studies, which would limit the comparability of results in the evidence base (e.g. if the criteria meant that the people deemed eligible for SenSura Mio in one

study were different to those selected for SenSura Mio in a different study). Moreover, a lack of standardised criteria also opens the study to potential bias, for example resulting in a study sample that was more suitable for one evaluated bag than another in a way that would not represent the true mix of people with a colostomy that would consider using both bags. This limitation was considered when interpreting the evidence.

Finally, the EAG noted that all published studies ([REDACTED]) included in the evidence review were sponsored by companies who produce 1-piece closed bags for adults with a colostomy. The source of funding for a study is a known risk of bias, since study authors have a financial conflict of interest in the findings of the research. In this case, a risk of bias may occur if elements of the study design allowed for bags produced by the sponsoring company to gain a greater advantage compared to clinical practice or as compared to bags evaluated in the same study produced by a competitor company. The EAG did not identify systematic issues with the cRCT study designs to confirm the presence of a bias, however noted that some aspects of the study design and risk of bias checklist were unclear.

[REDACTED] study is shown in Appendix E. [REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]

5.4. Results from the evidence base and evidence synthesis

Due to the paucity of data and methodological limitations in available studies, it was not feasible to conduct a meta-analysis or an intervention components analysis (ICA), as planned. This

The results of each study are reported separately in Table 8 to Table 12. The results are presented alongside a description of the participants included in the study. Given heterogeneity across the population of people with a colostomy, and the way in which individual needs affect the choice and outcome of a bag, the results should be interpreted as relevant to the study population only.

This crossover RCT included people in Denmark with a colostomy who normally use a 1-piece closed bag and did not have PSC at baseline. Most (78%) had flat skin around the stoma, and 29% had a hernia. People were a mean of 3 (SD 3) years following their stoma surgery. Most (72%) were using a Coloplast bag at baseline. The results showed no clear difference between the SenSura and Nova 1 bags for wearing time, rate of PSC, filter leakage, pancaking, odour, or perceived adhesion of the adhesive. SenSura was associated with a meaningfully lower rate of ballooning than Nova 1 (█████ vs. 53% of participants) and a lower rate of ████████ vs █████ of bags). The results showed that participants rated the SenSura bag more positively overall than the Nova 1 bag, and had slightly higher ratings for SenSura for comfort, ease of removal, flexibility and bag security. However, these outcomes were not considered reliable due to the ██████████ and (where standard deviations were reported) there was evidence of variability in participants' views.

As most participants were using a Coloplast bag at baseline, the EAG considered it plausible that these findings may have been influenced by participants' familiarity with Coloplast bags. Moreover, it was considered possible that participants included in the study may more closely represent people with a colostomy who would choose the features of a Coloplast bag over a Hollister & Dansac bag. In real terms, this distinction may not matter, as the results may more closely represent the outcomes experienced by people who would choose to use a Coloplast bag, and as personal choice is important when determining the use of a bag for a person with a colostomy, this may be appropriate. However, it may not be a fair representation of the outcomes associated with the Nova 1 bag, which may be preferred by a different group of people with a colostomy.

5.4.2. Teniere (2007) SenSura vs Moderma Flex

This crossover RCT included people in Germany with a colostomy who normally used a (non-convex) 1-piece closed bag and did not have bleeding or broken skin around their stoma at baseline. Participants were a mean of 5.4 (SD 4.8) years since their stoma surgery. Most (79%) had flat skin around the stoma and 22% had a hernia. Most people (65%) were using a Coloplast bag at baseline. The results showed no clear difference between the SenSura and Moderma Flex bags for filter leakage, odour, and the presence of skin conditions. A higher rate of ballooning was reported for the Moderma Flex bag (23% vs 6% of all bags) and more Moderma Flex bags were reported to exhibit a filter dysfunction for any reason (29.5% vs 10% of all bags). More participants rated that the SenSura bag had better bag security, improved tack, improved adhesion, improved flexibility, improved discretion, and easier to remove. However, these outcomes had limited reliability due to [REDACTED]. Many more people rated that the SenSura bag was their preferred bag (78% vs 22%).

The SenSura and Moderma Flex bags share potential innovations in the same features included in the NICE scope for this assessment: i.e. the two companies claim that each bag has innovations in baseplate shape, baseplate adhesive, bag shape, filter, material, and each had an inspection window. While the study reported no difference between bags for filter leakage, PSC and odour, all of which are key outcomes for people with a colostomy, the Moderma Flex bag was associated with a higher risk of filter dysfunction (most of which was reported to be related to ballooning). The differences between bags for these outcomes was considered by the EAG to be meaningful, potentially taking the occurrence of these events from being an occasional event (6% and 10% of SenSura bags) to being a more common event (23% and

29.5% of Moderma Flex bags). Participants were also more likely to prefer the SenSura bag and rate it more positively for various key outcomes, including security, discretion and adhesion. The EAG considered that these outcomes would be important for psychological and social outcomes in people with a colostomy, as they would be expected to influence the extent to which people feel confident wearing their bag during their daily lives. As these measures do not appear to be validated, the EAG noted some uncertainty about them, particularly in consideration that most participants in the study were previously using Coloplast bags and therefore may have a stronger preference and greater familiarity with their design. This means that the EAG was unsure whether the same results would be seen in a sample of participants who were using a bag made by the other company (Hollister) at baseline. As noted above, this may be appropriate as it may represent the outcomes of SenSura in a population that would be more likely to use this bag in practice, however it may not be a fair representation of the performance of the Moderma Flex bag.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

5.4.4. NCT01243294 SenSura vs [REDACTED]

This crossover RCT included 56 people in Denmark and Germany who had a colostomy with a diameter <45mm for at least 3 months, were using a flat 1-piece closed bag and were considered suitable (by a nurse) for a standard adhesive, flat base plate. No participants had a PSC at baseline. There were no details reported about the length of time since surgery, the bags used by participants at baseline, or the number of participants with a complex stoma. The results showed no clear difference between the SenSura and [REDACTED] bags on wear time, leakage when changing baseplates, self-reported handling of the bag, and intervention-related adverse events. A higher proportion of participants rated the [REDACTED] bag as having very good security and being comfortable, although these outcomes had limited reliability due to the lack of psychometric validation of the scales.

Overall, few outcomes were reported in the clinicaltrials.gov record for this study, meaning that there was little evidence through which to compare SenSura and [REDACTED]. Overall, the EAG considered that the bags appeared generally comparable, though with some limited evidence that more people may prefer the [REDACTED] bag.

5.4.5. Virgin-Elliston (2023) SenSura vs. SenSura Mio

This crossover RCT included 20 adults in Denmark who had a colostomy for at least six months, with a stoma with a diameter <60 mm, and used a flat baseplate. The study authors stated that the aim of the study was to evaluate the filters of the two bags: a dual filter on the SenSura bag compared to a full circle filter on SenSura Mio. The filters were designed to reduce ballooning, and this was therefore the primary outcome of interest in the study. Accordingly, they included participants who were regularly experiencing ballooning before the start of the trial (at least once ballooning event per week). The results showed that the frequency of ballooning was significantly lower with SenSura Mio compared to SenSura (11.2% of SenSura Mio bags vs 22.8% of SenSura bags). Other measures also showed a lower risk of ballooning with SenSura Mio. There were no significant differences in pancaking, odour issues, perception of bag discretion, or length of time between switching bags. Overall, six adverse events (AEs) were observed in four (20.0%) participants with a colostomy, of which one was a PSC considered to be related to use of SenSura Mio and led to discontinuation from the study.

As the focus of this study was to evaluate any difference in effect of the bag filters towards ballooning, few other outcomes were reported. The results indicated that SenSura Mio was associated with a reduced risk of ballooning compared to SenSura, but no difference in

pancaking, odour issues, or perceived discreetness. Given the small sample and low rates of AEs, the EAG did not consider there to be conclusive evidence of any difference in the risk of PSC between bags.

5.4.6. Results tables for all included studies

Table 8: Voergaard 2007 SenSura closed bag (Coloplast) vs. Nova 1 (Hollister & Dansac)

Population: 68 men and women in Denmark with a colostomy who normally use a 1-piece closed bag and did not have PSC at baseline. Most (78%) had flat skin around the stoma, and 29% had a hernia. People were a mean of 3 (SD 3) years following their stoma surgery. Most (72%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Nova 1 N	Results
Length of time before changing bags	Wearing time <i>Mean (SD)</i>	1 week	66	66	SenSura: 12.5 hours (NR); Nova1: 12.7 hours (NR)
Peristomal skin complications	Not defined	1 week	66	66	No difference between arms ($p=0.71$, 0-2 cm from stoma; $p=0.32$, 2-4 cm from stoma; $p=1.00$, outer rim of adhesive). Three participants experienced broken and bleeding skin or red and broken skin after using Nova 1 (3/66, 4.54%). Not stated that no events occurred with SenSura, though this could be inferred.
Leakage	Frequency of filter leakage. <i>Rate of leakage across all bags used</i>	1 week	66	66	SenSura: 6% Nova1: 9%
Pancaking events	Frequency of pancaking <i>Rate of pancaking across all bags used</i>	1 week	66	66	SenSura: 3% Nova1: 3%
Number of or time to ballooning events	Frequency of ballooning <i>Rate of ballooning across all bags used</i> <i>Percentage participants who stated that ballooning was 'some, much or very much'</i>	1 week	66	66	Rate across bags: SenSura: 7% Nova1: 27% Rate across participants: SenSura: ■ Nova1: 53%
Odour control	Odour <i>Rate of odour reported across all bags used</i>	1 week	66	66	SenSura: ■ Nova1: 1%

Population: 68 men and women in Denmark with a colostomy who normally use a 1-piece closed bag and did not have PSC at baseline. Most (78%) had flat skin around the stoma, and 29% had a hernia. People were a mean of 3 (SD 3) years following their stoma surgery. Most (72%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Nova 1 N	Results
Ease of use and acceptability	Overall evaluation <i>'What is your general assessment of the bag?': Median score on scale of 1 to 5 (very poor, poor, reasonable, good, very good)</i>	1 week	66	66	SenSura: 5.0 Nova1: 3.0
Ease of use and acceptability	Comfort <i>'What is your assessment of the comfort of the bag?': Median score on scale of 1 to 5 (very poor, poor, reasonable, good, very good)</i>	1 week	66	66	SenSura: 4.0 Nova1: 3.5
Ease of use and acceptability	Ease of removal <i>'Did you feel pain when removing the bag?': Mean (SD) score on scale of 1 to 5 (very much, much, some, a little, not at all)</i>	1 week	66	66	SenSura: [REDACTED] median: 5 Nova1: [REDACTED] median: 4
Ease of use and acceptability	Flexibility <i>'How was the flexibility of the adhesive?' Mean (SD) score on scale of 1 to 5 (very poor, poor, reasonable, good, very good)</i>	1 week	66	66	SenSura: [REDACTED] median: 5 Nova1: [REDACTED] median: 4
Ease of use and acceptability	Perceived bag security <i>'What is your assessment of the security with regard to the bag as a total?' Mean (SD) score on scale of 1 to 5 (very poor, poor, reasonable, good, very good)</i>	1 week	66	66	SenSura: [REDACTED] Nova1: [REDACTED]
Ease of use and acceptability	Adhesion <i>'How was the adhesion of the adhesive during use?': Mean (SD)</i>	1 week	66	66	SenSura: [REDACTED], median: 5 Nova1: [REDACTED] median: 4

Population: 68 men and women in Denmark with a colostomy who normally use a 1-piece closed bag and did not have PSC at baseline. Most (78%) had flat skin around the stoma, and 29% had a hernia. People were a mean of 3 (SD 3) years following their stoma surgery. Most (72%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Nova 1 N	Results
	<i>score on scale of 1 to 5 (very poor, poor, reasonable, good, very good)</i>				
Intervention-related adverse events	1. Intervention-related adverse events 2. Intervention-related adverse events 3. Intervention-related adverse events 4. Intervention-related adverse events	1 week	66	66	SenSura: 1.00 Nova1: 1.00 SenSura: 1.00, median: 1.00 Nova1: 1.00 median: 1.00

Abbreviations: NR, not reported; SD, standard deviation

Table 9: Teniere 2007 SenSura closed bag (Coloplast) vs. Moderma Flex closed bag (Dansac)

Population: 69 men and women in Germany with a colostomy who normally used a (non-convex) 1-piece closed bag and did not have bleeding or broken skin around the stoma at baseline. Participants were a mean of 5.4 (SD 4.8) years since their stoma surgery. Most (79%) had flat skin around the stoma and 22% had a hernia. Most people (63.8%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Moderma Flex N	Results
Leakage	Filter leakage <i>Percentage of participants</i>	NR	NR	NR	SenSura: 0% Moderma Flex: 1.4%
Number of or time to ballooning events	Rate of ballooning <i>Rate of ballooning across all bags used</i> [REDACTED]	NR	NR	NR	SenSura: 6%, [REDACTED] Moderma Flex: 23%, [REDACTED]
Number of or time to ballooning events	Ballooning at night <i>Percentage of participants who woke in the night due to air in the bag</i>	NR	NR	NR	SenSura: 15% Moderma Flex: 26%

Population: 69 men and women in Germany with a colostomy who normally used a (non-convex) 1-piece closed bag and did not have bleeding or broken skin around the stoma at baseline. Participants were a mean of 5.4 (SD 4.8) years since their stoma surgery. Most (79%) had flat skin around the stoma and 22% had a hernia. Most people (63.8%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Moderma Flex N	Results
Odour control	Unpleasant odour emanating from the bag <i>Rate across all bags used</i>	NR	NR	NR	SenSura: 3% Moderma Flex: 3%
Ease of use and acceptability	Perceived bag security <i>Percentage of participants who rated overall security of the bag as good or very good</i>	NR	NR	NR	SenSura: 77% Moderma Flex: 56%
Ease of use and acceptability	Filter dysfunction <i>Rate of all bags in which the filter did not function (not defined but includes ballooning events)</i>	NR	NR	NR	SenSura: 10% Moderma Flex: 29.5%
Ease of use and acceptability	Tack <i>Percentage of participants who assessed the immediate adhesion to the skin as good or very good</i>	NR	NR	NR	SenSura: 96.5% Moderma Flex: 90%
Ease of use and acceptability	Adhesion <i>Percentage of participants who assessed the adhesion of the adhesive as good or very good</i>	NR	NR	NR	SenSura: 77% Moderma Flex: 70%
Ease of use and acceptability	Flexibility <i>Percentage of participants who assessed the ability of the adhesive part of the bag to conform to their movements as good or very good</i>	NR	NR	NR	SenSura: 84% Moderma Flex: 77%
Ease of use and acceptability	Bag preference <i>Percentage of participants who stated they preferred this bag</i>	NR	NR	NR	SenSura: 78% Moderma Flex: 22%
Ease of use and acceptability	Discretion <i>Percentage of participants who assessed the discretion of the bag as good or very good</i>	NR	NR	NR	SenSura: 75% Moderma Flex: 53%
Ease of use and acceptability	Ease of removal	NR	NR	NR	Approximately 80% of participants in each arm reported that ease of

Population: 69 men and women in Germany with a colostomy who normally used a (non-convex) 1-piece closed bag and did not have bleeding or broken skin around the stoma at baseline. Participants were a mean of 5.4 (SD 4.8) years since their stoma surgery. Most (79%) had flat skin around the stoma and 22% had a hernia. Most people (63.8%) were using a Coloplast bag at baseline.

Outcome category	Definition of outcome	Follow-up	SenSura N	Moderma Flex N	Results
	<i>Percentage of participants who assessed the bag as easy or very easy to remove.</i>				removal was good or very good
Intervention-related adverse events	Skin conditions at follow-up <i>Measurement not defined</i>	NR	NR	NR	90% of participants across arms had normal skin, no difference between arms

Abbreviations: NR, not reported; SD, standard deviation

Table 10: [REDACTED]

[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Table 11: NCT01243294 (Coloplast) vs. SenSura closed bag (Coloplast)

Population: 56 men and women in Denmark and Germany who had a colostomy with a diameter <45mm for at least 3 months, were using a flat 1-piece closed bag and were considered suitable (by a nurse) for a standard adhesive, flat base plate. No participants had PSC at baseline. There were no details reported about the length of time since surgery, the bags used by participants at baseline, or the number of participants with a complex stoma.

Outcome category	Definition of outcome	Follow-up	N	SenSura N	Results
Length of time before switching bags	Mean time wearing each bag <i>Calculated from the time the subjects applied their product (date, year, time) to the time they detached the product (date, year, time). Wear time was estimated in hours per subject per baseplate and mean (SD) value was calculated.</i>	10 days +/-2	54	54	11.46 hours (7.07) SenSura 11.41 hours (6.41)
Leakage	Leakage when changing baseplate <i>Percentage of participants who scored leakage between 2 to 4. Leakage was evaluated after each change of baseplate on a 4-point scale from no leakage (1), leakage on the baseplate (2), leakage soiling clothes (3) and sudden leakage (4).</i>	10 days +/-2	54	54	2.77% SenSura 2.87%
Ease of use and acceptability	Security <i>Patient-reported security on a 5 point scale: very poor, poor, acceptable, good and very good. The results presented are % of participants reporting 'very good'</i>	10 days +/-2	54	54	48% SenSura 28%
Ease of use and acceptability	Handling	10 days +/-2	54	54	89%

	<i>Patient feeling of handling on a 5 point scale (very difficult, difficult, acceptable, easy, very easy). Results are % of participants reporting easy or very easy</i>				SenSura 91%
Ease of use and acceptability	Comfort <i>Patient assessment of comfort on a 5 point scale (very uncomfortable, uncomfortable, acceptable, comfortable, very comfortable). Results are % participants reporting very comfortable or comfortable</i>	10 days +/-2	54	54	██████ 93% SenSura 67%
Intervention-related adverse events	All-cause non-serious AEs <i>Percentage of participants</i>	10 days +/-2	54	54	██████ 1.85% SenSura 3.7%
Intervention-related adverse events	All-cause serious AEs <i>Percentage of participants</i>	10 days +/-2	54	54	██████ 0% SenSura 0%

Abbreviations: AE, adverse event; NR, not reported; SD, standard deviation

Table 12: Virgin-Elliston 2023 SenSura Mio (Coloplast) vs. SenSura (Coloplast)

Population: 20 men and women in Denmark who had a colostomy with a diameter <60mm for -/+6 months and who experienced a ballooning event at least once a week. People who irrigated their stoma or had bleeding or broken skin around the stoma, were excluded. There were no details reported about the length of time since surgery, the bags used by participants at baseline, or the number of participants with a complex stoma.

Outcome category	Definition of outcome	Follow-up	SenSura Mio N	SenSura N	Results
Length of time before switching bags	Mean time wearing each bag	14 days	20	20	SenSura Mio 10.6 (0.19) SenSura 10.3 (0.19)
Number of or time to ballooning events	Frequency of ballooning <i>Rate of ballooning across all bags used</i> <i>Distribution of ballooning events over 24 hours</i>	14 days	20	20	SenSura Mio 11.2% SenSura 22.8% For all time intervals, the incidence of ballooning was lower with SenSura Mio versus SenSura.

Number of or time to ballooning events	Frequency of ballooning <i>Ballooning events per person. Mean (SD)</i> <i>Ballooning events per person per day. Mean (SD)</i> <i>Percentage of participants who experienced less than five events</i>	14 days	20	20	Per person SenSura Mio 3 (3.71) SenSura 6.5 (6.54) Per person per day SenSura Mio 0.3 (0.33) SenSura 0.7 (1.22) Experience <5 events SenSura Mio 85% SenSura 50%
Number of or time to ballooning events	Time to ballooning	14 days	20	20	With the full-circle filter versus the dual filter, the time to ballooning was 74% (95% CI: 35, 124) longer.
Pancaking events	Rate of pancaking events <i>Number of bags with pancaking problems/total number of bags</i>	14 days	20	20	SenSura Mio 13.7% SenSura 9.2%
Odour control	Rate of odour control issues <i>Number of bags with odour problems/total number of bags</i>	14 days	20	20	SenSura Mio 11.2% SenSura 12.3%
Ease of use and acceptability	Perception of bag discretion <i>Via a questionnaire and optional interview</i>	14 days	20	20	Perception of bag discretion was similar with the two filters
Intervention-related adverse events	All-cause AEs <i>Via a questionnaire</i>	14 days	20	20	Overall, six AEs were observed in four (20.0%) participants. None of the AE's were considered serious
Intervention-related adverse events	Bag related AEs <i>Via a questionnaire</i>	14 days	20	20	One participant experienced skin redness and pruritus of moderate severity under the baseplate of the stoma bag (with the full-

					circle filter); this was considered bag-related but not related to the full-circle filter itself.

Abbreviations: AE, adverse event; NR, not reported; SD, standard deviation

5.4.7. Narrative synthesis

As statistical meta-analysis or ICA was not feasible based on the available evidence for this assessment, the EAG attempted to synthesise the review findings in the data using a narrative synthesis approach. This approach draws naïve, qualitative comparisons between the included studies in order to identify patterns in the data, such as whether there was consistent evidence of effects for certain bags or features. The evidence base identified for this assessment was not best suited to a narrative synthesis approach due the following issues: (a) a lack of detailed information about the study methods in some publications; (b) a lack of consistency in the way the same outcome was measured in different studies; and (c) variation in the study populations that would be expected to influence the results. These issues were considered in the quality appraisal of studies (Section 5.3), but a brief outline of (b) and (c) is provided for context in this section.

Lack of consistency in outcome reporting. Key outcomes for the assessment were not always assessed in the included studies. For example, PSC, psychological and social impact were particularly poorly reported across studies. Moreover, even where the same outcome was assessed in each study, there were different ways of assessing this and the definitions used by studies were sometimes not comparable, e.g. sometimes clinical outcomes were assessed as the number of events in participants and sometimes as the number of bags that exhibited the event. Studies also used different definitions of PSC in the studies, such as limiting to certain types of skin conditions or certain severity of conditions.

Variation in included participants. Studies did not always report important characteristics of the study populations, such as participants' body profiles, whether they had a complex stoma, the length of time since their surgery, their broader health needs, and the bags they were previously using. It was therefore difficult to understand how comparable the populations in the studies were, and to judge whether the findings were generalisable to a broader population of people with a colostomy who may be prescribed those bags. People with pre-existing skin conditions were mostly, though not always, excluded. One study included a higher risk population, in that they recruited people who were experiencing at least weekly ballooning at baseline, and variation in the outcomes of this study was noted compared to other studies. Due to the complex needs of each person with a colostomy, the EAG considered it appropriate that the eligibility criteria used in the included studies typically selected participants who were judged to be good candidates for the evaluated bags. However, a limitation of this approach is whether these judgements were sufficiently reproducible across studies, such that the same judgements

were being made in different studies of the same bags. Where these decisions matched those made by CNSs in stoma care in clinical practice, the EAG considered that this would be appropriate. However, as these decisions were not being guided by standardised indications for each bag, and explicit criteria used to guide these decisions were not provided, the EAG considered that there was a risk of selection bias in the way participants were selected, which could reduce the comparability of outcomes between studies.

Despite the limitations above, the EAG reports key outcomes for all base evaluated in the evidence base side by side in Table 13. The outcomes reported are those that were considered the most comparable between studies and coincided with outcomes identified by participants in the user preference workshop as being most important for bag choice. In the following text, the EAG reports some tentative findings from comparing outcomes between studies.

5.4.7.1. Consistency of results across studies evaluating the same bag

Only the SenSura and [REDACTED] bags were evaluated in more than one study. Results for the SenSura bag were reasonably comparable between Voergaard (2007) and NCT01243294. However, results differed in Virgin-Elliston (2023), where pancaking, ballooning and odour control were all reported at higher rates than in Voergaard (2007). This may have been due to the recruitment criteria used for Virgin-Elliston (2023), in which only participants who experienced ballooning at least once a week were included. Excluding Virgin-Elliston (2023), SenSura bags were associated with a low rate of pancaking, ballooning, odour issues, and leakage (although the EAG considered that a leakage rate of 6% of bags, reported in Voergaard, could be considered high, depending on how many people this rate was distributed over, which wasn't reported).

[REDACTED]

[REDACTED]

5.4.7.2. Relative effectiveness of evaluated bags and features

Most of the evaluated bags included potential innovations in the same feature categories, though the types of innovations used varied across bag. Comparisons between these bags (SenSura, SenSura Mio, Moderma Flex, [REDACTED]) suggested that there were similarities in many key outcomes between bags, and there was no consistent evidence of benefit for particular features over others. Three studies¹²⁻¹⁴ included in the review showed differences in ballooning between bags that had potential innovations in the filter. In two studies where both bags compared included potential innovations in the filter, one study¹² showed a meaningful benefit for ballooning in the SenSura bag compared to the Moderma Flex and one study¹³ reported that the filter in SenSura Mio was more effective for ballooning than in SenSura. A further study that compared a bag with (SenSura) and without (Nova 1) a potential innovation in the filter also reported differences in ballooning outcomes. Across all three studies, however, benefits in ballooning were not necessarily shown across other outcomes related to the filter measured by each study, such as pancaking, filter leakage and odour control [REDACTED]

[REDACTED]

[REDACTED]

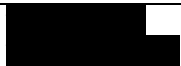
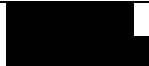
The EAG also compared the absolute outcomes reported for each of the bags (e.g. the rates of ballooning reported for each bag evaluated) to determine whether bags not evaluated in the same study could be naively compared. The EAG noted that such comparisons would be highly speculative due to variation in the study designs and populations across studies. Where comparisons in absolute outcomes were feasible (i.e. where the same outcome was assessed the same way across multiple studies), these did not appear markedly different for each bag. The exception to this was the Moderma Flex bag evaluated in one study,¹² which was associated with a greater risk of ballooning and small increased risk in odour compared to the results for the other bags, although there was no notable difference in rates of leakage. [REDACTED]

[REDACTED]

[REDACTED], it adds further complexity to drawing any conclusions by comparing across studies.

The results suggested that bag features may be associated with meaningful differences in outcomes for people with a colostomy. However, the paucity and limitations in the clinical effectiveness evidence for 1-piece closed bags for people with a colostomy meant that it was not possible to draw firm conclusions about the effectiveness of potentially innovative features of the bags, or about the relative or absolute effectiveness of any bag.

Table 13: Key outcomes for all bags evaluated in the review

	SenSura	SenSura Mio		Moderma Flex		Nova 1
Length of time before changing bags	12.5 hours (NR) [Voergaard] 11.41 (6.41) [NCT01243294] 10.3 (0.19) [Virgin-Elliston]	10.6 (0.19) [Virgin-Elliston]		NR		12.7 hours (NR) [Voergaard]
PSC	0% of participants [Voergaard]	NR		NR		4.5% of participants [Voergaard]
Leakage	6% of bags [Voergaard] 0% participants [Teniere] 2.87% participants [NCT01243294]	NR		1.4% participants [Teniere]		9% of bags [Voergaard]
Pancaking	3% of bags [Voergaard] 9.2% of bags [Virgin-Elliston]	13.7% of bags [Virgin-Elliston]		NR		3% of bags [Voergaard]
Ballooning	7% of bags [Voergaard] 6% of bags [Teniere] 22.8% of bags [Virgin-Elliston]	11.2% of bags [Virgin-Elliston]		23% of bags [Teniere]		27% of bags [Voergaard]
Odour control	 of bags [Voergaard] 3% of bags [Teniere] 12.3% of bags [Virgin-Elliston]	11.2% of bags [Virgin-Elliston]		3% of bags [Teniere]		1% of bags [Voergaard]

Abbreviations: NR, not reported, PSC, peristomal skin complications

5.5. Conclusions of the clinical and technological evidence review

At the time of the EAG assessment, there were 1506 1-piece closed bags listed on the NHS Drug Tariff ⁴ that were available for prescription to adults with a colostomy in the NHS. While many of these entries included variations within bag ranges, such as different sizes, colours, and baseplate sizes, the number was nevertheless striking given that the clinical evidence review for this assessment identified evidence for only five 1-piece closed bags: SenSura [Coloplast], SenSura Mio [Coloplast], Moderma Flex [Hollister], Nova 1 [Dansac] and [REDACTED]. The review therefore suggested that the vast majority of 1-piece closed bags available to adults with a colostomy in the NHS were therefore not supported with robust clinical effectiveness evidence. Based on the evidence identified, the results suggested that the presence of potential innovations in features, and variation in the types of innovations, could influence outcomes for adults with a colostomy. However, in many cases, these findings were not conclusive due to inconsistency in findings across outcomes (such as conflicting results in outcomes that should be closely related). In many instances, there was no difference in outcomes between the bags evaluated.

The evidence that was included in the review was based on only five studies, all of which were considered to be of low quality, even amongst the RCTs. As low-quality evidence, the EAG was not confident that the outcomes for the bags reported in the studies were robust, and therefore would be representative of outcomes that would be experienced by people with a colostomy using these bags in the NHS. As few studies were identified, and these varied in study design, it was also not possible for the EAG to draw meaningful comparisons across studies to help validate any study outcomes, or to identify patterns in the evidence that could be used to make assumptions about the clinical effectiveness of any particular bag or bag feature. The EAG explored other sources of evidence, including evidence for 2-piece closed bags and evidence that used mixed comparisons, though these data had unclear or highly limited relevance to understanding the clinical effectiveness of 1-piece closed bags for people with a colostomy. Overall, the EAG concluded that there were indications that variations between 1-piece closed bags may offer meaningful benefits to people with a colostomy, which was consistent with feedback from CNS in stoma care and people with lived experience. However, there was insufficient evidence to demonstrate the relationship between specific features and outcomes, including the impact of the presence or absence of a specific type of feature or variation within the same feature type. Given the vast number of 1-piece closed bags available and the variations in their features, as well as the complexity of the target population and the need to

ensure that bags are evaluated within the populations relevant to them, a large and robust evidence base would likely be needed to provide firm estimates for the magnitude of clinical effectiveness associated with 1-piece closed bags. While further research is doubtlessly needed, stakeholders to the assessment have highlighted the complexities in recruiting and conducting studies to evaluate 1-piece closed bags, and therefore this may lead to prolonged uncertainty about the potential value of 1-piece closed bags relative to their price.

6. ECONOMIC EVIDENCE SEARCHES AND SELECTION

6.1. Evidence search strategy and study selection

The economic searches sought to identify published economic evaluations, health-related quality of life (HRQoL) studies, and utility studies relevant to the decision problem. The population in the economic search was wider than the clinical search as it included people with a colostomy and/or ileostomy. This was due to both an anticipated paucity of economic evidence in general and also that any modelling studies identified based on ileostomy may also contain information of relevance to modelling colostomy.

Database searches were performed in Medline, Embase, HTA database, CEA registry and NHS EED. SchARR HUD was to have been searched, according to the protocol, but the search interface was no longer available. Association of Stoma Care Nurses (ACSN) UK conference abstracts were hand-searched for the years they were available. All evidence sources submitted by companies during the RFI process were assessed against the inclusion criteria – those that met these criteria were added to the screening process.

The search is fully described in the published [protocol](#)³ – no amendments to the planned search, beyond the unavailability of SchARR HUD, were made. Details of the search approach, including lists of databases, search strategies and outcomes, can be found in Appendix A.

Screening was performed using the inclusion and exclusion criteria described in the published protocol.³ In short, the EAG included studies in adults with a colostomy or ileostomy, regardless of the bag type used (although studies reporting outcomes for 1-piece closed bags were prioritised), for which an economic evaluation or assessment of utility or HRQoL was performed. Screening took place in Rayyan for title and abstract, and Excel for full text.

6.2. Included and excluded studies

A total of 8,101 records were retrieved by the database searches, with one further record retrieved from the hand-search of the ACSN UK Conference abstracts. Of these, 2,106 records were removed as duplicates, leaving 5,995 to be screened at title and abstract. From the title and abstract screen, 461 were identified for full text retrieval. However, in a deviation from the protocol, due to the large number of records, a pragmatic decision was made to limit full text retrieval to the last five years (2019 onwards). Consequently, 186 records were identified for full text retrieval, of which 175 were successfully retrieved.

After full text screening, the earlier (pre-2019) articles were re-screened at the title and abstract stage for papers that might fill data gaps (in particular, in terms of utilities or UK resource use) following the initial inclusion of papers. This resulted in an additional 36 papers being identified for full text retrieval, all of which were successfully retrieved.

Alongside this process, five records were added from the company RFI's. Also, nine records were retrieved following reference list checking of Johnson et al. (2022).¹⁸ Where abstracts were identified that were of particular interest for which no full paper or poster was available online, either the company sponsoring the abstract or the first author were contacted to provide the poster or presentation.

In total, 13 economic evaluation reports were included in the review, 5 reports of utilities for relevant complications, 19 studies reporting other information for quality of life and 26 studies reporting resource use. A list of studies excluded at full text along with the rationale for exclusion is provided in Appendix C. A PRISMA diagram of the search and screen process is provided in Appendix B. Whilst no previous studies were of direct relevance to the decision problem, a number were of value in informing the design of the decision analysis. These are summarised in Section 7.1.

7. ECONOMIC ANALYSES

Directly estimating the cost-effectiveness of specific 1-piece closed bags possessing certain features and benefits was not possible for this assessment. This was due to data constraints and conceptual difficulties in explicitly valuing such features and benefits without reference to any particular function or objective of the feature. The EAG therefore divided the analysis into three parts.

First, a regression analysis attempted to detect associations between drug tariff price of bags and the features claimed by companies. This analysis aimed to determine the relationship between the price of 1-piece closed bags and the type and number of features that the bags contained. This approach provided an initial assessment of any price variation companies were charging for the features over and above a bag without the features.

Second, the EAG calculated the maximum economically justifiable price (eJP)¹⁹ of a bag possessing features that fully or partially prevented a number of bag-related complications. To calculate the eJP, the EAG simply reversed the equation used to calculate an incremental cost-effectiveness ratio (ICER) in cost-effectiveness analyses, which is the staple of economic evaluation for NICE assessments. Rather than calculating the ICER with known intervention prices and comparing it to NICE's cost-effectiveness threshold, the EAG instead calculated the maximum justifiable intervention price for an intervention that provided specified benefits, converting health outcome gains to costs using NICE's cost-effectiveness threshold. This is particularly useful when, as is the case here, the cost of a particular feature is not available (Figure 1).

Figure 1: Calculating the eJP

$$\frac{c_2 - c_1}{e_2 - e_1} \leq \lambda$$

The above is the equation for the ICER. The difference in cost for one intervention compared with another divided by the difference in effect has to be less than or equal to the threshold, λ . In this case intervention 2 is a hypothetical bag that eliminates a complication whilst intervention 1 is a bag where the person with stoma is experiencing the complication. C_i is a function of the price of bag i , as well as other associated costs. The equation was solved for a price of bag 2 associated with λ equal to NICE's stated threshold of £20,000 / QALY.

In this assessment, the eJP can be interpreted as the maximum willingness to pay to resolve a particular complication, taking into account the costs and HRQoL impact of the complication and NICE's cost-effectiveness threshold. In other words, the eJP is the maximum cost that could be added to a 'basic' bag in exchange for a bag that completely (or partially) resolves the complication to yield an ICER equal to NICE's cost-effectiveness threshold (or equivalently to yield an incremental net monetary or health benefit of zero). For ease of interpretation, we added this to the cost of the cheapest bag included in the evaluation (Alliance Pharmaceutical's bag Opus NaturFit) to yield a maximum price the NHS should be willing to pay for a bag that claims to resolve a complication. The eJP analysis is subject to a number of important limitations and it should be noted that the findings do not mean that the intervention's price should be set to equal its eJP. Critically, this is the theoretical maximum price for a bag that perfectly eliminates the complication and is also the 'monopolist's price' meaning that there is zero net health benefit for NHS patients as a whole: for every QALY gained from expenditure on a particular bag, exactly 1 QALY is lost elsewhere in the health system. The maximum price for a bag that partially eliminates the problem will be commensurately lower. Furthermore, there are many areas of uncertainty in deriving the eJP, and many other factors may have a bearing on how an appropriate price is set for a 1-piece closed bag. These eJPs can be compared to the prices actually charged for bags with features that are expected to ease the relevant complications.

Third, where head-to-head comparisons of 1-piece closed bags included in the clinical evidence review reported a difference in outcomes between bags, an exploratory analysis was performed to determine whether the difference in bag price was explained by the difference in outcomes. This could only be performed for a very limited number of bags and was speculative only, given that the differences reported between bags were not considered to be reliable or robust (Section 5.4.7.2). Moreover, the analysis was conceptually problematic as it required the assumption that the price for the comparator bag was itself justified in order to make the comparison.

Section 7.1 summarises previous economic analyses that were reviewed to either identify existing models which would be suitable for adaptation to this decision problem, or, where such a model did not exist, to provide insight into development and data sources for a *de novo* model. The methods section (7.2) describes 1) the method for the regression analysis to determine whether there is any relationship between stoma bag features and price and 2) the approach to modelling. This section also includes details of a structured expert elicitation exercise (SEE) conducted by the EAG to identify qualitative and quantitative expert opinion for incorporation in

the analyses. The results are presented in Section 7.3, a summary of elements not captured in the model in Section 7.4 and a discussion and interpretation in Section 7.5.

7.1. Review of previous economic analyses

Thirteen papers were identified that reported the findings of economic evaluations relevant to the topic area and were used to inform this assessment. An overview of these evaluations is provided in Table 14.

The Berger (2018) evaluation came closest to addressing the decision problem, although this was not directly relevant to the assessment as the ADVOCATE trial that informed the evaluation assessed 2-piece closed bags that were not within the scope of the assessment. A further concern with this evaluation was that the publication made several assumptions that were not supported with clear evidence, including the following: risk differences for 2-piece bags were applied to 1-piece closed bags; the risk difference for first peristomal skin complication (PSC) was also applied to the second PSC; and use of additional accessories following an initial PSC were assumed to reduce the risk of a second PSC by an amount that was not linked to a specific source.

The Martins (2012) study was the only other economic analysis that evaluated the use of a stoma bag. This study looked at the use of a stoma bag with a double-layer adhesive (SenSura, Coloplast A/S), alongside regular visits to a CNS in stoma care over a 6 – 8-week treatment period, based on the results of the Dialogue study.²⁰ This study was excluded from the initial clinical evidence review as it included a mixed population (colostomy and ileostomy), evaluated mixed variations of SenSura (1- and 2-piece closed and open bags), and compared outcomes with a mixed comparator. This study was subsequently included in the expanded evidence base presented in Appendix J.

None of the other studies looked at either specific bags or features of bags. Formal quality assessment was therefore not conducted for any of the economic evaluations identified. The following themes could, however, be drawn from the available studies (Table 14):

- PSC was the complication most included in the analyses as being associated with bag use.^{18,21-27}
- People with a stoma can have PSC multiple times (models accounted for up to 4 times²⁷) and with differing levels of severity.^{18,21-27}

- Leakage was considered in a previous model with impact arising from both leaks as well as the fear of leaks.²²
- Bag and supporting product use both increased with certain bag-related complications (PSC, leakage, ballooning, and pancaking).^{18,21-28}
- Models looking at either the impact of bags or complications linked to bags generally had short to medium time horizons (7 weeks – 3 years).^{21,22,24-27}
- The impact of stomas on quality of life in the form of utilities was found to be relatively low in a meta-analysis for colostomy and ileostomy (10 studies for colostomy, 3 for ileostomy; range of utilities reported 0.86-0.92 for colostomy and 0.88-1.00 for ileostomy) and was considered similar for temporary and permanent stomas.²⁹

In addition to the information supplied in the literature, [REDACTED] was supplied by Alliance Pharmaceuticals in response to questions from the EAG. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Table 14: Summary of studies identified in the review of economic evaluations

Author & year	Funder	Assessed	Population	Handling of stoma complications	Time horizon	Country
Berger 2018 ²¹	Hollister	Ceramide-infused skin barrier vs standard barrier	Colostomy and ileostomy (based on ADVOCATE trial which assesses 2-piece bags)	Decision tree split into weeks 1 – 12 and weeks 13 – 52. Tracks no PSC, 1st PSC and 2nd PSC. PSC analysed by severity based on DET score using Ostomy Skin Tool v2.0 ^{30,31} (OST). Utility data for PSC impact from a Hollister data on file	1 year	Australia
Martins 2012 ²⁴ and Meisner 2012 ²⁵	Coloplast	Double-layer adhesive (SenSura, Coloplast A/S), alongside regular visits to a CNS in stoma care	Patients with stoma who reported regular or when needed visits to a CNS in stoma care or doctor	The model used a “treatment algorithm based on a global understanding from experts applied to average PSC cases”. It is not clear what this means. The model estimates what it costs to treat a PSC for 7 weeks by PSC severity according to the DET score	7 weeks	UK
Cawson 2023 ²²	Coloplast	Digital leakage notification system	People living with an ileostomy and people with a colostomy having liquid or mushy poo	Leakage impacts handled both through fear, impacts of leakage and impacts on PSC Rolls 2022 paper used for QoL impact De Fries Jensen 2023 used for resource use for leak events, source for cost for fear of leakage unclear	3 years	UK
Neil 2016 ²⁷	Hollister	Skin barrier and components use with clinical oversight to individualise fit/adhesion vs skin barrier alone	People with a stoma (1 or 2-piece systems)	Model looks at impact on cost (US \$) and resource utilisation from reduction in skin complications based on a nurse panel estimate that use of a supporting product (e.g. barrier ring, seal, paste....) following a first PSC reduces an individual's risk of having a subsequent PSC by 80% (first PSC only). The maximum number of PSC events included in the model is 4. Utility data for impact comes from a Hollister data on file	1 year	USA
Mohiuddin 2021 ³²	NIHR	Mesh prophylaxis to prevent	Patients undergoing end	Decision tree for complications Infection/necrosis/stenosis included as peristomal complications	Lifetime	UK

Author & year	Funder	Assessed	Population	Handling of stoma complications	Time horizon	Country
		parastomal hernia	colostomy creation for rectal cancer	Meta-analysis of 8 RCTs for short term complications Quality of life impact drawn predominantly from the CIPHER study Costs from standard NHS reference costs		
Dale 2019 ^{23,33}	NICE	Peristeen transanal irrigation system to manage bowel dysfunction	People with bowel dysfunction in any setting	Single health state for stoma Costs included are initial procedure, bags for a colostomy (twice per day), belt (one per month), skin barrier (twice per day), adhesive remover (twice per day) and peristomal complications £34.89 per episode; 61% of patients; 7.3 times per year for Peristeen vs 1 for standard care; cost taken from Meisner 2012 ²⁵	37 years	UK
Geisler 2023 ³⁴	Wing Tech	Cost associated with diverting stoma after rectal cancer surgery	Rectal cancer patients	Complications as defined in this assessment not considered Cost of stoma costed according to bags used (2 bags per day), use of flange extenders (3 per month), belts for convex bags (0.25 per month), support belts (0.25 per month) and adhesive removers (2 per month) based on the StoMap Programme Baseline Report ³⁵	Lifetime	USA, England, and Germany
Dossa 2020 ³⁶	Fellowship	Operative strategy	Patients with Hinchey III sigmoid diverticulitis	Temporary and permanent ileostomy and colostomy modelled separately. Utility assumed to be higher for ileostomy than colostomy (0.90 vs 0.82) based on a systematic review and meta-analysis of health state utility values for ileostomies and colostomies. ²⁹ Utility assumed to be the same for temporary and permanent stomas QALY decrement for re-operation of 0.25	Lifetime	Canada
Mockford 2018 ²⁶	Coloplast	Cost of identifying and treating PSCs	People with a stoma	PSC only was considered and an annual cost per patient of £1,781. A cost of treating PSCs of £240 per 7 weeks (only patients with PSCs), and it was assumed that there are 7.4 episodes per year	1 year	UK
Johnson 2022 ¹⁸	None	Mesenchymal Stem/stromal	Perianal Crohn's disease fistulas	Cost analysis using a decision tree	1 year	USA

Author & year	Funder	Assessed	Population	Handling of stoma complications	Time horizon	Country
		cell therapy vs fecal diversion		Stoma modelled as a node on the tree Complications looked at included parastomal hernia, retraction, prolapse, obstruction and skin breakdown. Skin breakdown was assumed to required 2 office visits to treat		
de Buck van Overstraeten 2020 ³⁷	None	Ileorectal anastomosis versus IPAA	35-year-old patient with ulcerative colitis and a relatively preserved rectum	Separate health states for stoma for rectal cancer and stoma for proctitis/bag failure, uses same utility for both Costs and resource use not included	40 years	Not stated – costs not included
Andeweg 2016 ³⁸	None	Strategy for treatment: resection vs wait and see	Recurrent colonic diverticulitis	Health states for persisting symptoms with and without colostomy Utilities relevant to stoma complications not included Costs and resource use not included	10 years	NL

Abbreviations: CNS, clinical nurse specialist; DET, discoloration, erosion and tissue overgrowth; IPAA, ileal pouch anal anastomosis; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; NL, Netherlands; OST, ostomy skin tool; PSC, peristomal skin complication; QALY, quality-adjusted life year; RCT, randomised controlled trial; TH, time horizon

7.2. Economic analyses methods

7.2.1. Regression analysis: cost of bags by feature

The potentially innovative features of bags for adults with a colostomy are often cited to justify the costs incurred by the NHS. The assumption is that these features improve people's quality of life by reducing complications and minimising the impact of their stoma on daily activities. This claim, if substantiated, would align with the principle of value-based pricing adopted by NICE, NHSE and the DHSC.¹ The EAG aimed to examine this claim by conducting a multiple regression analysis to estimate price as a function of the presence or absence of different features in a 1-piece closed bag for adults with a colostomy (based on the features outlined in Table 15).

Eight features were included in the analysis, as defined in the scope of this assessment by NICE:

- Baseplate additive
- Baseplate shape
- Baseplate adhesive
- Bag shape
- Filter
- Bag material
- Flushable disposal
- Inspection window

In addition to these features, convex, concave and mouldable baseplates were identified as an important feature in a sub-category of bags that improves body fit and is associated with increased cost. Consequently, the analysis was conducted separately for flat and concave/convex bags.

The EAG modelled specific features for each bag as binary dummy variables, with price as the dependent variable. Bag usage data were obtained from the Prescription Cost Analysis 2023.⁵ An ordinary least squares (OLS) regression was used because of 1) the small sample size in the analysis, 2) an absence of significant skewness or kurtosis in the dependent variable, and 3) the absence of zeroes in the dependent variable (the presence of which would suggest a gamma distribution on the errors would have been more appropriate). OLS regression also has the benefits of simplicity and ease of interpretation. The regression model used the number of 1-piece closed bags used at each price level to calculate a weighted average price per bag type based on the current price in the drug tariff (April 2024).⁴ This approach accounted for variation

in the price per bag based on the bag size, baseplate size and the number of bags in a package.

Data are summarised in Table 15 and Table 16: the first regression model for flat bags included 36 ranges of bags and the second regression model for convex bags included 27 ranges of bags. The protocol for this assessment excluded bags that were not listed in the April 2024 drug tariff (i.e., those not being used in the NHS at the time of the assessment). As a result, some of the bag types included in the RFIs from companies were excluded from this analysis (e.g. Esteem Body™ from ConvaTec). Two companies – Jade-Euro-Med and TJ Shannon – with products listed in the drug tariff were excluded as they did not engage with NICE and so did not provide a RFI, and the EAG was unable to identify a source of information on the features of their products. The EAG noted that there have been very few prescriptions for TJ Shannon and Jade-Euro-Med in the last 12 months (only 16 and 23 items sold in 2023 respectively).⁵ One of the ten companies (Oakmed) that responded to the RFI did not submit a list of their bags' features in response to the clarification questions by the EAG. In this case, the EAG used its own interpretation of the evidence sent in previous stages to list the features of each bag. The analysis for convex bags excluded flushable disposal because it was not a feature in any of the convex bags listed.

Table 15: Flat bags included in the analysis

Bag	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Price (£) per bag*	Source
Opus naturFit	Y	Y	Y	N	N	Y	N	Y	1.85	Company
Protea Vital with filter	N	Y	N	N	Y	Y	N	Y	2.46	Company
SuperFlat	N	N	Y	N	Y	N	N	N	2.52	EAG [□]
UltraMax Atlas	N	N	Y	Y	Y	N	N	N	2.52	EAG [□]
Confidence Gold	N	N	N	N	N	N	N	Y	2.56	Company
Dansac Nova	N	Y	Y	Y	N	N	N	N	2.80	Company
Emperor colostomy	N	N	N	N	Y	Y	N	Y	2.81	EAG [□]
Microskin bag	N	Y	N	N	N	N	N	N	2.82	EAG [†]
Assura inspire	N	Y	Y	Y	Y	Y	N	N	2.83	Company
UltraMax Plus	N	N	Y	Y	Y	N	N	N	2.83	EAG [□]
Assura	N	Y	Y	N	Y	Y	N	N	2.85	Company
ModermaFlex	N	Y	Y	Y	Y	Y	N	Y	2.88	Company
Softima Active	N	Y	Y	Y	Y	Y	N	Y	2.90	Company
Confidence Comfort	N	N	N	N	N	N	N	Y	3.03	Company
Softima closed	N	Y	Y	Y	Y	Y	N	N (except Maxi)	3.06	Company
Primo Hydrocolloid	N	N	Y	N	N	N	N	N	3.07	EAG [†]
Esteem™+ bag	Y	N	N	N	N	N	N	Y	3.08	Company
Trio Genii with Sil2 silicone flange with filter	N	Y	Y	N	N	Y	N	Y	3.09	Company
Oakmed Options Alginate	Y	N	N	N	N	N	N	N	3.09	EAG [†]
Colomate	N	Y	Y	Y	N	N	N	N	3.11	EAG [□]
Pelican Platinum	Y	Y	Y	N	N	Y	N	N	3.12	EAG [□]
NovaLife 1 colostomy	N	Y	Y	Y	Y	Y	N	Y	3.13	Company
Welland Aura Plus	Y	Y	Y	N	Y	Y	N	Y	3.14	Company
Moderma Flex with filter and CeraPlus skin barrier	Y	Y	Y	Y	Y	Y	N	Y	3.14	Company
Pelican Modavi	Y	N	N	Y	Y	Y	N	Y	3.14	EAG [□]
Confidence Natural Advance	Y	Y	Y	N	N	N	N	Y	3.16	Company
NovaLife TRE 1	Y	Y	Y	Y	Y	Y	N	Y	3.17	Company
Confidence BE	Y	Y	N	Y	Y	Y	N	Y	3.17	Company
Welland Aura	Y	N	Y	N	Y	Y	N	Y	3.18	Company
FreeStyle Vie	N	N	Y	N	Y	Y	N	Y	3.18	Company
Confidence Natural	Y	Y	N	N	N	N	N	Y	3.19	Company
SenSura	N	Y	Y	Y	Y	Y	N	Y	3.20	Company
SenSura Mio	N	Y	Y	Y	Y	Y	N	Y	3.20	Company
Welland Aura flushable	Y	N	Y	N	Y	Y	Y	N	3.81	Company
FreeStyle Vie flushable	N	N	Y	N	Y	Y	Y	N	3.84	Company

Notes: * price per bag is calculated as the weighted average according to usage in 2023; † interpretation of RFI; □ interpretation of publicly available data as no RFI received

Table 16: Convex/concave shaped bags included in the analysis

Bag	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Price (£) per bag*	Source
Opus naturFit convex	Y	Y	Y	N	N	Y	N	Y	2.30	EAG [□]
UltraMax Atlas convex (shallow/deep)	N	N	Y	Y	Y	N	N	N	2.52	EAG [□]
Assura colostomy seal convex	N	N	Y	N	Y	Y	N	N	2.82	Company
Emperor convex	N	N	N	N	Y	Y	N	Y	3.00	EAG [□]
Nova 1 Convex with filter	N	Y	Y	Y	N	N	N	N	3.02	Company
Assura inspire seal convex	N	Y	Y	Y	Y	Y	N	N	3.11	Company
Esteem™+ Soft Convex	N	N	N	Y	N	N	N	Y	3.19	Company
Softima convex	N	Y	Y	Y	Y	Y	N	N	3.26	Company
Confidence Natural convex	Y	N	Y	N	N	N	N	Y	3.26	EAG [□]
Welland Aura profile	Y	Y	Y	N	Y	Y	N	Y	3.29	Company
FreeStyle Vie Convex	N	N	Y	N	Y	Y	N	Y	3.30	Company
FreeStyle Vie Curvex	N	N	Y	N	Y	Y	N	Y	3.30	Company
Aura Convex	Y	Y	Y	N	Y	Y	N	Y	3.33	Company
Confidence Supersoft	N	N	N	N	N	N	N	Y	3.13	Company
Pelican Platinum convex	Y	Y	Y	N	N	Y	N	N	3.34	EAG [□]
Welland Aura Plus soft covex	Y	Y	Y	N	Y	Y	N	Y	3.41	Company
Esteem+ Flex convex	N	N	N	Y	N	N	N	Y	3.43	Company
Option soft convex	N	N	Y	N	N	N	N	Y	3.45	EAG [†]
ModermaFlex closed convex	N	Y	Y	Y	Y	Y	N	Y	3.48	Company
NovaLife 1 convex	N	Y	Y	Y	Y	Y	N	Y	3.49	Company
Oakmed Options Alginate convex	Y	Y	Y	N	N	N	N	N	3.49	EAG [†]
Colomate convex	N	Y	Y	Y	N	N	N	N	3.52	EAG [□]
Moderma Flex convex with filter and CeraPlus skin barrier	Y	Y	Y	Y	Y	Y	N	Y	3.53	Company
Confidence BE soft convex	Y	Y	Y	Y	Y	Y	N	Y	3.53	EAG [□]
Pelican Modavi convex	Y	N	N	Y	Y	Y	N	Y	3.53	EAG [□]
SenSura Mio concave	N	Y	Y	Y	Y	Y	N	Y	3.56	Company
NovaLife TRE 1 convex (soft/closed)	Y	Y	Y	Y	Y	Y	N	Y	3.57	Company
SenSura Mio convex (deep/light/soft)	N	Y	Y	Y	Y	Y	N	Y	3.58	Company

Notes: * price per bag is calculated as the weighted average according to usage in 2023; † interpretation of RFI; □ interpretation of publicly available data as no RFI received

7.2.2. Decision Model overview

Given that no economic model suitable for adaptation was identified, a *de novo* model was constructed. As no clinical data suitable to inform either the effectiveness of individual bags or potentially innovative features were identified, it was not possible for the EAG to evaluate the cost effectiveness of specific features of 1-piece closed bags (flat bags and convex bags), and so how much NHS services may expect to pay for bags that include these features. Based on the evidence currently available for the assessment, the EAG were instead only able to evaluate the maximum cost that NHS services should reasonably be expected to pay for bags that are effective at reducing the impact of complications related to the use of 1-piece closed bags in adults with a colostomy using their best estimate of current practice for people experiencing complications, and the impact of these on HRQoL and costs to the NHS.

To do this, we sought to quantify the impact of stoma complications that are related to bag use and were intended to be reduced by the features included in the NICE scope. We then calculated the eJP for a bag which either reduced the complication by 50% or 100% (i.e. a reduction of 100% means that the bag prevents all incidents of that complication). This approach provides:

- Insight into the complications and patient preferences that are most important to address through bag choice for people with a colostomy.
- A price that NHS services may be expected to pay for 1-piece closed bags that are effective in addressing these complications for the population who experience them.
- An indication of the factors that are influential to appropriate pricing of 1-piece closed bags (i.e. factors that the model results are sensitive to).

Given the limitations of the evidence base for this analysis, as well as the lack of evidence to determine the effectiveness of specific features and/or bags to addressing these complications and patient preferences, the EAG cautioned that this analysis is suggestive only and that further research would be needed to inform pricing decisions for 1-piece closed bags for adults with a colostomy. Further details about research needs are discussed in Section 8.

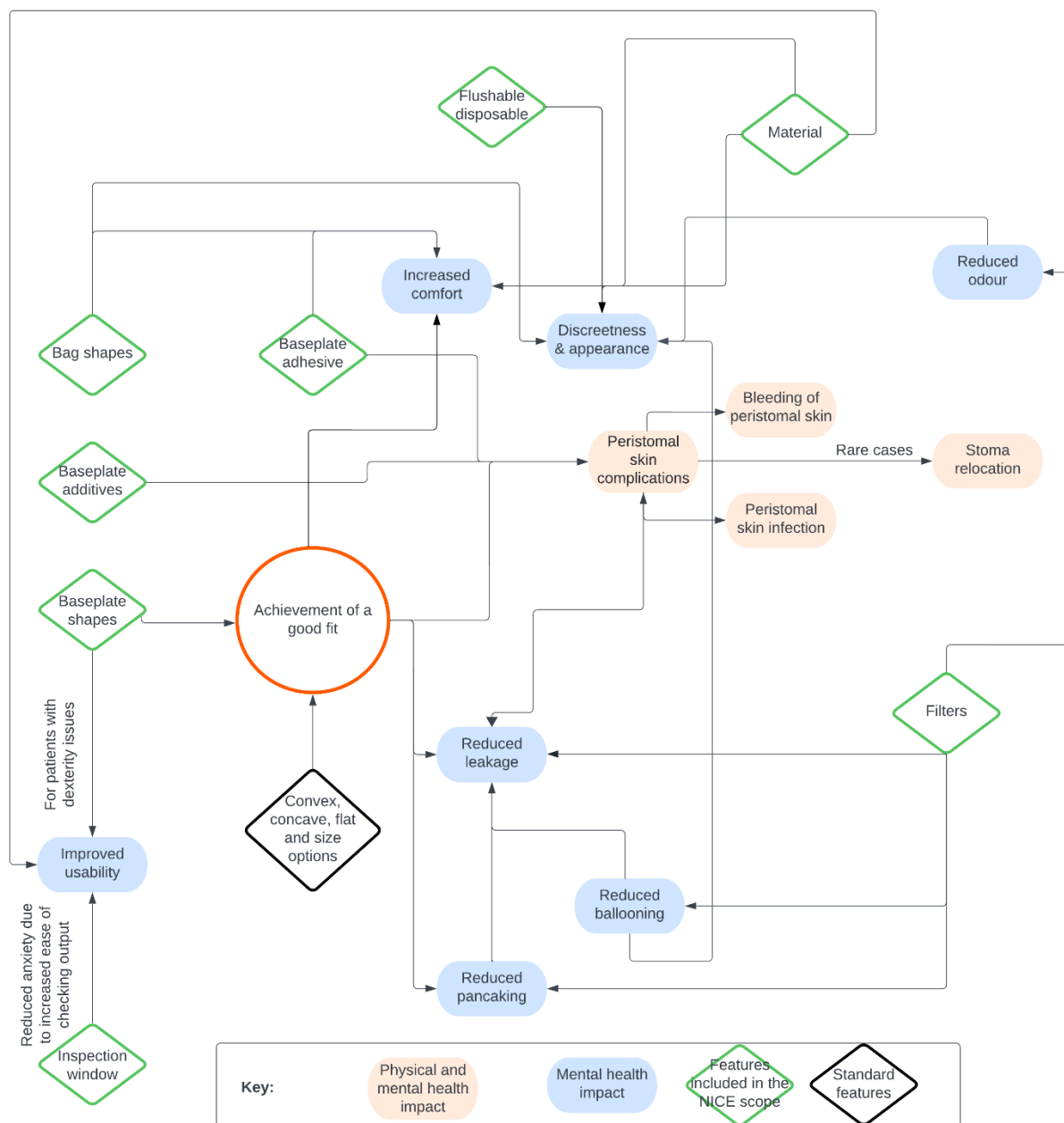
7.2.3. Decision Model structure

Our conceptual model (Figure 2) was based upon information and user preferences supplied by people with a colostomy and clinical experts to NICE, information supplied by companies on the features included within their bags and the purpose of those features, and interviews conducted with expert advisors to the EAG who were asked about the complications experienced by adults with a colostomy, how these are linked to bag use and how the features listed on the NICE scope are intended to benefit patients (Table 3).

We considered those issues that were expected by experts to be related to the choice of bag used (i.e., we did not consider stoma complications that were unlikely to be affected by the type of bag used). When asked to comment on the proposed model structure (per Figure 2 without comfort included) two experts proposed that the presence of a parastomal hernia should be included, however, later correspondence confirmed that the type of bag used does not contribute to the risk of hernia and therefore this remained excluded from the model. However, the expert CNSs in stoma care informed the EAG that once a patient develops a hernia, the cost of treatment increases as they would be expected to need a different type of bag and/or use more bags per day. They may also require more supporting products. One expert suggested to include comfort as a priority for bag choice, this was also noted as an important factor within the user preference workshops. Comfort (in the general sense) was therefore included in the model.

The model structure is shown in Figure 2. As can be seen in the figure, many of the bag features aim to reduce the chance or impact of more than one complication. In addition, some of the complications interact with each other. For example, baseplate shapes are designed to improve the fit of the bag, which in turn may reduce the chance of both leakage around the baseplate and PSC; leaks in turn increase the chance of PSC from poo sitting on the skin, and PSC increases the chance of leaks due to the increased complexity of achieving a good fit.

Figure 2: Conceptual model



Both clinical experts and people with lived experience of using 1-piece closed bags agreed that the two complications expected to be most impactful to adults with a colostomy and NHS resources were PSC and leakage. The model therefore accounted for 1) PSC, 2) leakage, 3) pancaking, 4) ballooning, 5) odour and 6) appearance, discreetness and comfort.

Following consideration of the conceptual model and given the paucity of evidence available, rather than constructing a single model capturing all elements simultaneously, the EAG

constructed state transition models to account for the cost and quality of life impact of each of the complications separately. Health states for each complication were defined as either simply presence or absence of the complication or mild/moderate/severe for PSC and leaks (where more data were available). A major but unavoidable limitation of this approach was that the analysis was unable to quantify the impact of a feature on multiple complications and account for the overlapping impact of multiple complications on people with a colostomy. Given the known relationship between bag features and complications, this limitation should be considered when viewing the results.

Results are presented deterministically as there was insufficient evidence to support a probabilistic analysis.

7.2.3.1. Time horizon

The model started at the point at which a new bag is prescribed to try to alleviate a particular complication.

A one-year time horizon was used for the analysis, representing an average year for a patient experiencing the relevant complication type. This was considered appropriate given the acute nature of the complications and a lack of information to indicate time dependency in their impact outside of the initial post-surgical period.

7.2.3.2. Perspective

An NHS and Personal Social Services perspective was taken in line with the NICE reference case.

7.2.3.3. Peristomal skin complications

PSCs can arise from a multitude of factors including leakage under the baseplate resulting in an irritant contact dermatitis and trauma, skin damage due to repeated stoma bag application and removal, and a retracted or poorly located stoma, which makes the achievement of a good fit more difficult.³⁹

PSCs can result in physical health problems including pain, itching, bleeding, and infection that can lead to hospitalisation and – in rare cases – even the need to re-site the stoma. In addition, they can impact on mental health due to pain and inability to sleep due to irritation, amongst other factors. According to the Ostomy Life Survey 2019⁴⁰ (n = 4,209; mixed stoma population), approximately one-third of people said that PSCs affected their daily activities in the way that

they stayed at home (33%), could not do light activities (32%), changed plans (34%), were unable to go out and meet family/friends (27%), or did not want to see people at all (28%).

According to the expert CNS in stoma care, PSCs can be treated by switching to a convex bag if there is a poor fit due to insufficient stoma protrusion or folds, changing bag (to one with a better fit or to one including additives within the baseplate), changing the bag more frequently, using supporting products or for more severe cases a topical steroid. Supporting products used by people experiencing PSCs may include stoma powder, barrier wipes/sprays and rings/seals for peristomal moisture associated skin damage; rings/seals in addition to topical steroids or steroid tape for inflammatory/autoimmune issues and paste, seals/rings and wound dressings for peristomal mucocutaneous separation. One clinical expert noted that as PSCs are most often due to the type of bag used, they would prefer to try a convex product rather than a seal, on the basis that they considered seals to be cost-ineffective due to the number of times bags needing to be changed.

The impact of PSCs was therefore modelled using the following information:

- Impact of PSCs according to severity on quality of life in the form of utilities.
- Duration of impact on quality of life.
- Increase in number of bags used per day.
- Increase in use of supporting products.
- Number of visits to CNS in stoma care and onward referrals required to resolve the complication.
- Chance of the patient choosing a different bag and cost of associated wastage of unused bags from their old prescription.
- Rates and costs of hospitalisation and stoma re-siting related to PSC.

7.2.3.4. Leakage

The impact of leakage and fear of leakage on mental health can also be considerable.^{40,41} According to the Ostomy Life Survey 2019⁴⁰ (n=4,209; mixed stoma population) the majority (92%) of people with a stoma worry about leakage to some degree. Two thirds (65%) of employed people reported that worry about leakage influenced their ability to work, 20%

reported that the risk of leakage made them decide to stay home 'often' or 'all the time', and 13% reported that they avoid other people 'often' or 'all the time'. The impact of leakage increased with the frequency of occurrence and whether leakage seeped onto clothes (as opposed to under the baseplate). People with a new stoma experienced the greatest burden; those with recent stoma surgery experienced significantly higher levels of weekly episodes of leakage onto clothes.

CNS in stoma care would first seek to investigate the cause of the leaks, for example clothes, diet, weight change, fullness of the bag / frequency of changes, technique, or use of baby wipes (which can cause residue). After determining the likely cause, they would discuss potential options for management with the person, which may include considering a change of bag or the use of a supporting product.

People experiencing leaks are likely to change their stoma bag more often and are also more likely to use more supporting products, particularly rings/seals, paste and flange extenders and support belts if the issue is linked to a hernia. A different type of bag may be required for some people e.g. convex bag if leakage is due to insufficient stoma protrusion or skin folds. As stated for PSC, one of the clinical experts noted that they considered that seals are cost-ineffective due to the number of times bags need to be changed.

The impact of leakage was therefore modelled using the following information:

- Impact of leakage according to frequency in the form of utilities.
- Duration of impact on quality of life.
- Increase in use of supporting products.
- Number of visits to CNS in stoma care required to resolve the complication.
- Chance of the patient choosing a different bag and cost of wastage of unused bags from their old prescription.

7.2.3.5. Pancaking and ballooning

Pancaking and ballooning impact on quality of life both independently and through an increased risk of leakage (as they impact on the seal between the baseplate and the skin or leaking through the filter when pancaking). In the case of ballooning, the stoma bag may also become more visible under clothes, which can cause anxiety around social interactions. According to

CNS in stoma care, the first advice given to people with a colostomy to reduce the chance of these complications involves changes to diet, fluid intake and bag change frequency (for those changing the bag less than daily), or lifting the baseplate slightly to release flatus (“burping the bag”). After these have been tried, people may look to change the bag to one with a different filter (or potentially to a different bag type, such as a 2-piece bag where air can be let out more easily or a convex bag for pancaking) or add supporting products (such as stickers to cover the filter to make sure it does not get wet for ballooning and lubricating oil or stoma bridges in the case of pancaking). People may also try poo softener, laxatives, or colostomy irrigation to reduce the chance of pancaking.

As no information on the impact on quality of life was identified in the form of utilities, CNS in stoma care were asked what would constitute a ‘regular’ issue with these complications. A definition of ‘daily’ was used in the model as four out of five experts mentioned this in their definitions, although we note that less frequent issues (i.e. from 2-3 times to once a week) may also be a regular problem for people with a colostomy.

The impact of pancaking and ballooning was therefore modelled using the following information:

- Impact of regular (daily) issues in the form of utilities (obtained from expert elicitation).
- Increase in use of supporting products.
- Number of visits to CNS in stoma care required to resolve the complication.
- Chance of the person choosing a different bag and cost of wastage of unused bags from their old prescription.

7.2.3.6. Odour

Similar to a person’s anxiety about leakages, anxiety around odour can impact on mental health and on the ability of people with stomas to participate in social activities.⁴² Odour can be caused by a poor seal between the stoma bag and the skin or an unsuitable or overloaded filter or leaks. People experiencing issues may make changes to their diet, change their bag more frequently, try a different sort of bag or use supporting products such as neutralising sprays, neutralising drops, over-the-counter essential oil drops or air fresheners.

Again, no information on the impact on quality of life was identified in the form of utilities. A definition of daily was used to represent a regular problem with odour, based on CNS in stoma care responses.

The impact of odour was therefore modelled using the following information:

- Impact of regular (daily) issues in the form of utilities (obtained from expert elicitation).
- Increase in number of bags used per day.
- Increase in use of supporting products.
- Number of visits to CNS in stoma care required to resolve the complication.
- Chance of the person choosing a different bag and cost of wastage of unused bags from their old prescription.

7.2.3.7. Appearance and discreetness

Having a bag that has a good appearance and is discreet can be important psychologically to people with a colostomy and can impact on willingness to participate in social and leisure activities.

A good bag appearance can mean different things to different people. Based on input from CNS experts and people with stomas at the user preference workshop the EAG understand that some factors which may influence preference include:

- Wanting a bag that matches their skin tone
- Wanting a bag that matches their underwear.

A small study of the lived experience of people with a stoma looking at the impact of bag opacity found that an opaque bag can improve postoperative comfort for some patients, although the majority of those sampled were indifferent.⁴³ Clinical experts considered it rare for a clear bag to be preferred as it encourages people to constantly check their poo. The EAG note comment from the Association of Stoma Nurses that clear pouches can be advantageous if people have visual issues to ensure that the pouch is positioned correctly.

Discreetness involves several different factors (in addition to odour, which has been captured separately), including visibility, noise, and disposal. Different types of bags suit different types of

clothes according to how they distribute weight and how big they are. It is important that the bag does not stick out of clothes and many people will prefer a bag which is less (or preferably not) visible under clothing and does not make a noise when moving under clothes. One of the clinical experts noted that being able to flush a bag can be important for some people psychologically. This is supported by a study of 86 people (the majority using 1-piece closed bags) conducted in Scotland on the impact of bag change and disposal, which found that 25% of participants found disposal of used bags the most difficult part of their bag change and disposal routine. They stated that current requirements for disposal impacted on their ability to socialise, and 14% would like to flush the bag down the toilet.⁴⁴

The impact of appearance and discreetness was therefore modelled using the following information:

- Impact of preferred appearance and discreetness in the form of utilities.
- CNS in stoma care visits required to find a suitable bag.
- Chance of the person choosing a different bag and cost of wastage of unused bags from their old prescription.

7.2.3.8. Comfort

Comfort was suggested as an additional factor to include in the economic model by one of the CNS in stoma care consulted after the expert elicitation exercise had been distributed.

A comfortable bag was defined in the user preference workshop as: “a bag that has material (both the fabric and edging) that is comfortable against the skin, doesn’t rub or itch when empty or full, and is quick to dry.”

After the elicitation exercise when CNS in stoma care were asked to review the outputs, they informed the EAG that the impact of comfort on utilities would be the same as for appearance and discreetness. These were therefore modelled as one complication.

7.2.3.9. Length of time before switching bags

The length of time and the probability of switching to another type of bag (different range and/or brand) were expected to impact both cost and the quality of life of patients, as experts advised the EAG that the main reason for people changing to another type of bag is experiencing complications with their current bag. [REDACTED]

The probability of switching to a different bag type is, however, a crude proxy for patient dissatisfaction. There are several factors that influence switching behaviour, some of which are likely independent of bag type being used (e.g. patient propensity to seek help) and others of which will be dependent (e.g. bag provider practices in patient follow-up in the area, size of range of the current bag provider etc.).

The EAG asked companies to share any data they had on the percentage of people who switch to another bag in a year, along with the average duration before making such a switch. Nine companies responded to the request, of whom six were able to provide pertinent data (Table 17). Two companies [REDACTED] stated that they could not provide these data [REDACTED]

Table 17: Probability of switching bags

Company	Probability of switching	Time since surgery
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

In many cases, companies did not report the characteristics of the population from which their results were derived. Where reported, the EAG noted that there was significant heterogeneity in the population from which the results were taken, particularly regarding the time since surgery.

[REDACTED] Furthermore, it was not always clear whether the data included switches within and beyond the same brand or only switches beyond the brand. Where stated, there was limited comparability across the data as some companies reported switching within the brand and to other brands, while some presented the total percentage of patients who switched.

Two CNS in stoma care were asked to comment on the differences in the probability of switching across companies. One responded that bag switching may be influenced by

marketing strategies from companies that they had witnessed in practice, for example, insisting that people switch to their latest branded products. CNS in stoma care also noted that people often switch within the first year due to multifactorial issues, and that where there is a larger range available (e.g. for Coloplast with convexity and Salts with different colours) there might be more incentive to switch to find a more ideal bag.

[REDACTED]

A clear finding from the data was that there was a substantial proportion of people who were experiencing complications who do not change the bag they are using. In a review of 23 studies focused on the clinical-epidemiological burden of PSCs, the incidence of PSCs ranged from 36.3% to 73.4%.⁴⁶ There was an increase change of onset of PSC in the initial 3 months after surgery. However, PSCs can occur at any time in a person's life, sometimes many years after surgery, because of factors such as skin changes due to aging, menopause, or pregnancy. Results from the interim patient survey submitted by Colostomy UK indicated that 53% of the 3,742 participants (including people with a colostomy, ileostomy and urostomy) reported that they were impacted by leakage, 48% by pancaking, 44% by skin irritation, 39% by ballooning, and 28% by odour. People who do not change their bag type may instead rely on supporting products (the evaluation of the effectiveness of which was out of the scope of this assessment) or may instead continue without any support.

Given the inconsistency in the data supplied by companies and the fact that these data were not in a format that could easily be used in the model (e.g. the probability of switching bag was only available overall than in response to specific bag-related complications), the EAG sought additional input from clinical experts (see Sections 7.2.4 and 7.2.5 for the methods used and results supplied).

7.2.4. Qualitative Expert input to decision model development

The EAG, along with NICE, had several discussions with clinical experts and people with lived experience to inform model development as the evidence base evolved. This included:

- Attendance at the NICE scoping workshop.

- Visits to stoma wards in Sheffield and Exeter.
- Attendance at the NICE user preference workshops.
- Questions were sent to all clinical experts and CNS in stoma care involved in this assessment to inform the design of the structured expert elicitation.
- Interviews were conducted with two CNS SCMs/experts in stoma care to inform model parameterisation for specific questions related to resource use.
- To gain additional insights, specific questions about a select number of publications were sent to Natasha Rolls, the first author.
- The draft EAG report was sent to all clinical experts and SCMs to review and provide comment.

Input provided is detailed in each of the relevant sections and has been used to inform the final model structure and model inputs.

7.2.5. Structured expert elicitation

Given the scarcity of evidence found in the available literature for several model parameters, the EAG conducted a structured expert elicitation to provide information to fill data gaps related to:

- quality of life parameters
- the probability of switching to a different bag type (from the same or an alternate brand) if a person experienced complications rather than using supporting products
- the probability of more serious complications such as hospitalisation or stoma re-siting happening due to PSCs.

The protocol used for this exercise is provided in Appendix D. The exercise was conducted using the resources and guidance provided on the STEER website via a survey tool recently developed by Valorem health.⁴⁷

Seven out of nine CNS in stoma care who were sent the survey completed it. Of the two who did not, one expressed concern that they could not complete it as the people they see are more complex than the patient population defined within the survey (they only see people referred to hospital) and the other was not able to complete the survey.

Of the seven responses received, five supplied answers that suggested a potential misunderstanding of the questions related to disutilities (i.e. submitted disutility estimates that lacked face validity, including inconsistency relative to their other responses) and were contacted to provide additional support and given the opportunity to revise their answers; three experts took this opportunity and two did not respond. In sum, the final sample size was five experts for questions relating to disutilities and seven experts for the other questions.

Characteristics of the experts who completed the exercise were as follows:

- Number of experts who completed the exercise = 7
- Mean years of experience = 11.5
- Facilities in which experts practice = Two tertiary care, two secondary care, one community health, one Higher education, one chose not to answer
- Band nurse (or equivalent) = Three Band 8, three Band 7, one chose not to answer
- Mean number of people with a colostomy managed per week = 13

Based upon the experts' characteristics, the EAG considered that they represented a more experienced group than the average CNS in stoma care with a considerable number of years of experience and employment at a higher band (majority of CNS in stoma care in practice are Band 6). The experts provided good coverage of the different settings of care and a reasonable coverage of different geographies (2 in Yorkshire, 3 in London, one in the South-West and one in the East of England).

In addition to the steps planned within the protocol, a call was organised with the clinical experts (25th June 2024) to agree the estimates, given the discrepancy between some of the results. The slides used for this call are provided in Appendix K. Changes were made to three outputs (the disutility for pancaking and proportion switching to a new type of bag for ballooning and pancaking); otherwise, the initial estimates were considered reasonable. The results are presented in Table 18.

Table 18: Results from structured expert elicitation

Parameter	Mean value from experts' answers
Disutility: Regular (daily) Ballooning	0.058
Disutility: Regular (daily) Pancaking	0.066
Disutility: Regular (daily) Bad odour	0.082
Utility gain: Discreet bag design with preferred appearance	0.077
Probability switching: 4 leaks/month	61.69%
Probability switching: 1 leak/ month	43.89%
Probability switching: 1 leak per 6 months	25.12%
Probability switching: PSC 2/10	29.97%
Probability switching: PSC moderate level of pain, itching and burning (5/10); no bleeding or ulcers	58.22%
Probability switching: PSC weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers	63.92%
Probability switching: PSC-bleeding or ulcers and a moderate level of pain, itching and burning (5/10)	63.25%
Probability switching severe PSC 8/10	73.50%
Probability switching: Regular (daily) Ballooning	44.10%
Probability switching: Regular (daily) Pancaking	52.26%
Probability switching: Regular (daily) Bad odour	61.17%
Probability: Hospitalisation due to skin complications	13.39%
Probability: stoma re-sited due to skin complications	1.95%

Abbreviation: PSC, peristomal skin complication

Note: probabilities of switching are the probability of switch to a different bag type or brand at any time in order to resolve a particular complication

7.2.6. Modelled population

As noted earlier, complications can occur in the post-operative phase or at any time later, as a person's body shape and skin change as they go through different stages of life.⁴⁸ Given that the aim of this analysis was to consider the eJP for different features for the average patient, we defined this within the model as a person who had adjusted to their colostomy (one year or more after surgery) based on input from clinical experts at the scoping workshop. A one-year timepoint was chosen so that patients will have largely healed from surgery, have a well-defined stoma shape, and have gained some experience with the use of stoma bags. We note that people with a new stoma are likely to have higher rates of complications and are likely to need to try a number of different types of bags to find one that suits their needs.

7.2.7. Effectiveness data

No data were identified that allowed for reliable quantification of the economic benefit of either specific features or specific types of bags.

Key clinical outcomes for all of the bags evaluated in studies included in the clinical evidence review are shown in Table 13. Due to the low quality of the included studies and a lack of consistency in the pattern of outcome data, there was no robust evidence for differences in outcomes between evaluated bags. However, for purposes of this analysis we identified instances where outcomes differed meaningfully between bags compared within the same study. Two bag-related complications were identified in the clinical review as having any evidence of difference in outcomes between bags. The first of these was ballooning where differences were reported in two studies: the Voergaard (2007)¹⁴ study reported rates of [REDACTED] for SenSura vs 53% Nova1 amongst participants; and the Virgin-Elliston (2023)¹³ study, which was likely of most direct relevance as it included participants who were experiencing at least one episode of ballooning per week at baseline, found rates of ballooning in 11.2% of bags with the SenSura Mio filter vs 22.8% of SenSura bags.

[REDACTED]
[REDACTED] None of the published [REDACTED] included studies found a meaningful difference between bags in the two most impactful complications according to the economic analysis (PSC and leaks).

The EAG conducted an exploratory analysis looking at whether the difference in price between the bags in the above two published studies was explained by the reduction in complications alone. It should be noted that the EAG did not consider this analysis to be robust due to the poor quality of the underlying studies. Specifically, quality issues with the studies (Section 5.3) mean that both the direction and the effects reported could be unreliable and the lack of consistency in reporting across studies, and the paucity of available data overall, meant that it is not possible to obtain any validation of the results. However, the findings of this analysis were considered to be indicative of the extent to which reported differences in bag-related complications were associated with price differences.

7.2.8. Resource use and cost parameters for complications

Of the 26 included studies looking at resource use, seven papers were identified in the evidence review that contained information on resource use and costs for complications associated with bag use (Table 19). Only one of these papers³² was specific to people with a colostomy and this

only included costs for infection. Additionally, Coloplast provided the EAG with a subgroup analysis for [REDACTED] for the analysis presented in the Nørtoft 2019 poster.

[REDACTED]

■ The majority of the papers used data from retrospective patient surveys conducted either in the UK or across multiple countries. Reporting of the methods used to calculate resource use and costs was generally poor. The Neil 2016 model²⁷ was considered as an additional source but was ruled out as it did not provide useful resource use data. This paper compared 1-piece and 2-piece bags (open and closed) with skin barrier alone vs. supporting products being used selectively, with clinical oversight, to individualise baseplate fit/adhesion. Rates appeared to be based solely on assumption. None of the other papers provided information in a format that was suitable to assess the impact of either individual complications or the impact of any of the features listed within the scope.

Table 19: Resource use and costing studies

Author	Rolls ⁴⁹	De Fries Jensen ^{22,50}	Nørtoft ²⁸	Berger ^{21,51}	Martins and Meisner ^{20,24,25}	Mockford ²⁶ (adapts Meisner)	Mohiuddin ³²
Year	2023	2023	2019	2018	2012	2018	2021
Price year	2019	2019	2019	N/A	2012	2016	2018
Funded by	Coloplast	Coloplast	Coloplast	Hollister	Coloplast	Coloplast	N/A
Countries	UK	UK, USA, France, Germany, and Denmark Costs are from UK only	UK	US, Canada and Europe	UK model based on study in 18 countries	UK	UK
Patient population	100% ileostomy	38% colostomy; 62% ileostomy	Subgroup of patients ██████████ ██████████	53% colostomy, 38% ileostomy, 9% urostomy	67% colostomy, 31% ileostomy, 2% urostomy	People with a stoma; split unclear	End colostomy
Study type	Retrospective survey of patients and HCPs	Retrospective online self-reported questionnaire	Retrospective cross-sectional observational study	Economic model based on ADVOCATE RCT	Economic model based on Dialogue study	Cost analysis	Economic model
Number of patients	105 patients, 51 HCPs (28 completed full survey)	596	████	153	3,000, 140 from UK	1,968	N/A
Complications considered	PSC*	Leakage [†]	PSC, BP, leakage, social concerns	PSC	PSC [‡]	PSC	Infection
Relevant information contained	Cost and resource use	Cost and resource use	Cost and resource use [‡]	Resource use for PSC and chance of multiple PSC [¥]	7-week cost of treatment for PSC based on severity and cause	Annual treatment cost and number of episodes per year (assumption)	Cost code

Author	Rolls ⁴⁹	De Fries Jensen ^{22,50}	Nørtoft ²⁸	Berger ^{21,51}	Martins and Meisner ^{20,24,25}	Mockford ²⁶ (adapts Meisner)	Mohiuddin ³²
Cost per event	Costs from £258 to £505 for mild to severe	£32.47	██████████ ██████████	N/A	Costs from £106 to £619 for mild to severe	£240 per 7 weeks of treatment	£1,636 NHS reference costs (FD10A-C)
EAG subjective assessment of quality and relevance	Self-reported questionnaire with disagreement between HCPs and patients, reasonable sample size, ileostomy only AMBER	Self-reported questionnaire, good sample size, proportion with colostomy relatively low AMBER	Poster, methods unclear, ██████████ AMBER	RCT data, Australian costs, methods used to derive the resource use RED	Open label, non-comparative, post marketing study, large sample size Historic data High proportion with colostomy Methods used unclear RED	Poster Resource use with costs updated from Meisner 2012, same issues apply RED	Population correct. Limited data of use and cost code based on assumption RED

Abbreviations: BP, ballooning/pancaking; HCP, healthcare practitioner; N/A, not applicable; PSC, peristomal skin complications; randomised-controlled trial
Notes:

*PSC severity defined using Ostomy Skin Tool v2.0^{30,31} which uses DET score. The patient survey was used to inform estimates of bag use and supporting product use for the cost calculations, while the HCP survey was used to inform estimates of symptom duration and treatment received by PSCs, including nurse consultations, referrals, medication, and stoma revision

† Leakage defined as leakage outside of the baseplate; costs and resource use associated with increased use of bags and supporting products and the potential need for additional health care professional interactions were considered

‡ Includes only change to the cost of bags and plates and supporting products; ██████████

* Severity defined by discoloration, erosion, and tissue overgrowth (DET) score. Resource use data was presented by arm on increase in pouching supplies, nurse visits (protocol dictated so not generalizable), physician visits and accessory use. The chance of multiple PSC and the impact of accessories on this is based on assumption alone. Costs are provided in the model but are in Australian dollars and were therefore not considered relevant. The model provides a comparison of ceramide-infused barrier to standard of care based on the ADVOCATE trial, which was a comparison of 2-piece bags. This study was therefore not considered in the clinical evidence review.

‡ Severity based on DET score; methods used to calculate costs were unclear, however information is provided on the cost code for resiting of a stoma (FZ10B) and the duration of first and follow-up CNS visits (60 and 20 – 30 minutes)

For EAG assessment of quality and relevance, **GREEN** indicates high quality, **AMBER** indicated lesser quality, and **RED** indicates poor quality.

7.2.8.1. Peristomal skin complications

Four studies presented an average UK cost for a PSC and one additional study presented resource use for PSC based on the ADVOCATE RCT.

Unfortunately, the methods used to derive the resource use from the ADVOCATE RCT were unclear and it was likely that much of this will have been protocol dictated and therefore lacking in generalisability to practice (i.e. it lacked external validity). This study was therefore only used to provide information on the rate of PSC and split by severity according to DET score. The rate of PSC was only reported in one other study which simply assumed that people with a colostomy would be experiencing PSC continuously throughout the year.²⁶ The split by severity was not reported in any other studies including people with a colostomy.

All of the papers that provided information on PSC by severity used the DET score.^{30,31} All studies included a mixed population: the percentage of participants with a colostomy ranged from 0 to 67% and the majority of the remaining patients had an ileostomy.

The EAG queried CNS in stoma care about the comparability of colostomy and ileostomy populations (see Appendix E). In brief, and in respect to the rate of complications between people with a colostomy and ileostomy, feedback from CNS in stoma care was conflicting although the majority of respondents thought that people with an ileostomy would be at greater risk of complications than people with a colostomy:

- 1 of 7 nurses considered that outcomes would be similar.
- 5 of 7 nurses considered that there would be differences with a higher risk of skin complications due to looser poo and the enzymes in the poo being more corrosive for people with an ileostomy.
- 1 of 7 nurses raised that people with an ileostomy generally keep their bags on longer, so the risks of irritation or complications is higher.

Two nurses were consulted on whether there would be a difference in the cost of treatment for colostomy as compared to ileostomy, both of whom agreed that there would be. In particular:

- Ileostomy-related to PSC was considered to be harder to treat.
- There are more bag changes per day for colostomy, the number of bags required would still increase with increasing severity of PSC.

- The types of supporting products used may be different for example there would be less use of rings and more use of flange extenders and adhesive removers for colostomy vs ileostomy in part this is due to more frequent bag changes being required.
- The time to healing was considered to be similar.
- Less likely to refer to a gastroenterologist for people with a colostomy (as less likely to be IBD-related)

The Nørtoft (2019)²⁸ subgroup analysis provided a cost of [REDACTED] whilst this was in the [REDACTED]. In addition, only a poster was available for this study and the goodness of fit of the statistical model used to derive estimates of the impact of complications based on the patient support programme dataset was not reported. Definitions used for the complications were also not provided.

The three remaining studies were reasonably consistent ranging from £240 per 7 weeks of treatment in Mockford (2018)²⁶ to £106 - £619 for mild to severe PSC in Martins (2012)²⁴ (on which the Mockford paper was based) and £258 to £505 for mild to severe per episode in Rolls (2023).⁴⁹

The paper that provided the most detail behind its methods was Rolls et al. (2023), which also appeared to be the most comprehensive in the types of resource use included: the patient survey (3-month recall period) was used to inform estimates of bag and supporting product use for the cost calculations, while the HCP survey was used to inform estimates of symptom duration and treatment received by PSCs, including nurse consultations, referrals, medication, and stoma revision. The drivers of cost differences between different PSC categories were nurse visits, requirement for revision/re-surgery and 1-piece closed bag costs. The total cost was estimated to be £258, £383, and £505 for the duration of a mild, moderate, or severe PSC, respectively.

The HCP survey asked respondents to estimate the number of nurse consultations that people would receive across three different categories: visits to a nurse, home care nurse visits, and non-face-to-face (online or telephone) consultations. There was some uncertainty regarding whether respondents considered these categories separately or in combination. The base case cost analysis therefore counted only in-person visits to a CNS in stoma care, which was the most frequent type of nurse consultation. When all nurse consultation types were included, the

estimated cost per PSC increased by approximately 36% relative to the base case. However, there was considerable discrepancy in the number of nurse visits recalled by patients compared to CNS in stoma care. When the PSC costs were recalculated using the number of nurse visits recalled by patients and reported in the patient survey, the PSC costs for mild, moderate, or severe were estimated to be £51, £91, and £161 respectively.

When we discussed this difference with clinical experts, they considered that reasons for this could be that patients may be slower to pick up on skin changes than CNS in stoma care and that there was a sizeable population of “lost ostomates” who do not seek help for complications; this may be particularly common for people who have had their stoma for a long time, as stoma care follow-up has changed considerably over time. This was supported by available literature (a study of 202 individuals found that 80% of people who were diagnosed with PSC did not seek professional help¹⁰). They considered the nurse survey to be the more reliable source, although we would note that information supplied by the patient and clinical experts during the assessment indicated that patient access to CNS in stoma care varies considerably across geographies and that levels of patient engagement also appeared to be highly variable.

In the EAG base case we therefore used the following estimates detailed in Table 20:

- Supporting product costs from Nørtoft (2019) subgroup analysis [REDACTED] – as this came from the [REDACTED].
- Other resource based on Rolls (2023), with changes to adapt to a colostomy population as suggested by two CNS in stoma care with some additional consultation for the number of 1-piece closed bags per day to validate inputs following commentary from one SCM that the values initially input appeared too high (Appendix).

Table 20: EAG base case cost and resource use assumptions for treating PSC

Cost / resource use item	EAG base case input	Source
Number of 1-piece closed bags per day	No PSC: 1.5 Mild: 3 Moderate: 4.5 Severe: 5.5	Clinical expert opinion (2 CNS in stoma care)
Cost per bag	£3.02	Bennett Institute ⁵ average bag cost 2023

Cost / resource use item	EAG base case input	Source
Cost of wastage when bag type is switched	½ of an average prescription of 75 bags (60 or 90 bags are usually supplied)	Clinical expert opinion (2 CNS in stoma care)
Supporting products cost	██████████ per month	Nørtoft 2019 ²⁸ subgroup analysis Assumed not to vary by PSC type as data on this not available
Duration of symptoms	Mild: 1.67 weeks Moderate: 2.63 weeks Severe: 3.61 weeks	Rolls (2023) ⁴⁹ HCP survey Confirmed appropriate by 2 CNS in stoma care
Number of CNS in stoma care consultations	Mild: 2 phone/online contacts, one face to face contact Moderate and severe: 50% and 86% increase in contact overall based on Rolls (2023)	Clinical expert opinion (2 CNS in stoma care); both noted an increased use of emailed pictures and phone appointments to reduce the need for face-to-face contact Rolls (2023) ⁴⁹ HCP survey
Cost per CNS in stoma care consultation	Face to face: £76.80 Telephone/online: £45.17	Band 6 nurse cost from PSSRU 2023 ⁵² * 1.2 to include indirect time N24AN Specialist Nursing, Stoma Care Services, Adult, Non face to face from NHS cost ref 2021/2022 ⁵³ inflated to 2023 cost using PSSRU
Proportion of patients referred	Dermatologist: 0% mild, 4%, moderate 8% severe Gastroenterologist: 0.5% mild, 1% moderate, 2.5% severe GP: 0% Surgeon: 1% mild, 2% moderate, 7% severe	Rolls (2023) ⁴⁹ HCP survey One CNS in stoma care considered the dermatologist values reasonable, the other had never referred Both CNS in stoma care considered gastroenterologist referrals to be less likely for colostomy so have assumed ½ Both CNS in stoma care considered that referral to GPs did not happen (which also reflects GP consultation) and this was instead incorrect logging of prescription requests Both CNS in stoma care considered that surgical referral values were reasonable NHS cost ref 2021/2022 ⁵³ inflated to 2023 cost using PSSRU
Cost of referrals	Dermatologist: £163.39 Gastroenterologist: £215.57	Consultant-led outpatient appointments service codes: 330; WF01B

Cost / resource use item	EAG base case input	Source
	Surgeon: £216.38 Then inflated by 7.03% to 2022/2023 prices	301; WF01B 100; WF01B NHS reference costs 2021/2022 ⁵³
Proportion of patients prescribed medication	Steroids: 3% mild, 17% moderate, 20% severe Silver nitrate: mild 1%, moderate 2%, severe 9% Tacrolimus: 0%	Rolls (2023) ⁴⁹ HCP survey CNS in stoma care noted that very few drugs are licensed for use with a stoma on the skin. Both CNS in stoma care stated that tacrolimus is unlikely to be used for colostomy but otherwise values appeared reasonable
Cost of medications	Topical corticosteroids: £10.21 Silver nitrate: £4.28	CNS in stoma care stated they used beclomethasone inhalers or fludrocortide tape. Costs taken from eMIT ⁵⁴ and BNF ⁵⁵ Cost of silver nitrate from BNF ⁵⁵
Hospitalisation	13.4%	Expert elicitation mean. Aligns with hospital readmissions within the 120 days following surgery (47% vs. 33% without PSCs) from Taneja (2017) ⁵⁶
Cost of hospitalisation	£489 Then inflated by 7.03% to 2022/2023 prices	Weighted average cost codes JD07E – JD07K as day case from NHS reference costs 2021/2022 ⁵³
Stoma resiting	1% at all severities	Rolls (2023) ⁴⁹ HCP survey
Cost per stoma resite	£4,463 Then inflated by 7.03% to 2022/2023 prices	Weighted average cost of elective surgery for codes WH07A-G from NHS reference costs 2021/2022 ⁵³ Cost code taken from Mohiuddin 2021 ³²
Number of PSCs per year	$2.4 [41 / (74 * 12) * (365.25 / 7)]$	ADVOCATE RCT ⁵¹ standard of care arm – assumes constant rate over a year
Severity split	44% mild, 48% moderate, 8% severe	ADVOCATE RCT ⁵¹

Abbreviations: BNF, British National Formulary; GP, general practitioner; HCP, healthcare professional; NHS, National Health Service; PSC, peristomal skin complication; PSSRU, Personal Social Services Research Unit; CNS, stoma care nurse

The EAG base case assumptions resulted in a total cost of [REDACTED] associated with PSCs per event for 52 weeks for mild, moderate and severe, respectively.

In sensitivity analysis, we considered the following alternatives: Mockford (2018)²⁶ and Martins (2012)²⁴ inflated to present day costs: £289.63 per PSC and £149.04, £188.31 and £377.87 for a mild, moderate and severe PSC respectively.

We note that the EAG base case assumed a considerably higher cost for treatment of PSC than the other available publications. We considered this to be more comprehensive as more cost items were included and costs were included for a full year rather than the shorter time periods used in the majority of other sources, although noted that this still most likely represents people who are actively engaged with health care services and not so-called “lost ostomates”.

7.2.8.2. Leakage

Two studies (De Fries Jensen 2023⁵⁰ and Nørtoft 2019²⁸) examined costs and resource use utilisation related to leakage. One further study (Cawson 2023²²) utilised the costs from the De Fries Jensen publication and included an additional cost for fear of leakage of £8.27 at a weekly risk of 49.8%, although it was not clear how this was derived (reporting of this and Nørtoft were limited to posters).

De Fries Jensen (2023)⁵⁰ conducted a retrospective self-reported questionnaire among members of the Coloplast Online Research Engine (CORE) survey panel, representing the UK, USA, France, Germany, and Denmark. The population was adults with a stoma, of whom 38.4% had a colostomy.

The Nørtoft (2019)²⁸ poster reports results of a retrospective observational study using deidentified data from the Stoma Partnership programme in the UK. Subgroup analysis was provided for [REDACTED].

The De Fries Jensen study provided data for people experiencing leakage outside of the baseplate and included costs and resource use associated with increased use of bags, supporting products and the potential need for additional interactions with HCPs. The Nørtoft poster only included the cost of bags and supporting products and considerably less detail was available for the methods used, however, [REDACTED].

Six out of seven CNS in stoma care considered that people with an ileostomy would be at more risk of leaks than people with a colostomy, while one thought it would be similar as although the liquidity of poo with ileostomy increases the risk of leaks, people with a colostomy experience pancaking which can lead to leakage. One of two CNS in stoma care consulted for additional

clarification also noted that leakages would have more of an impact for people with an ileostomy relative to those with a colostomy as the poo is looser and therefore leakages are likely to be runnier and have more force to them.

De Fries Jensen (2023) and Nørtoft (2019) used different cost items within their analyses and different time horizons (Nørtoft (2019) considers the impact of leakage on costs per month and De Fries Jensen (2023) considers leakage within the last 3 months). Despite these, the cost per leak estimated in were similar: £32.47 vs [REDACTED] in 2019 prices.

The EAG presented the cost breakdown from De Fries Jensen (2023) to two CNS in stoma care for comment and asked about how likely people were to reach out according to the frequencies of leakage onto clothes presented in the Rolls (2022)⁵⁷ study available for utility data (Section 7.2.4). They both considered that people experiencing two leakage events onto clothes per year would be unlikely to reach out for support. They judged that the value in De Fries Jensen for the proportion reaching out for support (21%) is what would be expected for people experiencing one event of leakage onto clothes per month. They would further expect that the vast majority of people would reach out if they were experiencing four events of leakage onto clothes per month (90 – 100%). They did not expect that the use of supporting products would change according to leakage frequency.

Given the information available, the EAG base case used:

- Data from the Nørtoft (2019) subgroup analysis to represent the cost of additional supporting products and changing bag type for all leakage frequencies
[REDACTED]
- Data from De Fries Jensen (2023) to calculate the cost of consultation with CNS in stoma care (Table 21) to resolve issues with leakages with a proportional increase to 95% consultation for people experiencing leaks most frequently.
- It was assumed that leakages with four times per month frequency would need three weeks to be resolved based on discussions with CNS in stoma care, and an assumption that twice yearly leaks are not resolved as people would be unlikely to contact their stoma service for support. Note that resolution here is defined as resolution to an acceptable level rather than a complete absence of leaks. Many people will continue to experience the occasional leak even with an optimal bag.

The cost of CNS in stoma care consultations was the same as that presented in Table 20. The cost of a home care visit was assumed to be the same as a face-to-face visit in surgery plus a 5% additional cost for travel time based on PSSRU. Based on advice from CNS in stoma care and GPs that GPs were rarely involved in delivering care to people with a colostomy, consultations were assumed to involve an in-person visit with a CNS in stoma care.

Unfortunately, the EAG could not find any information on the proportion of people experiencing different leak frequencies and therefore results were produced separately by leak frequency (Table 21).

Table 21: EAG base case inputs for chance of CNS in stoma care consultation by leak frequency

	% of patients experiencing a leak onto clothes		
	twice yearly	monthly*	Four times a month
Consultation with an HCP	0%	21.40%	95%
Physical visit with a CNS in stoma care (in the hospital, practice, or the patient's home)	N/A	9.90%	43.9%
Telephone or online consultation with a CNS in stoma care	N/A	15.40%	68.4%
Physical visit from a home care nurse	N/A	2.90%	12.9%
A face-to-face visit with a general practitioner (GP)	N/A	1.80%	8.0%
Don't know	N/A	1%	4.4%
Not in contact with any HCP	100%	78.60%	5%

Abbreviations: GP, general practitioner; HCP, healthcare professional; N/A, not applicable

Notes: *This is the value reported in De Fries Jenssen 2023; respondents could choose more than one type of consultation if they had been in contact with multiple HCPs within the past 3 months. Percentages are the proportion of all respondents ($n=384$) experiencing leakage outside the baseplate at least once over the 3 months

The EAG model assumed an incremental cost of [REDACTED] for twice yearly, monthly and four monthly leaks. This was considerably higher than the cost presented in De Fries Jensen (2023) [REDACTED] (£36.53 [REDACTED]) which was used in sensitivity analysis; however, more types of costs were included (wastage due to switching bag type and increased use of pouches due to leaks).

7.2.8.3. Pancaking and ballooning

Only one publication reported resource use associated with pancaking and ballooning: Nørtoft (2019).²⁸ A cost of [REDACTED] was reported for people who reported experiencing issues during the

study period. This included only the additional cost of bags and supporting products. Additionally, the definition used would include people with less severe problems than the definition of regular issues indicated by the CNS in stoma care (daily).

Consultation with two CNS in stoma care indicated that, for most people who get in touch, a couple of phone calls or a call and a face-to-face visit with hints and tips relating to diet and use of the bag and filter are usually enough to resolve both issues. The EAG was, however, informed that CNS in stoma care are not always contacted when issues are experienced and that there may be a sizeable population of “lost ostomates” who do not seek help for complications. However, comments from a manufacturer pointed out that care may be delivered through the DAC rather than the CNS in stoma care.

For pancaking, tips may include covering the filter and using toilet roll to reduce the vacuum in the bag, dietary intervention and the use of poo softener medication. If these don't work, the CNS in stoma care may recommend more frequent bag changes (e.g. doubling the use), a different bag (less strong filter or a convex bag), stoma bridges (10%) or lubricating oil (10%), although prescription formulary recommendations may vary by area and could include general household products such as baby oil. They noted that companies will often fit the bridges into the bags as a bespoke service. The other CNS in stoma care discussed that the primary way to reduce issues with pancaking is changes to diet, use of toilet rolls and bag attachment, which can include having the baseplate cut larger and using a barrier wipe to prevent skin getting sore. They rarely used other supporting products and did not use stoma bridges.

For ballooning, bag use may also increase (a change during the night may be added for example). If this does not work, then a bigger bag may be needed or a different type of bag (drainable or 2-piece). One of the CNS in stoma care noted that this was not a concern for which she frequently saw people.

Given the available information, the EAG base case used the cost reported in the Nørtoft (2019) subgroup analysis to represent the additional cost of bags and supporting products and assumed two telephone consultations and one face-to-face visit with a CNS in stoma care as sufficient on average to resolve the issue of pancaking and that two phone calls are sufficient to resolve issues with ballooning. The EAG assumed that 50% of people with regular ballooning required an additional bag change at night and that 50% of people with regular pancaking doubled their bag use. Finally, we assumed that the average time to resolution of issues for both complications was three weeks.

7.2.8.4. Odour

No directly relevant publications were identified. The discrete-choice experiment conducted by Bonnicksen et al (2011)⁵⁸ did, however, indicate that filter lifetime was the least important of the attributes asked about within their study (with the most important being reducing the number of leakages).

One of the CNS in stoma care consulted considered that there should not be an issue with odour unless there is a fault with the bag or filter, or a leak if the bag has not been applied correctly. There may be odour issues when taking the bag off. The other CNS in stoma care consulted also noted that smell when taking the bag off can be an issue for some people and can impact on their confidence going out in public. In this case, drops or sprays may be given (around 10% of people with odour issues).

A CNS in stoma care would first check on a person's bag fitting technique, check for issues with leaks and check their diet. This would usually be done with an initial phone call and then an appointment to observe and demonstrate technique.

It was assumed that, on average, one phone call/online appointment and one in-person visit would be required to reduce issues with odour to the point where impact on HRQoL is minimal. Based on the weighted average of the relevant BNF codes⁵⁵ the average cost of one bottle of drops was £7.96; the average cost of one bottle of spray was £10.40. It was assumed that one of each would be required per week for people using them (estimated to be 10% of people). Finally, we assumed that the average time to resolution of odour issues was three weeks.

7.2.8.5. Discreetness, appearance and comfort

No relevant publications were identified. The CNS in stoma care consulted considered that finding a bag that meets a person's preference in terms of discreetness and appearance is usually possible with a limited number of contacts, and that this may even be possible with a single phone contact in many cases.

Preferences for appearance vary considerably across individuals. One CNS in stoma care raised that meeting preferences is hardest when people are switching from the oldest bags that have been discontinued, as these had a large capacity and most newer bags are made with a much smaller capacity, necessitating more frequent changes. They noted that it can take several weeks to gain the person's trust and then weeks again to find a bag that they are comfortable with.

The CNS in stoma care noted that it is likely to take a few contacts and free samples being sent to find a comfortable bag (although this may take a little longer than identifying a bag based on appearance). People may benefit from at least one of the appointments being face-to-face to allow them to see and feel multiple different bags and work through the context of what might be appropriate for their lifestyle. They noted that the over-riding factor was always fit (i.e. preventing leaks) and that this can reduce patient choice in other areas such as appearance (e.g. choice of colour and style).

We assumed that an average of two phone calls and one face-to-face appointment were required to find a bag with the right appearance, discreetness, and level of comfort and that the bags given for people to trial come at zero cost. Finally, we assumed that the average time to resolution of issues to a satisfactory level was 3 weeks.

7.2.9. Health state utilities (by complication)

Five studies were identified in the evidence review which contained relevant information on utilities. Two of these studies reported data from the same original source, and therefore only four papers were included (Table 22).

Although systematic reviews like Jeong 2016⁵⁹ and Dossa 2018²⁹ provided background utilities for people with a stoma, neither of them delved into a detailed analysis of specific issues related to stoma complications, such as PSCs, leakages, and other associated complications.

The remaining papers either did not include data in the form of utilities or did not focus on issues related to complications that may be affected by bag use.

Table 22: Key HRQoL studies included

Author	Rolls ^{57†}	Berger ^{21,60 *}	Nichols ⁶¹	Scheffell ⁶²	Dossa ^{36**}	Mohiuddin ³²
Year	2022	2018	2019	2023	2020	2021
Funded by	Coloplast	Hollister	Hollister	Coloplast	Fellowship	N/A
Countries	UK	CEA: Australia, utility sample: USA	USA/Canada/UK	Sweden	Canada	UK
Study type	Survey	CEA	Cross sectional survey	Survey	CEA	CEA
Participant population	Adult UK general population	Approx. 40% colostomy, 44% ileostomy, 13% urostomy	41.7% colostomy, 40.7% ileostomy, 16.2% urostomy, 1.4% multiple stomas (UK)	Adult Swedish general population	Hinchey III sigmoid diverticulitis	End colostomy
Number of participants	758	2,329 from the USA	505 from the UK	54	N/A	18,280 patient episodes
Complications considered	PSCs [§] and leakage ^{***}	PSCs [¶]	PSCs	PSCs and leakage [‡]	Re-operation	Infection ^{****}
Method of elicitation	Vignettes for generic stoma population	SF-36v2	SF-36v2	Vignettes for generic stoma population	Unclear	EQ-5D
Method of evaluation	TTO	SF-6D which uses SG	SF-6D which uses SG	TTO	Unclear	UK tariff
Baseline stoma utilities reported	Yes	Yes	Yes	Yes	No	No
Relevant information contained	Utilities and disutilities	Utilities	Utilities	Utilities and disutilities	QALY decrement	Hospital stay disutility
EAG subjective assessment of quality and relevance	Vignettes using TTO. Vignettes do not account for background disease. RED	Data from patients using a generic preference instrument to value utilities. Mixed population. Not NICE's preferred instrument AMBER	Data from patients using a generic preference instrument to value utilities. Mixed population. Not NICE's preferred instrument AMBER	Small study based on vignettes. Same issues as Rolls 2022. AMBER	Method of elicitation and valuation unclear RED	EQ-5D data based on meta-analysis but health-state of limited relevance AMBER

Abbreviations: PSCs, Peristomal Skin Complications, TTO, Time Trade Off, CEA, Cost Effectiveness Analysis, SF-36v2, Short Form Health Survey questionnaire version 2, SF-6D, Short Form 6 dimensions, SG, Standard Gamble, N/A, not applicable, EQ-5D, 5 dimensions EuroQol Group questionnaire, CUA, Cost Utility Analysis

Notes:

§PSC severity defined using Ostomy Skin Tool v2.0^{30,31} which uses DET score

* Defined as a DET scores

‡ Leakage defined as leakage onto clothes; PSC severity mild, moderate, severe; measure used to define these not clear

▣ Defined into 4 health states derived from a self-assessment questionnaire

* Neil 2016 and Nichols 2018 use the same utilities as Berger 2018 which are referenced to a Data on File from Hollister; the Data on File supplied by Hollister provides these numbers again with little additional detail. There is some minor variation in the exact utilities across the papers, the reason for which is unclear

** Original source of QALY decrement is unclear as it cannot be found in any of the papers referenced in the paper

*** Defined as leakage onto clothes or leakage around the baseplate

**** Original source is Coroni-Cronenberg 2013⁶³

† Cawson 2023 uses utilities from Rolls 2022

For EAG assessment of quality and relevance, **GREEN** indicates high quality, **AMBER** indicated lesser quality, and **RED** indicates poor quality.

7.2.9.1. Peristomal skin complications

Four studies provided information on the impact of PSCs on quality of life in the form of utilities. None of these provided data using the EQ-5D, which is NICE's preferred measure as stated in [section 4 of NICE's health technology evaluations manual](#).⁶⁴

In the study by Rolls (2022),⁵⁷ health state utilities related to stoma complications were quantified using the time trade-off (TTO) method. Respondents were comprised of a panel of email respondents from the UK general population. The study utilised vignettes based on the validated Ostomy Skin Tool 2.0 (OST)^{30,31} which delineates various categories of PSC severity, and expert workshop discussions with health economists and medical experts. The vignette used was provided by Coloplast which enabled the EAG to more fully assess the methods used. Although the description of the health states specifically related to PSC and leakage appears well thought through and avoided the issue of double counting the impact of PSC and leaks, unfortunately, the paper did not meet NICE's Decision Support Unit guidance for the reporting of vignettes.⁶⁵ In particular, the inclusion of generic aspects of HRQoL from participants' underlying disease was not accounted for. There is an extensive range of conditions requiring intestinal stoma as part of their management, including colorectal (and other) cancers, inflammatory bowel disease, diverticular disease with obstruction, penetrating bowel injuries, anal incontinence, protection of a distal anastomosis, gangrenous /ischaemic bowel, sigmoid volvulus, Fournier gangrene, and anastomotic leak. This makes it difficult for a vignette to take background conditions into account and limits the appropriateness of this methodology in this patient population. Not accounting for underlying conditions is likely to lead to overestimates of the impact of stoma-related complications. Additionally, the descriptions related to leakage included the following wording around worry for all health states "you worry about when the leakage will happen." According to Jeppesen et al. (2022),⁴⁰ there is a positive correlation between worry about leakage and frequency of leakage underneath the baseplate and/or onto clothes with people having leakage onto clothes only once a year still experiencing significant emotional impact on the Ostomy Leakage Tool. Finally, the vignettes were valued by the UK general population via TTO, rather than following DSU guidance that suggests that they should be generated using an appropriate sample of patients completing the EQ-5D for each vignette and then scored using the UK tariff.

Nichols (2019) and Berger (2018) assessed the relationship between PSCs and health utilities in a cross-sectional survey using data from a Pouch Impact Assessment conducted by Hollister, which involved 3,123 patients with stomas across the US, UK and Canada. Sub-group data are

provided for the UK and US samples from the overall total in these two publications respectively and the related Nichols (2018) paper which also reports the US sample. The SF-6D preference-based utility index was used to evaluate PSC health states in a post-surgical population with a range of reasons for the creation of stoma (not reported). Skin assessments, which informed health state utilities, were obtained through a survey where participants responded to self-assessment questions. It was unclear from the publication,

[REDACTED], how the questions were derived.

[REDACTED], although the Nichols (2018) publication stated that “skin assessment was self-reported through the response to two ordinal questions of identical scale: the respondent’s perception of the usual condition of their skin and the condition of the skin at the time of the survey.” No evidence of use of a validated tool for assessment of PSC was provided.

[REDACTED] Additionally, there were minor variations in the numbers presented [REDACTED], Berger (2018) and Nichols (2018), e.g., normal skin utility of [REDACTED] and 0.755 in the latter, which were unexplained.

Scheffel (2023) was only available as a poster. Utility values were generated by presenting a small sample (n=54) of people with a stoma in Sweden with vignettes and asking them to value them via TTO.

During the assessment, a concern arose regarding the potential risk of bias of presenting results from a heterogeneous population (colostomy, ileostomy and urostomy patients). After consulting with two CNS in stoma care, both considered the risk substantial as people with an ileostomy are more likely to experience a larger impact on their quality of life from PSC even within health states than people with a colostomy, as their poo is looser and more acidic and more likely to irritate, and additionally people with ileostomy are generally younger and therefore the level of impact is likely to be higher relative to general quality of life. Both the Berger (2018) and Nichols (2019) studies contained a substantial proportion of participants with an ileostomy (53% and 42%, respectively).

Regarding health states, Rolls (2022) introduced six PSC states, whereas Nichols (2019), Berger (2018) and Scheffel (2023) focused on four. In the Rolls study, health states were adapted from the OST tool which assessed skin using three categories as follows:

- ‘Compromised broken skin’ (ulcers, bleeding, weeping skin).
- ‘Sensation symptoms’ (pain, itching, burning).
- ‘Discolouration without broken skin or sensation symptoms’.

Utilities were calculated by weighting vignettes that related Pain Itching or Burning scores (PIB which ranged from 0/10 to 8/10) with the occurrence of bleeding or weeping skin.

In the Nichols (2019) study, the four health states were briefly described as follows:

- Normal skin: characterised by intact skin with no presence of irritation.
- Mild skin irritation: characterised by occasional reddening and irritation caused by stomal discharge or adhesives.
- Moderate skin irritation: characterised by always being reddened or irritated by stoma discharge or adhesives, and occasional but slight blistering.
- Severe skin irritation: characterised by skin that is always blistered or damaged, where blistering often results in denuded skin caused by the mechanical process of repeated application and removal of a stoma bag.

Definitions were unclear in the other two studies.

The “Normal skin” health state in Nichols (2019), with a utility score of 0.734, corresponds to the “No PSC” health state in Rolls (2022) with a utility score of 0.802; uncomplicated stoma state in Berger (2018) with a utility score of 0.754 and no PSC health state in Scheffel (2023) with a utility score of 0.972. The latter of these was clearly unrealistic given the age of the population involved, the utilities in Nichols (2019) and Berger (2018) papers, however, appeared low relative to EQ-5D scores for the overall population from the available systematic reviews^{29,59} which was likely due to differences in the instrument used.

Given the limitations of the various studies, none of them formed an ideal data source. All were likely to incorporate biases, which indicated they were likely to overestimate the impact of individual stoma complications for people with a colostomy.

Table 23 provides information on the utility and disutility values associated with each level of severity for PSCs. Having investigated the limitations of each of the sources, the Nichols 2019

paper was chosen for the EAG base case. This was because it came from a direct evaluation of quality of life for people with a stoma and it provided a more plausible evaluation of the impact of severe PSC (in reference to a disutility of 0.086 reported for patients with symptomatic parastomal hernia on the EQ-5D in Mohiuddin et al. 2021³²). Alternative sources were considered in scenario analyses.

It was assumed that the DET score used for the studies included for resource use to define health states was roughly equivalent to the scores used within the Nichols 2019 study. In scenario analysis where the Rolls 2022 study was used, conversion was conducted between the PIB score and the DET score based on expert input (see Appendix G). This introduced additional uncertainty to the analysis.

Table 23: Summary of peristomal skin complications HRQoL health states and mean utilities

	Rolls 2022	Nichols 2019	Berger 2018 / Nichols 2018	Scheffel 2023		
PSC utilities						
No PSC (PSC group)	0.802	Normal 0.7340	Uncomplicated stoma	0.7540	No PSC	0.972
Mild PSC with PIB = 2	0.773	Mild 0.6860			Mild PSC with PIB = 2	0.941
Moderate PSC with PIB =5	0.693	Moderate 0.6400			Moderate (PIB=5)	0.927
Moderate PSC with PIB =5 and weeping skin	0.688				Moderate (PIB=5 + weeping	0.894
Severe PSC with PIB =5 and bleeding skin	0.640	Severe 0.6100			Severe (PIB=5 + bleeding)	0.832
Severe PSC with PIB = 8 and bleeding skin	0.518				Severe (PIB=8 + bleeding	0.712
PSC disutilities						
Severe PSC with PIB = 8 and bleeding skin	0.287	Severe PSC 0.124	Severe PSC	0.1650	Severe PSC with PIB = 8 and bleeding skin	0.244
Severe PSC from bleeding skin and a PIB score of 5 vs no PSC	0.161				Severe PSC from bleeding skin and a PIB score of 5 vs no PSC	0.124
Moderate PSC with a PIB score of 5 with weeping skin vs no PSC	0.112	Moderate PSC 0.094	Moderate PSC	0.1070	Moderate PSC with a PIB score of 5 with weeping skin vs no PSC	0.060
Moderate PSC with a PIB score of 5 without weeping skin vs no PSC	0.106				Moderate PSC with a PIB score of 5 without weeping skin vs no PSC	0.040
Mild PSC with a PIB score of 2 vs no PSC: disutility	0.025	Mild PSC 0.048	Mild PSC	0.0570	Mild PSC with a PIB score of 2 vs no PSC: disutility	0.027
Bleeding skin vs skin with no weeping or bleeding	0.053					
Weeping skin alone vs no PSC	NS					

Abbreviations: NS, non-significant; PIB, pain itching and bleeding; PSC, peristomal skin complications

A rare consequence of PSCs is the need for the stoma to be re-sited, as discussed in section 7.2.8.1. Only one paper was identified that contained information on the HRQoL impact of re-operation.³⁶ In this paper, a one off QALY decrement of 0.25 was applied. Despite the sources cited not mentioning this value, and therefore its source being unclear, it was considered by the EAG to be a reasonable estimate due to both the physical and psychological impact of re-operation.

One paper was identified containing information on the impact of hospitalisation on quality of life. A decrement of 0.083 was applied during the hospital stay.^{32,63} We assumed an average duration of 4.2 days based on duration of stay data for readmission with PSC from Taneja et al. (2019).⁶⁶

7.2.9.2. Leakage

The assessment of leakage related QoL was conducted only in the Rolls (2022) and Scheffell (2023) studies. Both report data for the impact of leakage onto clothes according to the frequency of leaks, with Rolls (2022) additionally reporting the impact of leaks outside of the baseplate.

Given the sample sizes involved (n=758 vs n=54) and the fact Rolls (2022) was conducted with UK rather than Swedish participants, the Rolls (2022) study was chosen for the EAG base case. We would, however, like to reiterate that this study was likely to overestimate the impact of leaks as it did not account for participants' other underlying conditions.

In addition, the EAG was aware that there was likely to be overlap between leaks and PSC as experiencing one can cause the other in both directions, and having more leaks is likely to worsen the severity of PSC and vice versa. Therefore, although we investigated the impact of these factors in isolation due to lack of alternate data, it is unlikely that the HRQoL impacts would in fact be additive.

Table 24: Leakage QoL values

	Rolls 2022	Scheffell 2023
No PSC (Leakage group)	0.8100	0.897
Health state with 4 leakage events per month	0.6910	0.794
One leakage event per month	0.7510	0.858
Two leakage events per year	0.7820	0.906
Health state with no leak- age events due to a digital notification solution	0.8070	0.932

	Rolls 2022	Scheffel 2023
Leakage Disutilities (vs no PSC or vs Digital solution)		
4 events/month ($p < .0001$)	0.1140	0.101
1 event/month ($p < .0001$)	0.0570	0.053
2 events/year ($p < .0001$)*	0.0220	0.110

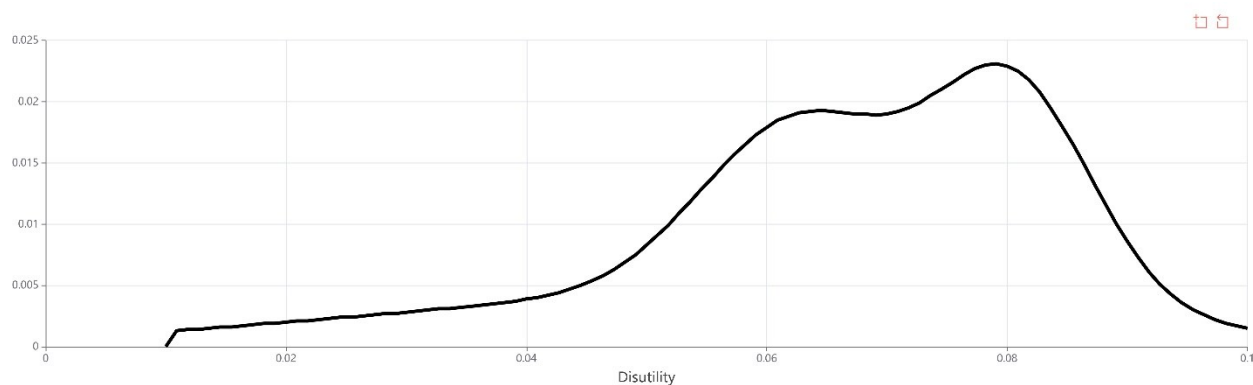
Abbreviation: PSC, peristomal skin complication

Note: Rolls 2022 based on 2 and Scheffel 2023 based on 4 events per year.

7.2.9.3. Pancaking and ballooning

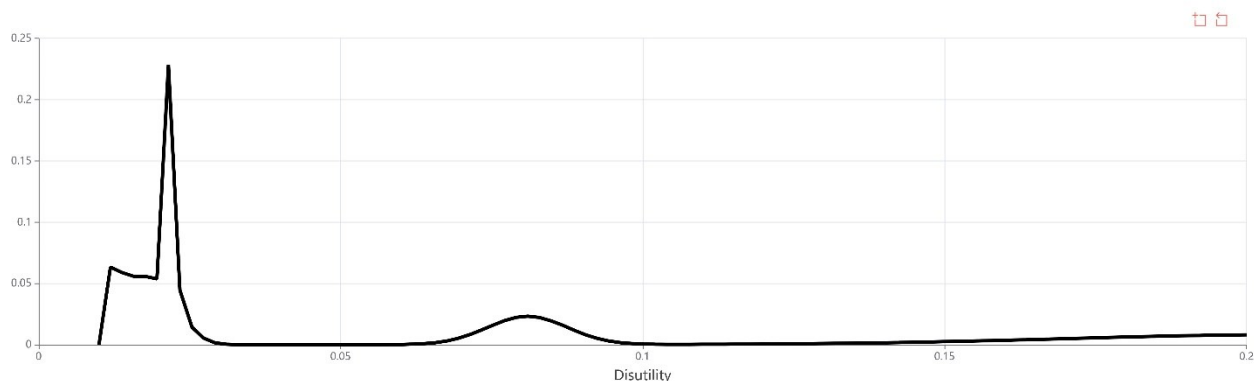
In the absence of alternative data, the utility decrement associated with regular (daily) pancaking estimated from the structured expert elicitation was 0.0664 (SD: 0.020). During the meeting on 25th June 2024, the experts agreed that the mean impact originally presented (0.162) was too high relative to the disutilities for leakage onto clothes and considered that this was likely to be due to overlap in the answers, as pancaking can cause leaks. Given this, the expert estimates where this appeared to be the case from the answers given in free text were excluded. The pooled distribution of participant responses is shown in Figure 3.

Figure 3: Pooled distribution from structured expert elicitation: impact of regular (daily) pancaking (n=3)



The utility decrement associated with regular (daily) ballooning from the structured expert elicitation was 0.0580 (SD: 0.020). During the meeting on 25th June 2024 the experts agreed this appeared reasonable. Key impacts related to ballooning raised in the free text were related to visibility of the bag and the impact of this on the ability of people to feel confident socialising and on anxiety. Most respondents noted that they did not consider this to impact HRQoL to the same extent as leakages. The pooled distribution of participant responses is shown in Figure 4.

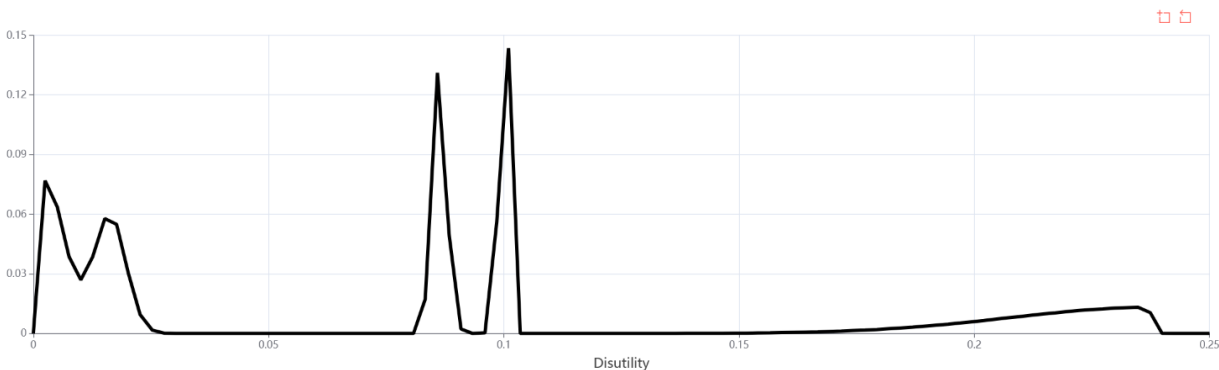
Figure 4: Pooled distribution from structured expert elicitation: impact of regular (daily) ballooning (n=5)



7.2.9.4. Odour

In the absence of alternative data, the utility decrement associated with regular (daily) odour issues from the structured expert elicitation was 0.0820 (SD: 0.074). Of the five CNS in stoma care who provided validated answers to this question, three estimated a much higher impact of this complication than the other two. In the notes, the expert who provided the highest estimates stated: “odour is likely one of the complications that may affect patients HRQoL and wellbeing the most, as they constantly worry about it, thinking that others will know they have a stoma, and therefore, they may isolate from people.” During the meeting on 25th June 2024 the experts agreed that the mean impact was about right compared to the other complications discussed. The pooled distribution of participant responses is shown in Figure 5.

Figure 5: Pooled distribution from structured expert elicitation: impact of regular (daily) issues with bad odour (n=5)

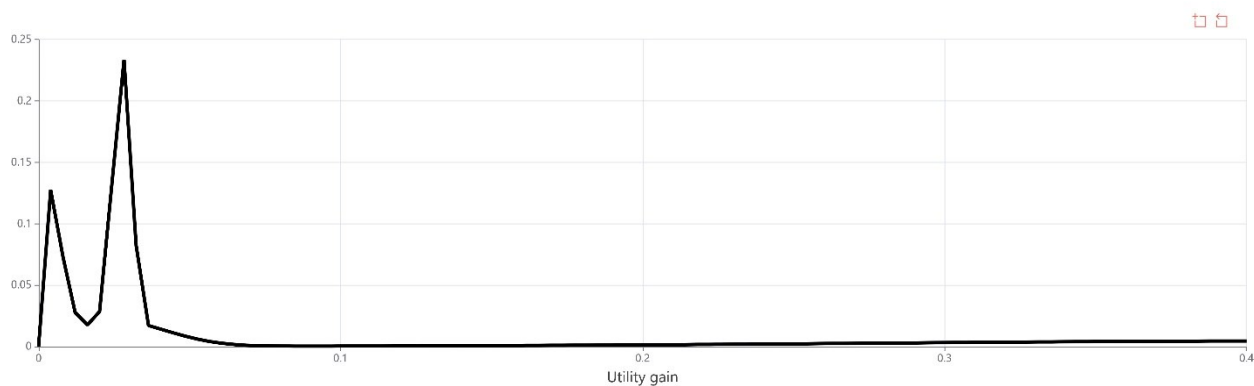


7.2.9.5. Discreetness, appearance and comfort

In the absence of alternative data, the utility gain associated with a discreet bag design with preferred appearance from the structured expert elicitation was 0.0775 (SD: 0.123). During the meeting on 25th June 2024 the experts agreed that the mean impact was about right compared to the other complications discussed. In addition, the CNS in stoma care considered that the impact of comfort would be like discreetness – a person wouldn't wear the bag if it was very uncomfortable, so it would influence bag choice but any bag they're using wouldn't be so uncomfortable as to make a larger reduction in HRQoL. Another CNS in stoma care noted that there's no point in having other factors like skin health if people don't feel confident leaving the house.

Comfort of the bag against the skin was ranked as the 8th most important factor when choosing a bag in the user preference assessment with criteria related to filter functionality (such as odour prevention) ranking 6th, reduced noise ranking 11th and appearance ranking 14th. Given this, the EAG bundled together discreetness, appearance, and comfort into one within the analysis. The pooled distribution of participant responses is shown in Figure 6.

Figure 6: Pooled distribution from structured expert elicitation: impact of discreet bag design with preferred appearance (n=5)



A summary table with all model inputs can be found in Appendix I.

7.2.10. Decision Model Analytic approach

Each complication was analysed separately. The expected cost and QALYs accrued over one year were calculated for a patient experiencing the complication. The expected cost and QALYs accrued from a hypothetical bag that eliminates the complication completely was also calculated. The incremental net monetary and health benefit (INMB and INHB) between these was calculated at a specific willingness to pay threshold. The analysis was reverse engineered to find a per-bag price associated with an INMB or INHB of £0 (using the 'goal seek' function in MS Excel). This price represented the maximum willingness to pay to resolve the complication and thus the premium over and above the cost of a 'basic' bag the NHS should be willing to pay for a bag that completely resolves the complication. This is reported in the results as 'incremental eJP per bag'. For ease of comparison, the EAG then calculated the maximum eJP for a bag as the cost of a 'basic' bag (set at the cheapest bag available) plus the premium (referred to as 'total eJP'). This analysis was repeated assuming the bag feature resulted in a 50% and 25% resolution of the complication.

A bag with a feature that resolves a complication may be good value for money if it costs less than the total eJP and poor value for money if it costs more than the total eJP. Where a bag costs the same as the eJP, its INHB would be zero. Bags with features that only partially resolve the complication will have a lower eJP – the EAG conducted scenario analyses assuming a 25% and 50% reduction in the complication to demonstrate this and guide decisions where this is considered to be more likely.

Where a particular bag possesses features claiming to resolve more than one complication, the absolute maximum incremental eJP could be a simple sum of the willingness to pay to resolve each issue (i.e. sum of the incremental eJPs). However, this is likely to be a considerable overestimate as the combined disutility and cost of experiencing multiple adverse events is unlikely to be summative (e.g. a person is likely to seek help for all complications simultaneously rather than separate consultations for each one so the cost of consultations will be lower). The EAG's analyses explores two extremes where the incremental eJP is indeed summative, and where the incremental eJP for multiple complications is set as the maximum of each of the individual complications.

The EAG's base case used a willingness to pay of £20,000 per QALY gained. Additionally, the EAG conducted a sensitivity analysis setting the threshold equal to the most recent estimate of the marginal productivity of the NHS (£8,000 per QALY gained⁶⁷).

7.2.11. Exploratory analysis for specific bags

Where data were available, the EAG conducted an exploratory analysis comparing the difference in price between 1-piece closed bags where differences in outcomes were reported in evidence identified in the clinical effectiveness review. Two studies explored differences in ballooning rates between bags and [REDACTED] (see Table 35). The incremental eJP for resolving a complication was multiplied by the proportionate difference in rate observed in the studies. This provided an estimate of the maximum reasonable price difference between the two bags. This was compared with the actual price difference.

For example, the incremental eJP for eliminating ballooning was 64p per bag (Table 28). One study reported the difference in ballooning between two bags as [REDACTED]%. Therefore, the maximum premium for the more effective bag should be approximately 64p*[REDACTED]. The EAG noted that this was still likely to be an overestimate of the eJP as there is a non-linear relationship between rate of improvement and incremental eJP. However, the EAG considered that the analysis could provide insight into the relationship between bag price and published differences in outcomes.

7.3. Economic Analysis Results

This section presents the results of the economic analyses, beginning with the results of the regression analysis estimating the relationship between current bag prices and features. Next, section 7.3.2 presents the base case results of the decision model, estimating the eJP for resolution of each of the six complications. Scenario analyses are presented in section 0 and exploratory analyses for specific bags are presented in section 7.3.4.

7.3.1. Regression results

The R squared for all bags was 0.42, indicating that 42% of the variability in price was accounted for by the presence of different features. This value suggests that other variables, not included in the model, also affected prices. In other words, the presence of potentially innovative features only partially explained the price for 1-piece closed bags. The F-statistic was 19.38 (p-value = 0.0000) indicating that the model as a whole is statistically significant, meaning that the predictors collectively have a significant relationship with the dependent variable (price). Additional diagnostic tests conducted can be found in Appendix L and demonstrate robustness of the fitted model. Since the model uses robust standard errors, the results account for potential heteroscedasticity, providing more reliable standard errors, and thus more trustworthy significance tests, even if the assumptions of homoscedasticity or normality of errors were violated.

The model has several significant predictors. The most impactful features in terms of price increase appear to be the flushable disposal and convexity features. These features are not just statistically significant but also have large coefficients, meaning they considerably raise the price. Other features like modified bag shape also contribute to the price, though their impact is less pronounced. Features such as modified baseplate shape, modified filter, and modified material do not significantly affect the price, suggesting they may not be key drivers of cost.

One of the bags included in the regression was found to be a potential outlier (Opus Naturfit); when this bag was removed from the analysis two additional features were found to be significant predictors of price (the presence of baseplate additives and the presence of an inspection window with an impact on price of 14p and 16p, respectively). However, it remained the case that <50% of the variability in price was accounted for by the presence of different features,

The separate regressions for flat and convex bags showed similar results to the regression including all bags although the model fitted for convex bags had a relatively low number of observations (n=27) and lower R squared value (0.26) and therefore should be interpreted with caution.

More broadly, the results suggested that the pricing of 1-piece closed bags is not totally explained by features suggesting potential deviation from the value-based pricing principle. However, the EAG noted that the analysis has limitations due to the uncertainties in the features that were recorded for each bag (see Section 2), as well as small sample size and other data limitations.

Table 25: Regression output (all)

Regression Statistics						
F(9, 53)	19.38					
Prob > F	0.0000					
R Squared	0.4189					
Observations	63					
	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	2.768	0.087	31.960	0.000	2.594	2.942
Baseplate additive	0.100	0.072	1.380	0.172	-0.045	0.245
Baseplate shape	0.042	0.088	0.480	0.631	-0.134	0.219
Baseplate adhesive	-0.030	0.103	-0.290	0.774	-0.237	0.177
Bag shape	0.145	0.065	2.230	0.030	0.015	0.274
Filter	0.039	0.188	0.210	0.838	-0.339	0.416
Material	-0.061	0.172	-0.350	0.725	-0.405	0.284
Flushable disposal	1.059	0.128	8.270	0.000	0.802	1.315
Inspection window	0.145	0.074	1.970	0.054	-0.002	0.293
Convexity	0.305	0.081	3.760	0.000	0.143	0.468

Table 26: Regression output (Flat bags)

Regression Statistics						
F(8, 27)	18.51					
Prob > F	0.0000					
R Squared	0.403					
Observations	36					
	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	2.816	0.097	29.120	0.000	2.618	3.015
Baseplate additive	0.117	0.106	1.110	0.277	-0.100	0.333
Baseplate shape	-0.022	0.112	-0.200	0.842	-0.252	0.207
Baseplate adhesive	0.009	0.145	0.060	0.953	-0.288	0.305
Bag shape	0.133	0.106	1.260	0.218	-0.083	0.350
Filter	-0.012	0.212	-0.060	0.955	-0.446	0.422
Material	-0.017	0.189	-0.090	0.931	-0.404	0.371
Flushable disposal	0.970	0.167	5.820	0.000	0.628	1.312
Inspection window	0.095	0.089	1.070	0.295	-0.087	0.277

Table 27: Regression output (Convex/concave bags)

Regression Statistics						
F(7, 19)	2.32					
Prob > F	0.0685					
R Squared	0.2253					
Observations	Observations					
Observations	27					
	<i>Coefficients</i>	<i>Robust Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	3.082	0.228	13.53	0.000	2.605	3.590
Baseplate additive	0.044	0.128	0.350	0.732	-0.224	0.313
Baseplate shape	0.180	0.160	1.120	0.275	-0.155	0.514
Baseplate adhesive	-0.134	0.206	-0.650	0.524	-0.566	0.298
Bag shape	0.097	0.136	0.710	0.484	-0.187	0.381
Filter	0.112	0.482	0.230	0.819	-0.896	1.120
Material	-0.140	0.460	-0.300	0.764	-1.102	0.822
Inspection window	0.212	0.151	1.400	0.177	-0.105	0.529

7.3.2. Model base case results

The base case results demonstrated that the most impactful of the potential bag-related complications was PSC, followed by leaks, pancaking, ballooning, discreteness, appearance and comfort, and then lastly, odour (Table 28 and Table 29).

When interpreting the tables, it is important to note that comparator QALYs are lower, as would be expected, and the cost is also consistently higher than the intervention cost. This is because the analysis included the increased costs associated with treating complications without the increased cost of the intervention bag, as calculating the eJP was the purpose of the analysis. This is different to ICER tables which readers may be more used to viewing where the intervention cost is included and therefore an increase in costs is usually seen.

The incremental eJPs for fully preventing a particular complication in those who would otherwise experience it ranged from 37p (odour) to £2.39 (PSC). The corresponding total eJPs (i.e. maximum willingness to pay for a bag) were £2.22 (odour) and £4.24 (PSC) for the people using flat bags, while for people using convex bags the eJPs were £2.66 (odour) and £4.69 (PSC). This dropped from £2.01 to £3.00 and £2.45 to £3.44 for flat and convex bags, respectively, for a bag that reduced the chance of complications by 50%. This compares to a current average flat bag price of £3.02 and a cost of £1.85 for the cheapest flat bag and £2.30 for the cheapest convex bag included in the evaluation (Alliance bag Opus NaturFit). Whether the prices currently being charged represented value for money depended on their effectiveness at resolving complications, which was for the large part unknown.

The fall in eJP between a 100% and 50% reduction in the impact of complications was not linear as some costs are unavoidable, such as wastage for changing bag type mid-way through a prescription. Additionally, for leakage, a larger eJP was predicted for twice yearly leaks compared to monthly leaks, as the model assumed (based on clinical expert feedback) that people experiencing less frequent leaks would not seek support from CNS in stoma care to resolve the issue. This meant that they experienced reduced costs compared to monthly leaks, but their complication would not get resolved and the impact on HRQoL applied for the full year.

The EAG did not identify any robust data on how effective any of the features considered within the scope are at reducing the likelihood or incidence of the relevant complications. However, based on information received from CNS in stoma care, information is provided in Table 28 about which features may reduce the chance or impact of each complication. This can be used

as a guide to the maximum reasonable price for a bag possessing that feature assuming that feature completely eliminates (Table 28) or partially eliminates (Table 29) the complication. The EAG noted that this is a strong assumption in the absence of robust evidence of effectiveness.

Table 28: Economic analysis results: 100% improvement

Comp	Trt	Total costs	Total QALYs	Inc. costs	Inc. QALYs	eJP per year (inc)	Inc. eJP per bag	Total eJP per bag*		% of people**	Features designed to reduce chance / impact
								Flat	Conv		
PSC	Comparator	■	0.721							44%	Baseplate additives Baseplate shape Baseplate adhesive Convex, concave, flat and size options
	Intervention	■	0.732	-£1,093	0.011	£1,312	£2.39	£4.24	£4.69		
Leakage 2 times yearly	Comparator	■	0.785							53%	Baseplate shape Baseplate adhesive Convex, concave, flat and size options
	Intervention	■	0.807	-£430	0.022	£868	£1.58	£3.43	£3.88		
Leakage monthly	Comparator	■	0.804								
	Intervention	■	0.807	-£462	0.003	£526	£0.96	£2.81	£3.26		
Leakage 4 x monthly	Comparator	■	0.801								
	Intervention	■	0.807	-£540	0.007	£670	£1.22	£3.07	£3.52		
Pancaking	Comparator	■	0.728							48%	Type of filter Baseplate shape Convex, concave, flat and size options
	Intervention	■	0.731	-£381	0.004	£457	£0.83	£2.68	£3.13		
Ballooning	Comparator	■	0.728							39%	Type of filter
	Intervention	■	0.731	-£285	0.003	£352	£0.64	£2.49	£2.94		
Odour	Comparator	£175	0.727							28%	Type of filter
	Intervention	£69	0.731	-£106	0.005	£201	£0.37	£2.22	£2.66		

Comp	Trt	Total costs	Total QALYs	Inc. costs	Inc. QALYs	eJP per year (inc)	Inc. eJP per bag	Total eJP per bag*		% of people**	Features designed to reduce chance
Discreetness, Appearance and Comfort	Comparator	£236	0.727							NR	Bag shape Baseplate shape Baseplate adhesive Bag materials Flushable disposable Convex, concave, flat and size options
	Intervention	£69	0.731	-£167	0.004	£256	£0.47	£2.32	£2.76		

Abbreviations: comp, complication; conv, convex; eJP, economically justifiable price; Inc, incremental; NR, not reported; PSC, peristomal skin complications; trt, treatment; QALY, quality-adjusted life-year

Notes:

* Total eJP is calculated by adding the addition of the WTP for complications to the price of the cheapest bag

** Survey data from Colostomy UK's patient organisation submission. Survey carried out between December 2023 and March 2024 with 3,742 responses from a mixed population of people with a stoma

Table 29: Economic analysis results: 50% improvement

Comp	Trt	Total costs	Total QALYs	Inc. costs	Inc. QALYs	eJP per year (inc)	Inc. eJP per bag	Total eJP per bag*		% of people**	Features designed to reduce chance / impact
								Flat	Conv		
PSC	Comparator	████	0.7205							44%	Baseplate additives Baseplate shape Baseplate adhesive Convex, concave, flat and size options
	Intervention	████	0.7260	- £519.32	0.0055	£628.66	£1.15	£3.00	£3.44		
Leakage 2 times yearly	Comparator	████	0.7853							53%	Baseplate shape Baseplate adhesive Convex, concave, flat and size options
	Intervention	████	0.7963	- £189.30	0.0110	£409.30	£0.75	£2.60	£3.04		
Leakage monthly	Comparator	████	0.8040								
	Intervention	████	0.8056	- £211.76	0.0016	£243.76	£0.44	£2.29	£2.74		
Leakage 4 x monthly	Comparator	████	0.8007								
	Intervention	████	0.8040	- £256.78	0.0033	£322.78	£0.59	£2.44	£2.88		
Pancaking	Comparator	████	0.7277							48%	Type of filter Baseplate shape Convex, concave, flat and size options
	Intervention	████	0.7296	- £174.01	0.0019	£212.17	£0.39	£2.24	£2.68		
Ballooning	Comparator	████	0.7282							39%	Type of filter
	Intervention	████	0.7298	- £123.18	0.0017	£156.54	£0.29	£2.14	£2.58		
Odour	Comparator	£175.12	0.7268							28%	Type of filter
	Intervention	£135.41	0.7291	-£39.71	0.0024	£86.87	£0.16	£2.01	£2.45		

Comp	Trt	Total costs	Total QALYs	Inc. costs	Inc. QALYs	eJP per year (inc)	Inc. eJP per bag	Total eJP per bag*		% of people**	Features designed to reduce chance
Discreetness, Appearance and Comfort	Comparator	£236.08	0.7270							NR	Bag shape Baseplate shape Baseplate adhesive Bag materials Flushable disposable Convex, concave, flat and size options
	Intervention	£152.51	0.7293	-£83.57	0.0022	£128.11	£0.23	£2.08	£2.53		

Abbreviations: comp, complication; conv, convex; eJP, economically justifiable price; Inc, incremental; NR, not reported; PSC, peristomal skin complications; trt, treatment; QALY, quality-adjusted life-year

Notes:

* Total eJP is calculated by adding the addition of the WTP for complications to the price of the cheapest bag

** Survey data from Colostomy UK's patient organisation submission. Survey carried out between December 2023 and March 2024 with 3,742 responses from a mixed population of people with a stoma

The results presented in Table 28 and Table 29 considered each complication in isolation. However, as previously discussed, the EAG was aware that some complications overlap and the impact of the combination of complications on both health state utility and NHS cost will be less than the sum of their parts. For example, PSC, leaks, and pancaking would be likely to co-occur but a person would likely not seek assistance for each issue separately. Therefore, the eJP for a feature that prevented all three of these would be less than the sum of the three eJPs if considered individually. To explore the effect of additive complications, the EAG explored two different approaches using a hypothetical example of a bag that addressed all of the complications considered (Table 30). Two methods are presented: firstly, the eJP was additive across all of the complications (i.e. this approach assumed no overlap in HRQoL or cost impact between complications); secondly, the eJP for the complication with the maximum effect only was used. The EAG considered that both of these approaches were implausible, though considered that the appropriate eJP would likely lie somewhere between the two results. The results showed that for bags that impact on multiple complications, the method used to account for the impact across them all makes a large difference. Future economic studies should consider the impact of bags across complications where possible rather than focussing specifically on one area.

Table 30: Maximum eJP for a bag that reduces the rate of all complications

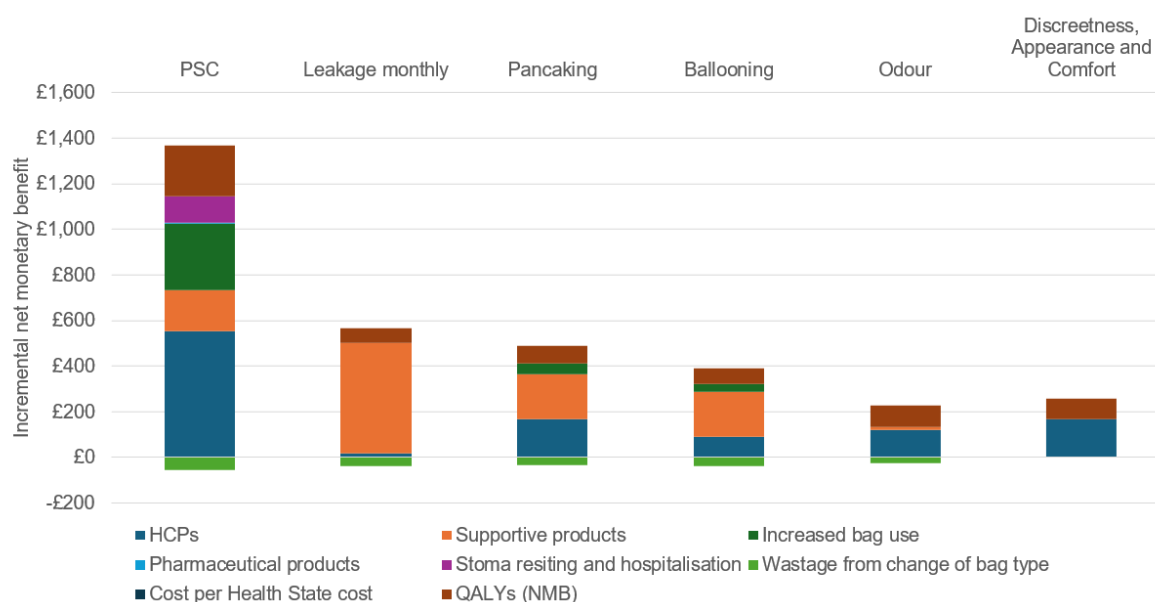
% Reduction in complications	Total eJP per bag assuming complications are additive		Total eJP per bag assuming only the benefit from the maximum impact complication applies	
	Flat	Convex	Flat	Convex
100%	£7.52	£7.96	£4.24	£4.69
75%	£6.01	£6.46	£3.62	£4.07
50%	£4.51	£4.95	£3.00	£3.44
25%	£3.00	£3.45	£2.37	£2.82
10%	£2.10	£2.55	£2.00	£2.44

Incremental net monetary benefit breakdowns are presented using the flat bag prices to allow investigation of the key drivers of the results. As the only difference between the convex bag and flat bag eJPs was the price of the cheapest bag used for baseline within the calculations, the drivers would be the same for both bag types.

The difference in net monetary benefit between comparator and intervention (and therefore the eJP) was primarily driven by HCP costs for three of the complications (PSC, odour and

discreetness, appearance and comfort) with supportive product costs and additional bag use driving the case for leakage, pancaking and ballooning and playing a major role for PSC (Figure 7 and Figure 8). QALYs were the third key driver making up between 11% and 37% of the incremental net monetary benefit per complication (Table 31 and Table 32).

Figure 7: Breakdown of incremental net monetary benefit (100% improvement) – flat bag

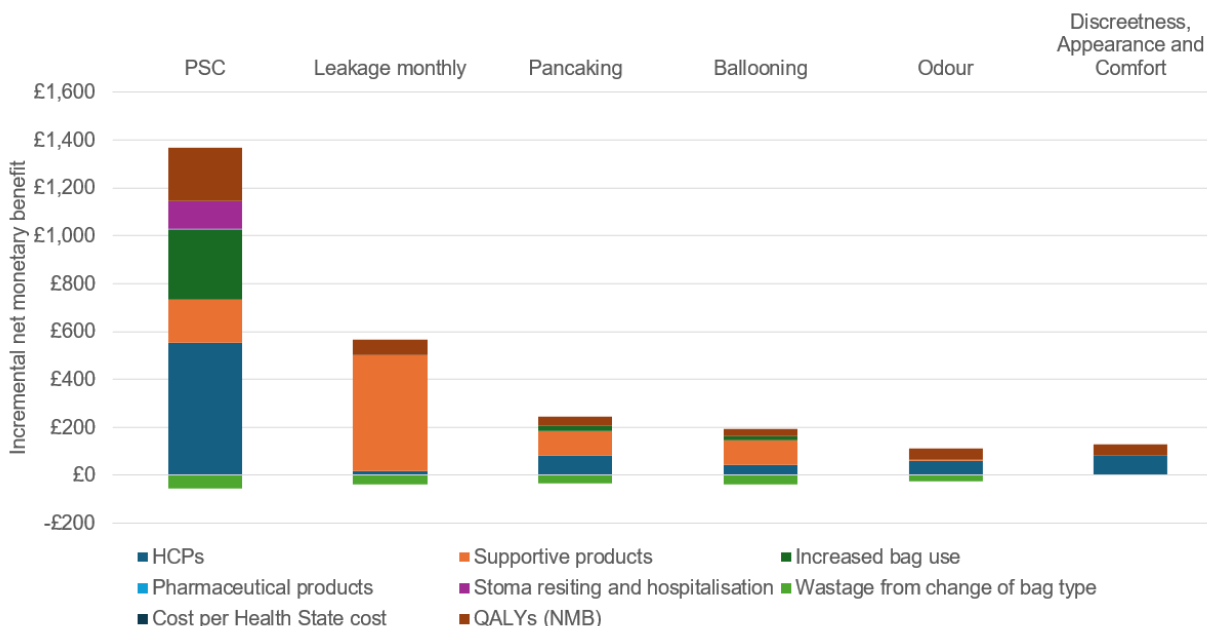


Abbreviations: eJP, economically justifiable price; HCP, health care provider; NMB, net monetary benefit; PSC, peristomal skin complications; QALY, quality-adjusted life-year

Table 31: Breakdown of absolute incremental net monetary benefit (100% improvement) – flat bag

Complication	HCPs	Supportiv e products	Increase d bag use	Pharmaceutical products	Stoma resiting and hospitalisatio n	Wastage from change of bag type	QALYs (NMB)
PSC	39%	13%	21%	0%	8%	4%	15%
Leakage monthly	3%	80%		0%	0%	6%	11%
Pancaking	32%	38%	9%	0%	0%	6%	15%
Ballooning	21%	46%	8%	0%	0%	9%	16%
Odour	48%	4%	0%	0%	0%	11%	37%
Discreetness, Appearance and Comfort	65%	0%	0%	0%	0%	0%	35%

Abbreviations: eJP, economically justifiable price; HCP, health care provider; NMB, net monetary benefit; PSC, peristomal skin complications; QALY, quality-adjusted life-year

Figure 8: Breakdown of incremental net monetary benefit (50% improvement) – flat bag


Abbreviations: eJP, economically justifiable price; HCP, health care provider; NMB, net monetary benefit; PSC, peristomal skin complications; QALY, quality-adjusted life-year

Table 32: Breakdown of absolute incremental net monetary benefit (50% improvement) – flat bag

Complication	HCPs	Supportive products	Increased bag use	Pharmaceutical products	Stoma resiting and hospitalisation	Wastage from change of bag type	QALYs (NMB)
PSC	39%	13%	21%	0%	8%	4%	15%
Leakage monthly	3%	80%		0%	0%	6%	11%
Pancaking	30%	36%	9%	0%	0%	12%	14%
Ballooning	19%	43%	7%	0%	0%	16%	14%
Odour	43%	4%	0%	0%	0%	19%	34%
Discreetness, Appearance and Comfort	65%	0%	0%	0%	0%	0%	35%

Abbreviations: eJP, economically justifiable price; HCP, health care provider; NMB, net monetary benefit; PSC, peristomal skin complications; QALY, quality-adjusted life-year

7.3.3. Scenario analysis results

Scenario analysis results (Table 33 and Table 34) demonstrate that the scenarios with the most impact on the eJP were:

- Use of alternate (lower impact) sources of resource use for PSC – decreased the eJP
- Use of alternate (higher impact) sources of utilities for PSC – increased the eJP
- Use of alternative (higher) estimates of the number of bags per day for patients with no complications – decreased the eJP
- Scenarios around the willingness to pay threshold particularly for PSC – decreased the eJP
- Time to resolution for PSC – higher time increased the eJP, lower time decreased the eJP

Results for complications other than PSC were generally robust to the scenarios tested.

Table 33: Scenario analysis results – Flat Bag

Scenario label	Complication	eJP per bag 100% improvement	eJP per bag 50% improvement	Difference vs base case 100% improvement	Difference vs base case 50% improvement
Base Case	PSC	£4.24	£3.00	-	-
	Leakage	£2.81	£2.29	-	-
	Pancaking	£2.68	£2.24	-	-
	Odour	£2.22	£2.01	-	-
	Ballooning	£2.49	£2.14	-	-
	Discreetness	£2.32	£2.08	-	-
Cost-effectiveness threshold £8,000	PSC	£4.00	£2.88	-£0.24	-£0.12
Mockford 2018 for PSC RU costs	PSC	£3.43	£2.59	-£0.82	-£0.41
Martins 2012 for PSC RU costs	PSC	£2.97	£2.36	-£1.27	-£0.64
Rolls 2022 for PSC utilities	PSC	£4.65	£3.20	£0.41	£0.21
Berger 2018 for PSC utilities	PSC	£4.30	£3.03	£0.06	£0.03
Scheffel 2023 for PSC utilities	PSC	£4.19	£2.97	-£0.05	-£0.02
Time to resolution from patient survey	PSC	£3.63	£2.69	-£0.61	-£0.31
Mean price of a bag- £2.62 (mean price in Scotland)	PSC	£4.19	£2.98	-£0.06	-£0.02
Mean bags per day: no complications - 2	PSC	£3.57	£2.67	-£0.67	-£0.32
Cost-effectiveness threshold £8,000	Leakage	£2.74	£2.26	-£0.07	-£0.03
De Fries Jensen for leakage RU costs	Leakage	£2.73	£2.26	-£0.08	-£0.04
Scheffel 2023 for leakage utilities	Leakage	£2.80	£2.29	-£0.01	£0.00
Mean price of a bag- £2.62	Leakage	£2.89	£2.34	£0.08	£0.04
Bags per day: no complications - 2	Leakage	£2.81	£2.30	£0.00	£0.00
Cost-effectiveness threshold £8,000	Pancaking	£2.60	£2.20	-£0.08	-£0.04
Time to resolution - 1 week	Pancaking	£2.53	£2.16	-£0.15	-£0.08
Time to resolution - 5 weeks	Pancaking	£2.84	£2.31	£0.15	£0.08
Mean price of a bag- £2.62 (mean price in Scotland)	Pancaking	£2.68	£2.24	£0.00	£0.00
Mean bags per day: no complications - 2	Pancaking	£2.48	£2.14	-£0.20	-£0.10

Scenario label	Complication	eJP per bag 100% improvement	eJP per bag 50% improvement	Difference vs base case 100% improvement	Difference vs base case 50% improvement
Cost-effectiveness threshold £8,000	Odour	£2.11	£1.96	-£0.10	-£0.05
Time to resolution - 1 week	Odour	£2.10	£1.95	-£0.11	-£0.06
Time to resolution - 5 weeks	Odour	£2.33	£2.07	£0.11	£0.06
Mean price of a bag- £2.62 (mean price in Scotland)	Odour	£2.22	£2.02	£0.01	£0.01
Mean bags per day: no complications - 2	Odour	£2.11	£1.96	-£0.10	-£0.05
Cost-effectiveness threshold £8,000	Ballooning	£2.42	£2.10	-£0.07	-£0.04
Time to resolution - 1 week	Ballooning	£2.37	£2.07	-£0.12	-£0.06
Time to resolution - 5 weeks	Ballooning	£2.61	£2.20	£0.12	£0.06
Mean price of a bag- £2.62 (mean price in Scotland)	Ballooning	£2.49	£2.14	£0.00	£0.01
Mean bags per day: no complications - 2	Ballooning	£2.31	£2.05	-£0.18	-£0.09
Cost-effectiveness threshold £8,000	Discreetness	£2.22	£2.04	-£0.10	-£0.05
Time to resolution - 1 week	Discreetness	£2.26	£2.06	-£0.05	-£0.03
Time to resolution - 5 weeks	Discreetness	£2.32	£2.08	£0.00	£0.00
Mean bags per day: no complications - 2	Discreetness	£2.20	£2.03	-£0.12	-£0.06

Abbreviations: eJP, economically justified price; PSC, peristomal skin complications

Note: leakage results are presented for monthly leaks only

Table 34: Scenario analysis results – Convex Bag

Scenario label	Complication	eJP per bag 100% improvement	eJP per bag 50% improvement	Difference vs base case 100% improvement	Difference vs base case 50% improvement
Base Case	PSC	£4.69	£3.44		
	Leakage	£3.26	£2.74		
	Pancaking	£3.13	£2.68		
	Odour	£2.66	£2.45		
	Ballooning	£2.94	£2.58		
	Discreetness	£2.76	£2.53		
Cost-effectiveness threshold £8,000	PSC	£4.45	£3.32	-£0.24	-£0.12
Mockford 2018 for PSC RU costs	PSC	£3.87	£3.03	-£0.82	-£0.41
Martins 2012 for PSC RU costs	PSC	£3.42	£2.81	-£1.27	-£0.64
Rolls 2022 for PSC utilities	PSC	£5.10	£3.65	£0.41	£0.21
Berger 2018 for PSC utilities	PSC	£4.75	£3.47	£0.06	£0.03
Scheffel 2023 for PSC utilities	PSC	£4.64	£3.42	-£0.05	-£0.02
Time to resolution from patient survey	PSC	£4.08	£3.14	-£0.61	-£0.31
Mean price of a bag- £2.62 (mean price in Scotland)	PSC	£4.63	£3.42	-£0.06	-£0.02
Mean bags per day: no complications - 2	PSC	£4.02	£3.12	-£0.67	-£0.32
Cost-effectiveness threshold £8,000	Leakage	£3.19	£2.71	£0.07	£0.03
De Fries Jensen for leakage RU costs	Leakage	£3.18	£2.70	£0.08	£0.04
Scheffel 2023 for leakage utilities	Leakage	£3.25	£2.74	£0.01	£0.00
Mean price of a bag- £2.62	Leakage	£3.34	£2.78	-£0.08	-£0.04
Mean bags per day: no complications - 2	Leakage	£3.26	£2.74	£0.00	£0.00
Cost-effectiveness threshold £8,000	Pancaking	£3.05	£2.64	£0.08	£0.04
Time to resolution - 1 week	Pancaking	£2.98	£2.61	£0.15	£0.08
Time to resolution - 5 weeks	Pancaking	£3.28	£2.76	-£0.15	-£0.08
Mean price of a bag- £2.62 (mean price in Scotland)	Pancaking	£3.13	£2.68	£0.00	£0.00

Scenario label	Complication	eJP per bag 100% improvement	eJP per bag 50% improvement	Difference vs base case 100% improvement	Difference vs base case 50% improvement
Mean bags per day: no complications - 2	Pancaking	£2.93	£2.58	£0.20	£0.10
Cost-effectiveness threshold £8,000	Odour	£2.56	£2.40	£0.10	£0.05
Time to resolution - 1 week	Odour	£2.55	£2.40	£0.11	£0.06
Time to resolution - 5 weeks	Odour	£2.78	£2.51	-£0.11	-£0.06
Mean price of a bag- £2.62 (mean price in Scotland)	Odour	£2.67	£2.46	-£0.01	-£0.01
Mean bags per day: no complications - 2	Odour	£2.56	£2.40	£0.10	£0.05
Cost-effectiveness threshold £8,000	Ballooning	£2.86	£2.54	£0.07	£0.04
Time to resolution - 1 week	Ballooning	£2.81	£2.52	£0.12	£0.06
Time to resolution - 5 weeks	Ballooning	£3.06	£2.64	-£0.12	-£0.06
Mean price of a bag- £2.62 (mean price in Scotland)	Ballooning	£2.94	£2.59	£0.00	-£0.01
Mean bags per day: no complications - 2	Ballooning	£2.76	£2.49	£0.18	£0.09
Cost-effectiveness threshold £8,000	Discreetness	£2.67	£2.48	£0.10	£0.05
Time to resolution - 1 week	Discreetness	£2.71	£2.50	£0.05	£0.03
Time to resolution - 5 weeks	Discreetness	£2.76	£2.53	£0.00	£0.00
Mean bags per day: no complications - 2	Discreetness	£2.65	£2.47	£0.12	£0.06

Abbreviations: eJP, economically justified price; PSC, peristomal skin complications

Note: leakage results are presented for monthly leaks only

7.3.4. Exploratory analysis for specific bags

The results of the exploratory analyses to evaluate the association with bag prices and reported differences in outcomes based on the data identified in the clinical review (see section 7.2.7) are provided in this section. In one comparison, the bag with the lower rates of complications (SenSura) was priced higher on the drug tariff, but the price difference was not explained by the difference in ballooning rates in the study as it was higher than the eJP per bag. In a second comparison (SenSura vs SenSura Mio), the two bags were priced the same on the tariff, suggesting that the difference in outcomes was not justified. In the final comparison, [REDACTED] (Table 35). Overall, in only one of the three exploratory analyses was the bag with the higher price associated with greater benefits to participants but even then, the price difference was higher than the difference justified by the additional health benefits. While the difference in outcomes were not considered to necessarily be robust, these analyses were nevertheless considered to provide further evidence that there may be limited association between current pricing and demonstrated or expected clinical benefits of 1-piece closed bags for people with a colostomy. These results support the findings of the regression analyses, reported in Section 7.3.1.

Table 35: Exploratory analysis of justification of price differences for specific bags

	Rate	Price per bag ⁴	Price difference per bag ⁴	Incremental eJP per bag	Justified?
Voergaard 2007 ¹⁴ – Rate of ballooning in participants					
Nova	53%	£2.88			No (The price difference is higher than the incremental eJP)
SenSura	■	£3.20	£0.36	■	
Virgin-Elliston 2023 ¹³ – Rate of ballooning in bags					
SenSura	22.8%	£3.20			No price difference
SenSura Mio	11.2%	£3.20	£0.00	£0.074	
■■■■■■■■■■					
■■■■■■■■■■	■■■■	■■■■	■	■	■■

Abbreviations: eJP, economically justifiable price

Notes: SenSura and SenSura Mio prices are for a flat bag. For both products, prices do not vary according to size. SenSura, [REDACTED] prices are the weighted average of all flat bag options. The Nova rather than Nova1 bag is used for the price within the analysis for Voergaard 2007 as the study states that no participants were using a convex bag and the Nova1 on the current drug tariff is only available as a convex bag

7.4. Factors not included in the decision model

In England, it is common for manufacturers of stoma bags and related products to provide sponsorship of stoma care services, wards or CNS in stoma care and pharmacists, as well as to be affiliated with preferred Dispensing Appliance Contractors (DACs) (see Table 36).³⁵

Manufacturers also reported providing training, education, and patient advice to assist in product selection, IT support, telephone helplines, post-discharge care and services for people with a colostomy such as post-cutting and home delivery (Table 36). DACs often provide additional services such as cutting services for those who prefer not to or cannot cut bag openings to size.

Table 36: Sponsorship arrangements between manufacturers and NHS England

Manufacturer	Market Share	Sponsorship arrangements with NHS England & in-kind services
Coloplast	36.6%	
Hollister Ltd	28.6%	
Salts Healthcare	14.1%	
Welland Medical Ltd	9.2%	

Manufacturer	Market Share	Sponsorship arrangements with NHS England & in-kind services
		     
ConvaTec Inc	3.7%	No sponsorship, provide training, education and patient advice
Oakmed Ltd	1.9%	
B. Braun Medical Ltd	<1%	     
Bullen Healthcare	<1%	    
Trio Healthcare Ltd	<1%	
Alliance Pharmaceuticals Ltd	<1%	 

Abbreviations: DAC, dispensing appliance contractor; FoC, free of charge; HCP, healthcare professional; IT, information technology; NHS, National Health Service; PROM, patient reported outcome measure; UK, United Kingdom

Sources: Market share calculated from 2023 prescriptions data by number of bags, NHS England, Bennet Institute.⁵ Hollister figures include Dansac Ltd.

A survey and review of the experiences of registered stoma care nurses in the NHS summarised their relationship with industry as ‘complicated’,⁷ with the authors advocating increased awareness of professional codes, the Bribery Act 2010 and existing NHS guidance on managing conflicts of interest. The survey was conducted in early 2020 (prior to the major impact of the COVID pandemic) and received 108 responses from across NHS England. Seventy seven percent of respondents worked in services that were either directly funded by or sponsored by industry in both the acute and community care setting. Several respondents

(28%) highlighted areas where the relationship works well, but a greater number (35%) highlighted concern.

Areas where industry involvement was seen as a benefit included provision of home delivery services, free stock for hospitals, educational events for staff and patients, and increases in number of staff available, with a belief that the services were ethical and in the best interests of patients.

However, concern was voiced over the involvement (and sometimes reliance) on the financial support of manufacturers to deliver the stoma care service. Concerns were raised about the ethical implications of the conflict of interest and damage to the credibility of the service, with the NHS “committed to relationships that are damaging the economic viability of the NHS... but the alternative, [the NHS paying for the contracts], is also not economically viable: it is a financial and moral mess”. Respondents also reported levels of distrust between NHS and industry funded nurses, with perceptions that quality of care may be influenced by commercial considerations, despite NHS England guidelines stating that sponsored postholders are not to promote or favour the sponsor’s products over others.⁶⁸ Anecdotal evidence to the EAG from clinical experts suggested that there may be some disparity in service provision across NHS England. For example, manufacturer funding allows sponsored nurses and pharmacists to provide appliance review in people’s homes, whereas clinic-based visits are typically offered by unsponsored staff. One SCM, a person with lived experience, also queried whether the current sponsorship model is compatible with a “patient first” approach when reviewing the initial draft of the EAG report.

In NHS Scotland, sponsorship of CNS in stoma care ended in 2008, with a two-year transition period whereby manufacturers continued to fund the nurses before they were transferred to the NHS payroll.^{69,70}

According to NHS Scotland, the price per bag is currently (April 2024) capped at £1.67 per bag for products dispensed in hospital, based on the median price previously offered by companies, with no products permitted to be provided free of charge for stocking.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Data for NHS England suggest a mean cost per bag for use in hospitals in 2023 of £3.02 (weighted average of all relevant bags).⁷¹ These numbers are not directly comparable to the price paid in Scotland as companies often discount hospital-supplied bags compared with those dispensed in the community, with many provided free of charge, thus the cost per use is unknown. Differences in which bags are promoted by companies and selected by patients will also lead to a difference in the mean price per bag between England and Scotland. However, the 'cost per item' (prescription rather than bag, each prescription contains multiple bags) reported in the prescriptions cost analysis for England for 2022-2023⁷² was £225.93, and £196.19 in Scotland⁷³ (both reporting community dispensed prescriptions for BNF section 2335).

Both the pros and cons of the impact of ending nurse sponsorship in Scotland have been reported. The advantages were that people with a colostomy now had freedom of choice of DACs as well as products from any manufacturer; in England, people with a stoma may be directed to manufacturers' chosen DACs, potentially limiting choice.^{35,74} The disadvantages were risks of lower staff numbers (team size per patient). A survey⁷⁵ conducted in 2023 by the Scottish Stoma Forum (an industry body) found a number of patients reported dissatisfaction with the services they received in Scotland, although it is unknown how this compares to satisfaction rates in England.

In summary, the EAG noted that the mean price per item was substantially lower in NHS Scotland (where sponsorship was stopped) than that charged to NHS England. However, in return, NHS England receives additional services, in particular additional funding for CNS in stoma care, access to educational events, IT services and additional services for people with stomas such as at-home appliance reviews. These services do vary from trust to trust, depending on commercial arrangements, which may raise issues of equity and equality of access. Formal assessment of the pros and cons of the arrangements are beyond the scope of this assessment.

[REDACTED]

7.5. Summary and interpretation of the economic evidence

There is a large difference in price between the cheapest and most expensive bags available on the drug tariff (cheapest per bag: £1.85 [Alliance Opus NaturFit flat bag]; most expensive £3.84 [Welland Medical FreeStyle Vie Flushable]).

No data were identified that allowed for reliable quantification of the cost-effectiveness of either specific features or specific types of bags. Only two bag-related complications were identified in the clinical review as having any evidence of difference in outcomes between bags, evidence for which was not robust. None of the included studies found any difference between bags in the two most impactful complications according to the economic analysis (PSC and leaks).

The data that were identified for the impact of bag-related complications on HRQoL and resource use were generally from a mixed population (a high proportion of ileostomy relative to colostomy) and either used methods that did not align with the NICE reference case – such as vignettes or the SF-6D for utilities – or were poorly reported. It was, however, clear from the available data that these complications had an impact on quality of life and NHS resource use, with the two complications found to have the greatest impact and with the most available literature being PSC and leaks. Potentially innovative features that reduce the rate or impact of bag-related complications would be expected to be able to justify an increased price relative to a bag that does not include these features.

Given the sparsity and low quality of the data available the EAG pursued a 3-pronged strategy:

- Regression analysis to assess the correlation between drug tariff prices and potentially innovative features of 1-piece closed bags.
- Decision modelling to calculate the cost-effective price for bags that prevent complications impacting HRQoL and NHS costs.
- Exploratory analysis on studies showing significant outcome differences between bags (n=3) to determine if any price differences are explained by the difference in outcomes.

The regression analysis was unable to detect a significant association between price and features included in the NICE scope, except for flushable disposal (for flat 1-piece closed bags), implying that there was generally little relationship between the two.

The maximum economically justifiable price for a bag which completely eliminates the chance of any of the complications is £4.24 for a flat bag and £4.69 for a convex bag. The biggest reduction reported in the clinical evidence base was a ■■■ relative reduction for ballooning in Voergaard (2007); as only two other papers demonstrated a significant difference between bags, and the overall clinical evidence base did not generally provide strong evidence for differences in outcomes between bags, the complete elimination of any bag-related complication may be considered to be unrealistic. As noted previously, the only other outcome for which a difference was demonstrated for bags on the Drug Tariff was pancaking where a ■■■ difference was observed.

As shown in Table 31, the maximum eJP that reduces the chance of complications by 50% was £3.00 and £4.51 for flat and convex bags respectively (for a single complication) and £3.00 to £4.51 and £3.44 and £4.795 for flat bags and convex bags respectively for all complications. The maximum eJP that reduced the chance of complications by 25% was £3.00 and £3.45 for flat and convex bags respectively (for a single complication) and £2.37 to £2.82 for all complications. A bag that improves all complications by 25% would command a lower price than both the average bag price in 2023 (£3.02) and the cost of the most expensive bag (£3.84).

It should be noted that our analysis made several optimistic assumptions:

- All people experiencing complications are currently using the cheapest bag in the current range – this is unlikely to be the case.
- The price for a bag should be set equal to its eJP. This is optimistic as there are many areas of uncertainty in deriving the eJP, and many other factors may have a bearing on pricing decisions. If a bag's price was set to equal to its eJP, the net health benefit from such a bag would be exactly zero (i.e. this is equal to the monopolist's price).
- The sources of resource use impact were used for PSC and leaks that assigned the largest impact to these complications.

The incremental eJP of reducing or eliminating multiple, concurrent complications is unknown but is likely to lie between the incremental eJP of the single most impactful complication and the sum of the incremental eJP of all of the complications. The latter (the additive approach) is highly likely to overestimate impacts as there is considerable overlap between complications (particularly PSC, leakage and pancaking), and the combined impact on disutility and cost to the NHS is unlikely to be summative.

The current analysis therefore indicates that there are a large number of bags for which the current pricing cannot be explained relative to the cheapest bag available on the tariff based on the impact on health-related quality of life and resource use alone.

The analysis was driven by the unit cost and frequency of HCP interactions, the cost of supporting products and expected QALY gains. Future research should focus on collecting better data on the impact of bags/features on these 3 key elements. The impact of PSC was the most uncertain, however, this may be in part due to their being the most alternate sources of data to test the uncertainty.

Exploratory analysis of bag price versus demonstrated benefit for the two published [REDACTED] studies, where such data were available, provided further evidence to support the conclusion of the regression analysis that there is little link between current pricing and demonstrated or expected benefits for the bags.

Our analysis had a number of limitations. These were above all driven by the paucity of data necessitating (1) calculation of a maximum reasonable price for a stoma bag that completely or partially resolved a complication rather than estimating whether various bags were cost-effective at their current market prices, (2) separate analyses on each complication individually rather than a single combined analysis and (3) extensive use of expert elicitation in place of empirical data to inform model inputs. Of note is that the only feature that had a significant impact on price in the regression analysis (for flat bags) – flushable disposal – was not included in the EAG's eJP analysis as it was unrelated to stoma-related complications.

Finally, the analysis did not consider the impact of sponsorship and additional services provided by manufacturers and DACs. It was unclear whether the net value of such arrangements represents a net benefit to NHS patients in England and value for money for the taxpayer. This was beyond the scope of this assessment. In Scotland, where sponsorship of stoma nurses ended in 2008, a reduction in bag prices relative to England was observed (13% lower mean prescription item cost in 2022-2023). However, according to anecdotal evidence received by NHS Scotland, this has come at the cost of a loss of nursing staff and a decrease in banding and skill mix.

In conclusion, the evidence available was insufficient to support price variation for any of the features considered. This is due to an absence of evidence rather than evidence of no benefit associated with the features. Our exploratory analyses suggested 1) that there was very little

correlation between bag prices and features/benefits, and 2) that drawing on the limited evidence that was available on value to patients and cost to the NHS of resolving complications, there were a large number of bags for which the current price did not appear to match a reasonable willingness to pay for the claimed feature/benefit.

8. EVIDENCE GAPS AND RESEARCH RECOMMENDATIONS

8.1. Evidence gap analysis

An overview of the available evidence base for the assessment of 1-piece closed bags for adults with a colostomy is shown in Table 37. The table demonstrates the large gaps in the evidence base, including areas where evidence was of insufficient quality to inform robust decision-making.

Table cells marked red denote areas where no in-scope evidence was available, and amber denotes limited evidence. There were no outcomes with high quality evidence.

None of the included studies reported as outcomes the number of appointments required with CNS during stoma care, the use of medication and supporting products, pancaking events, mucocutaneous separation, or HRQoL (although the EAG noted that estimates for some of these were available for the economic analysis from surveys and other, non-trial sources). There was some evidence for all other outcomes, including wear time, leakage, PSC, ballooning, pancaking, user acceptability, and adverse events. None of the evaluated bags included baseplate additives or flushable disposal, meaning that no evidence was identified for 1-piece closed bags with these features. All the evidence available – as described in Section 5.1 – was of limited and/or low quality. A particular area where evidence was required was where a bag or feature impacts on more than one complication. Evidence on the health-related quality of life associated with experiencing more than one simultaneously as well as the cost to the NHS of managing the complications would be of value.

Table 37: Evidence gap analysis

Types of potentially innovative features specified in the NICE Scope									
		Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window
Outcomes specified in the NICE scope	Leakage	N = 0 studies RED	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 0 studies RED	N = 4 studies Limited quality AMBER
	Length of time before switching bags	N = 0 studies RED	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 0 studies RED	N = 3 studies Limited quality AMBER
	Number of appointments with CNS's in stoma care	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
	Medicine use	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
	Number of or time to ballooning events	N = 0 studies RED	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 0 studies RED	N = 4 studies Limited quality AMBER
	Odour control	N = 0 studies RED	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 4 studies Limited quality AMBER	N = 0 studies RED	N = 4 studies Limited quality AMBER
	Supporting product use for attachment and removal	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies	N = 0 studies	N = 0 studies	N = 0 studies	N = 0 studies RED

Types of potentially innovative features specified in the NICE Scope									
					RED	RED	RED	RED	
Pancaking events	N = 0 studies RED	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 0 studies RED	N = 3 studies Limited quality AMBER
Peristomal skin complications	N = 0 studies RED	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 0 studies RED	N = 1 study Limited quality AMBER
Mucocutaneous separation	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Other intervention related adverse events	N = 0 studies RED	N = 5 studies Limited quality AMBER	N = 5 studies Limited quality AMBER	N = 5 studies Limited quality AMBER	N = 5 studies Limited quality AMBER	N = 5 studies Limited quality AMBER	N = 5 studies Limited quality AMBER	N = 0 studies RED	N = 5 studies Limited quality AMBER
Ease of use and acceptability	N = 0 studies RED	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 3 studies Limited quality AMBER	N = 0 studies RED	N = 3 studies Limited quality AMBER
Health-related quality of life (for individual complications and jointly)	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Psychological and social impact	N = 0 studies RED	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 1 study Limited quality AMBER	N = 0 studies RED	N = 1 study Limited quality AMBER

Note: Bag features are listed as columns and outcomes as rows.

8.2. Ongoing studies

There were three records that were excluded at full text as being a directly relevant study that were only available as a protocol, with no results available, and where the study was expected to be ongoing. Two other records were also marked as a protocol but were excluded for other reasons. The first was excluded as it was an evaluation of Heylo, a digital stoma supporting product.⁷⁶ (i.e. wrong intervention). The second was excluded as it did not collect data for a specific product or set of products, but rather collected patient reported data over a five-year period for people with a stoma and their caregivers⁷⁷ (i.e. wrong study type).

The three remaining ongoing study protocols are described in Table 38. Two of them were randomised trials – one in China (ChiCTR2300072043)⁷⁸ and one in Denmark (NCT05641168).⁷⁹ The third protocol described a prospective, post market follow-up study (NCT05373888).⁸⁰ One study is co-sponsored by Zhende medical ostomy products, one by Coloplast A/S, and one by B. Braun Medical SAS.

The Chinese trial (ChiCTR2300072043) is relatively small, with 40 people in each arm, and it was not clear how long follow-up is planned to be. The trial is a randomised, parallel group, non-inferiority trial (that aims to identify whether Zhende medical ostomy products are not inferior to that of Coloplast products). The outcomes being measured include leakage rate, wear time, incidence of dermatitis, and patient satisfaction. The EAG welcomed the fact that the trial will have a parallel group design (rather than another crossover trial – see section 5.3 for a critique of crossover trials) but does not expect that it will significantly address any of the evidence gaps identified.

There is a more ambitious enrolment target of 400 in the Danish trial (NCT05641168) – although follow up is planned to be just one week. Again, the study design is for parallel assignment, which is welcome. However, the primary outcome of interest is narrow – just the adherent area, as assessed by photography. The study will compare a new adhesive material from Coloplast to an adhesive material already on the market (from SenSura Mio [Coloplast]). Depending on whether a range of secondary outcomes are also to be measured, the primary outcome will not in itself address any of the evidence gaps.

The B. Braun post-market follow-up (NCT05373888) has a planned enrolment of 200 participants. Again, the trial is relatively short: the investigation will consist of an enrolment visit and a final visit separated by 14 (± 3) days. The bag being evaluated is the Softima® bag. The

study includes a small number of outcomes, including adverse bag effects, particularly dermatitis and infectious conditions. While the adverse event outcomes are likely to be a small but useful addition to the evidence base, the findings are unlikely to fill any evidence gaps.

Table 38: Ongoing studies

Name, sponsor and registry number	Date and country	Study type and population	Research objective	Outcomes
A randomised, open, parallel, positive-controlled, multicenter, non-inferior clinical trial on the safety and effectiveness of deshutuo ostomy products in nursing patients with a stoma. Sponsor: Zhende medical supplies ChiCTR2300072043	Registration: 01 Jun 2023 Last update: 28 Jul 2023 Country: China	Randomised, open, parallel, positive-controlled, multicentre, non-inferior clinical trial Participants will have a DET score of 0 for peristomy dermatitis and a stoma that meets the requirements for using a convex chassis	To evaluate the safety and effectiveness of Zhende medical ostomy products, and the related performance of the products is not inferior to that of Coloplast stoma care products.	Leakage Length of time before switching bags Incidence of dermatitis Comfort Patient satisfaction
A Pilot Evaluation Exploring New Adhesive Materials and Their Ability to Adhere to Abdominal and Peristomal Skin Sponsor: Coloplast A/S NCT05641168	Registration: 15 Nov 2022 Last update: 7 Dec 2022 Country: Denmark	Randomised, open, parallel assignment trial Participants will have had a colostomy, ileostomy or urostomy for more than one year and have suitable peristomal skin area (assessed by investigator)	A pilot evaluation exploring new adhesive materials and their ability to adhere to abdominal and peristomal skin.	Adherent area (assessed by photos of adhesive materials)
Safety and Performance of Softima® Stoma Appliances in Enterostomy Patients Sponsor: B. Braun Medical SAS NCT05373888	Registration: 15 Nov 2022 Last update: 7 Dec 2022 Country: Spain	Non-interventional, prospective, international, multi-centre, post market follow-up investigation Participants will be Flexima/Softima users – both new and experienced users – with either a colostomy, ileostomy or jejunostomy	To evaluate the number of patients with at least one adverse bag effect	Allergic contact dermatitis Mechanical dermatitis – trauma Irritant-chemical dermatitis Infectious conditions Any other bag related complication (as judged by a clinician)

Abbreviations: DET, discolouration, erosion, tissue overgrowth; QoL, quality of life; UK, United Kingdom; USA, United States of America

8.3. Key areas for evidence generation

The clinical effectiveness review identified a significant absence of evidence for understanding the clinical effectiveness of 1-piece closed bags and their features for adults with a colostomy. Based on the studies included in the evidence review and consideration of evidence that was identified in the evidence searches but excluded from the evidence review, the EAG identified several key needs for future research. A summary of the key gaps and needs is presented in this section. A selection of key research recommendations relevant to this assessment are then described in section 8.4.

Population gaps

- The majority of the evidence included in the evidence review included general or mixed populations and did not report outcomes specifically in subgroups of people with a colostomy who may have more complex needs. There was only one exception to this, in that one study¹³ only included participants who were experiencing regular ballooning with their usual bag (at least once weekly). The EAG identified many groups of people with a colostomy who may have particularly complex needs from their bag (discussed in sections 3 and 4), and considered that results in all identified groups would be informative to support bag choice and to determine the potential value of 1-piece closed bags and their features. In particular, the EAG considered the absence of evidence in people with PSC at baseline and the minimal evidence amongst people who regularly experience gas to be notable, given that features such as baseplate additives and bag filters are intended to tackle these outcomes. The EAG was also aware that many adults with a colostomy will have a complex stoma type and/or a body shape or hernia that makes the fit of their bag more difficult. To fully understand the outcomes of 1-piece closed bags and their features, the EAG considered that evidence to explore outcomes in people with complex needs was needed.
- Many of the studies identified in the evidence search evaluated 1-piece bags for people with an ileostomy or in a mixed population of people with colostomies and ileostomies (and without subgroup analysis to report results for people with a colostomy separately). Following feedback from CNSs in stoma care (Appendix E), this evidence was not considered to be generalisable to people with a colostomy, meaning that outcomes for people with an ileostomy or from a mixed population may not be the same as the outcomes that would be experienced by a group of people with a colostomy using the same bag. The EAG also excluded evidence that evaluated 1-piece closed bags in healthy volunteers or

within lab-based assessment only (i.e. evaluation of a filter in a lab where the filter was not attached to a 1-piece closed bag or not worn by a person with a colostomy). Based on feedback from people with lived experience, the EAG considered that these studies were not informative for determining the outcomes of 1-piece closed bags in a way that accounted for the needs and preferences of people with colostomy. Future research is needed that considers outcomes of 1-piece closed bags and their features in people with a stoma and reports outcomes separately for people with different needs, including different stoma complexity, and for people who have more than one stoma.

Intervention gaps

- The clinical evidence covered only a small number of the 1-piece closed bags available to adults with a colostomy via prescription in the NHS. As shown in Table 36, based 2023 prescriptions data from NHS England,⁵ four companies dominated the market at the time of the assessment: Coloplast (36.6% market share), Hollister Ltd (28.6%), Salts Healthcare (14.1%) and CliniMed (9.2%). All publicly available studies were sponsored by Coloplast and Coloplast bags were included in all studies.

Bags produced by Hollister and Dansac (now part of Hollister) were included as comparators only and no bags produced by Salts Healthcare, CliniMed, or any of the other companies currently providing bags for adults with a colostomy to NHS England, were evaluated in the available evidence base. Broader sources for study funding would augment the evidence base and allow for the comparison of results between companies. The EAG noted that many companies that produce 1-piece closed bags for prescription within the NHS have published evidence for their bags, though many of these studies were excluded as the design did not meet the eligibility criteria for the assessment; that is to say, the study designs and outcomes were not pertinent to estimating the direction and magnitude of outcomes associated with the bags in a way that would be informative to determining cost effectiveness.

- All of the evidence included in the review evaluated 1-piece closed bags that are currently available for prescription in the NHS, however, three of the included studies^{11,12,14} were published more than 10 years prior to this assessment. The EAG were unsure to what extent outcomes for adults with a colostomy may have changed over time since those studies were conducted, though it considered it plausible that people's needs with regards to nutrition, physical health, wellbeing and personal preferences are likely to have changed

with time. There may also have been small incremental changes to some products over time. The EAG therefore considered that more recent evidence to evaluate 1-piece closed bags for adults with a colostomy would best represent the outcomes of these bags in the current target population and health service.

- Amongst the overall paucity of evidence, the EAG further noted that none of the bags evaluated in the review included baseplate additives or had flushable disposal. People with lived experience also expressed an interest in 1-piece closed bags that were environmentally friendly, for example they use sustainable materials and/or were biodegradable. At the time of the assessment, there were no 1-piece closed bags that were marketed with this feature.

Comparator gaps

- The literature search identified multiple studies that compared a single 1-piece closed bag to a mix of bags. For example, single-arm studies where participants using different bags at baseline were all switched to a new bag and their outcomes assessed before and after, or comparative studies where participants used a new bag and were compared with a control arm of participants who were using various different bags. These studies were excluded from the evidence review as by comparing multiple variations in bag features, the results were not informative for understanding the effectiveness of any one feature or bag. For example, if a new bag was associated with half the rate of ballooning than a mixed comparator, it would not be possible to determine whether the bag was twice as effective as all the bags in the comparator mix or more effective than some and less effective than others. As each of the bags in the mix would also have different features, it would also not be possible to know which difference in features was driving the benefit for ballooning. For completeness, this evidence was included in the expanded evidence base presented in Appendix J. While the EAG considered that studies with mixed comparators may be easier for companies to conduct, as controlled studies are more costly and it would require a smaller sample in an observational study, the outcomes from these studies are difficult to interpret. Overall, the EAG determined that these studies would not be able to provide the clinical or cost effectiveness data needed for this assessment. There was therefore a need for studies to determine the benefits of specific bags or features in a meaningful and reliable way. The EAG has provided a summary of a potential approach to this within its research recommendations (section 8.4).

Outcome gaps

- Results based on unvalidated scales were excluded in the protocol for the evidence review but were ultimately included in a protocol deviation, given the paucity of evidence identified in the review (section 5.2). [REDACTED]¹⁵ Teniere (2007),¹² and Voergaard (2007)¹⁴ were assessed using outcome scales that appeared to have not been psychometrically validated. This meant that the EAG was unsure whether the results from these outcomes would be reliable and would accurately represent the outcomes that would be experienced by adults with a colostomy using a bag in real life. One of the limitations of using measures that have not been validated is that it is not possible to confirm that participants in the studies answered the question that was intended. For example, whether participants would all interpret ‘ballooning at night’ the same way, or whether participants interpreted terms such as “sometimes”, “often”, “good”, or “very good” in the same way. The lack of validation also meant that it was not possible to judge how much a change of, for example, good to very good, would mean to people with a colostomy in real life (i.e. would this be life changing or would it have a small improvement on people’s lives?). Validation of measures that assess key outcomes of 1-piece closed bags in adults with a colostomy would be important for ensuring that the results of studies are robust as well as for guiding the interpretation of findings. The EAG noted that some outcomes, such as odour and comfort, may be highly subjective and so may be particularly challenging to assess in a robust way. However, further research to explore this would be beneficial since these outcomes are of importance to people with a colostomy.
- Many of the outcomes specified in the final scope were either not represented in the included clinical evidence or included in just one study. These included:
 - HRQoL (zero studies).
 - Number of appointments with CNSs in stoma care (zero studies).
 - Medicine use (zero studies).
 - Supporting products use for attachment and removal (zero studies).
 - Mucocutaneous separation (zero studies).
 - Psychological and social impact (one study).

- Peristomal skin complications (one study).
- The EAG noted that HRQoL is crucial for cost effectiveness analysis, particularly for conditions where interventions do not change life expectancy. Its absence from the included evidence was therefore a significant limitation in the available evidence base. Of particular value for future research would be understanding of the combined impact of experiencing multiple complications simultaneously on HRQoL.
- The EAG was aware that psychological and social impacts of 1-piece closed bags are important determinants of bag choice for adults with a colostomy. A bag that is not reliable or causes complications can be devastating for a person's lifestyle, their relationships and their mental health. The absence of reliable evidence on this aspect of people's experience of living with a bag for their colostomy is a significant evidence gap – future research into this outcome would be a meaningful contribution to decision making.
- PSCs are one of the biggest concerns for people with a colostomy and arguably the most important issue for bags to address given the major clinical, cost and psychological impacts of this outcome. Future research on the effect of 1-piece closed bags and their features for PSC will be crucial for informing treatment decisions and understanding the costs to the NHS. The EAG noted that PSC is one of the few areas where validated tools for assessing outcomes exist, which may facilitate evidence in this area.
- The EAG identified an ongoing study, sponsored by Hollister (NCT03715179),⁷⁷ that is collecting patient-reported data over a five-year period for people with a stoma and their caregivers. This observational study has an enrolment target of 600 people, although it was not clear if this included caregivers as well as people with a stoma (ileostomy, colostomy or urostomy). The study was designed to investigate associations between stoma devices (both bags and accessories) with PSC, HRQoL, caregiver burden, product satisfaction, and healthcare resource utilisation (HRU). The study may provide useful real-world evidence to complement the trial data presented in this assessment, and therefore help fill some of the above gaps.

Other clinical considerations

- All of the included RCTs were crossover trials. While not unnecessarily an inappropriate study design for evaluating 1-piece closed bags, the EAG noted several potential limitations and biases of this study design (section 5.3). Future studies may benefit from using a

crossover design that aims to reduce these limitations, and/or may choose to use a parallel group design.⁸¹

Economic evidence gaps

In addition to the gaps in clinical evidence described above, which led to an inability to determine a link between innovative features and their impact on bag-related complications and key outcomes, the EAG encountered evidence gaps during development of the economic analysis. These included:

- The absence of a standardised definition for what classes as an 'innovative feature' in each category would be a requirement for implementation of any feature-based pricing approach. As described in section 2, stakeholders to the assessment noted that judgements about whether features were standard or potentially innovative were subjective, which may lead to differences in opinion across companies and other stakeholders as to the presence of potentially innovative features in 1-piece closed bags.
- Standardised definitions of bag-related complications were lacking, which led to difficulties in defining health states within the economic analysis.
- Utility values for each bag-related complication were also lacking. Most of these had to be estimated through expert elicitation and, where literature was available (PSCs and leaks), it did not meet the NICE reference case either by not being from health states described by patients or by not being valued using the EQ-5D.i
- Assessment of the appropriateness (or not) of EQ-5D to measure the impact of bag-related complications.
- Resource use implications for each bag-related complication was lacking and had to be estimated using expert input.
- Information on the chance of switching bag type or brand in response to complications was lacking and had to be estimated through expert elicitation.
- Whilst information was available from Colostomy UK for the proportion of people with a stoma experiencing most of the complications, data were generally not available on how often complications re-occurred (e.g. weekly, monthly or annual rates).

- The impact on people with a colostomy of experiencing multiple, concurrent complications was not available. Therefore, the EAG presented the Committee with the best and worst-case information for this (additive and worst complication impact approaches).
- Data to inform how the economic impact of potentially innovative features or bag-related complications may differ across population subgroups was also lacking.

8.4. Research recommendations and optimal research designs

The EAG considered that there were two major challenges for developing evidence for 1-piece closed bags for adults with a colostomy to inform a NICE assessment:

1. **There is paucity of evidence needed to inform a NICE assessment.** The EAG believed that, to date, the manufacturers of 1-piece closed bags for adults with a colostomy have developed evidence to support the licensing of their products and to inform marketing strategies and have not been developing an evidence base to inform a NICE assessment. There is also a paucity of evidence that is important for supporting the development of these studies, such as: accurate epidemiological data in people with a colostomy; validation of HRQoL measures and other clinical and patient-reported outcomes; development of real world evidence sources that can estimate bag use data (e.g. length of time before changing bags, number of bags used by people, patterns in changing bags over time, time for onset and resolution of complications).
2. **There are many ‘indications’ amongst adults with a colostomy that are not clearly defined but need to be considered separately.** Adults with a colostomy are a highly diverse group of people, from the reason for their colostomy surgery, to the complexity of their stoma, their digestive and comorbid health, and their personal lifestyles and preferences. The same bag will patently not be suitable for every person, and therefore may only ever be used by a subgroup of people with a colostomy (and never even tried in others). Within the population of people with a colostomy, this means that there are an unknown number of separate ‘indications’, i.e. groupings of people for whom a particular bag or set of bags may be appropriate. To the knowledge of the EAG, there is not a clear breakdown of these indications that could be used to guide study selection criteria, and given the high level of variation in needs, the EAG is unsure if this could be possible. This means that there are ‘appropriate’ and ‘inappropriate’ comparisons – i.e. some bags should never be compared with others, as they are intended for different populations. It also means that a bag A may perform better than bag B in one population

and worse than bag B in another population, meaning that the eligibility criteria in the studies are crucial for determining meaning in the results.

The challenges above must be considered within the context of the value of the information yielded compared with the cost. A formal value of information analysis was outside the scope of this analysis, but the benefits of a particular research project would be reduced uncertainty as to (1) the appropriate bag for a particular person with colostomy or (2) the appropriate price for the bag and thus opportunity cost borne by other patients. Given the number of bags prescribed in the NHS each year, and the impact of complications on quality of life, the value of information yielded from research in the area to the NHS as a whole could be high relative to the cost of conducting it.

With the above considerations in mind, the EAG identified a number of important research recommendations for this topic. This list is not intended to be exhaustive but is rather a short list of key recommendations that arose during consideration of the evidence for this assessment and would be expected to be informative to any future NICE evaluation of 1-piece closed bags for people with a colostomy.

Evidence is needed to generate robust estimates of clinical effectiveness of 1-piece closed bags OR of features of 1-piece closed bags for adults with a colostomy.

Study design: RCT or crossover RCT comparing a bag with a single other bag (e.g. SenSura vs SenSura Mio) or comparing a change in a single feature between bags (e.g. Dansac NovaLife with the usual filter vs Dansac NovaLife with a newly developed filter). To identify the effectiveness of specific features, it may also be feasible to compare bags that vary in multiple features (e.g. OakMed options Alginate [baseplate additive] vs Salts Confidence Natural [baseplate additive, modified baseplate shape, modified baseplate adhesive]), although this means that a broader evidence base is needed to perform ICA and associate portions of the effectiveness estimates to each feature. Crossover trials should ensure that they randomise the order of bag use, as the EAG considers that carry-on effects may be present in this topic (e.g. skin complications that occur when using the first bag may continue to affect patients when they switch to the second bag).

Population: Adults with a colostomy who are considered, by CNS in stoma care, to be appropriate candidates for the bags under evaluation. This approach was typically taken by the studies included in the clinical evidence review. CNS in stoma care determining eligibility should

be independent (i.e. not able to make decisions using their expertise and not guided by the study sponsor) to ensure that decisions on eligibility are robust. Where appropriate, it would be useful for CNS in stoma care to provide a summary of the factors influencing their decisions, i.e. provide a description of the participants that would and would not be considered suitable. It would also be useful for CNS in stoma care to comment on whether there are any meaningful gaps in the study populations who may also be suitable candidates for the bags, as this will help to understand the generalisability of the evidence to practice. To help understand variation in outcomes within the eligible population, where feasible, the sponsors may also wish to consider subgroup analyses to evaluate change in the outcomes of bags in certain groups, e.g. different baseline risk (such as whether participants were experiencing a high rate of ballooning before the study) and stoma complexity. Key characteristics of the populations should be described, including factors that may affect the choice or outcome of bag.

Studies should be conducted with people with a colostomy, rather than in healthy populations. Where studies are conducted in a mixed population of people with different types of stomas, results should be presented separately for people with each type of stoma, due to the specific needs of people with a colostomy and the lack of generalisability between these populations.

Intervention/comparators: in addition to the information about interventions and comparators included in the study design section above, the EAG also considered that studies should seek to collect information about the background care received by participants during the study. This includes the supporting products that participants used (if any), what treatments participants were using to manage complications, and whether participants were permitted to use other bags during the study follow-up (e.g. change to a different bag than the one being evaluated while playing sport or swimming). Finally, understanding of the effectiveness of 1-piece closed bags in evaluations would be aided by clear communication of the features of those bags, and their intended mechanisms of action. This information should therefore be reported in all studies.

Outcomes: Studies should assess the outcomes on the NICE scope and identified in the NICE user preference assessment, as these outcomes were considered important to determining the choice of bag for people with a colostomy. In particular, evidence for the effect of bags on bag-related complications (PSC, leakage, pancaking, ballooning) and on HRQoL and psychological wellbeing. Ideally, outcomes should also be measured using standardised and (where relevant) validated measures to ensure that data are reliable, valid, and comparable between studies. The measurement of HRQoL using the EQ-5D would be informative for health economic

evaluation. In addition, it would be useful for studies to report event rate data as a proportion of the population (i.e. the number of participants who experienced the event) and the number of bags (i.e. the number of bags used in the study that exhibited the event): both measures are informative and reporting both increases comparability across studies. It would also be useful for studies to calculate the proportion of people using the bag who experience a clinically meaningful benefit in the outcome: it is likely that there is no minimally clinically important difference (MCID) threshold that will represent all people with a colostomy, but studies may wish to report data at a number of thresholds that could be used to inform bag choice by people with a colostomy (e.g. proportion of participants with 1 leakage event a week, 2 leakage events a month, 1 leakage event a month etc). Guidance on this from a core outcome set would be useful.

Outcomes should be assessed over a meaningful timeframe to allow for people to adjust to the bag and for any change in outcomes to occur (e.g. for complications to occur or for the bag to affect a person's quality of life). Longer follow-up would therefore be best, although in this case, studies will need to use methods to fully account for attrition, as participants who have negative outcomes will be more likely to discontinue using the bag before final follow-up. Feedback from one SCM was that they would typically try out a bag for 2-weeks before making a decision, implying that a minimum follow-up of 2-weeks should be used, but the EAG was unsure how consistent this would be across all adults with a colostomy.

Other considerations: CNS in stoma care advised the EAG that there is variability in the use of bag and supporting product use, engagement with health services, and outcomes for adults with a colostomy in different countries, which may influence the generalisability of evidence conducted in other countries to the NHS. The EAG was also aware that there is variability in care across locations in the UK, which should also be considered in evaluations. Overall, studies conducted in NHS settings would therefore be most applicable to future decision-making, however comprehensive descriptions of study methods and participants characteristics may aid decisions on generalisability.

Development of a core outcome set and validated patient-reported outcomes for evaluating 1-piece closed bags for adults with a colostomy

The EAG considered that the outcomes listed in the NICE scope for this assessment and those identified in the user preference assessment were the key outcomes for evaluating 1-piece closed bags for adults with a colostomy. The development of a core outcome set for evaluating

these bags would define the list of outcomes that should be reported in all studies evaluating 1-piece closed bags, to ensure that each bag is assessed using all the outcomes that are important for adults with a colostomy in choosing a bag. The core outcome set should also specify ideal methods for assessing each of these outcomes, including how to define the outcome (e.g. what level of leakage is considered to be 'a leak'), how to measure the outcome (e.g. proportion of participants who experienced a leak, proportion of bags that leaked, and/or participant-reported change in their experience of leaks). Where feasible, the core outcome set should also advise the selection of standardised measures for assessing patient-reported outcomes, such as which measures should be used to assess HRQoL and psychological wellbeing. Finally, the core outcome set should also specify whether there are thresholds for guiding the interpretation of outcomes, such as whether there are MCIDs for each outcome (i.e. a level of change in an outcome that is meaningful to people with a colostomy or would affect their decision to choose or discontinue a bag).

Identification of key groups or 'indications' for adults with a colostomy that could be used to guide evaluations

It would be useful for research to define subgroups of adults with a colostomy that could be appropriate candidates for the same bag. As part of this assessment, the EAG spoke with CNS in stoma care who were able to describe several characteristics of people with a colostomy (e.g. body shape, stoma complexity, presence of PSC, digestive and comorbid health) that would suggest modification in a specific feature would be useful. The EAG therefore considered that it may be possible to identify a target population for each available bag on a limited number of characteristics. These characteristics should define those who could be candidates for a bag based on their needs, but this would not necessarily mean that each person with those characteristics would choose to use that bag due to their own personal preferences. It would also not necessarily mean that people with different characteristics would not choose to use a bag. However, the development of bag indications could nevertheless represent an approximate group of people who would be suitable for the bag, and therefore may be useful in guiding patient choice and determining which participants should be invited to participate in studies evaluating those bags. It may also be useful to identify groups of adults with a colostomy for whom limited options exist.

Identification of ‘the lost ostomates’ and those with poor outcomes from their bags

The EAG received advice from CNS in stoma care that there are an unknown number of people referred to as ‘the lost ostomates’ who are not engaging with health services and may be experiencing poor physical and mental health related to their bag. The EAG also received advice that there are people with a colostomy who have low engagement with health services, including a lack of disclosure to CNS in stoma care about the complications they are experiencing or difficulties with their psychological wellbeing associated with their colostomy. The EAG considered that there was an unmet need for treatment in these people, and that research to identify them and the reasons for low engagement would be pertinent to understanding how their treatment and outcomes could be improved.

9. DISCUSSION

The clinical effectiveness review identified an absence of robust evidence that evaluated outcomes associated with 1-piece closed bags for adults with a colostomy. A total of five studies were included in the review reporting outcomes for five different 1-piece closed bags: SenSura, SenSura Mio, Moderma Flex, Nova 1 [REDACTED]. All of the evaluated bags included multiple potentially innovative features as specified in the NICE scope for the assessment. There was some evidence that outcomes varied according to the presence or absence of certain types of features, or when bags varied in the type of feature used. However, there were challenges in drawing conclusions from the available evidence. The studies varied in their methods, including the populations included in the studies and the definition and measurement of study outcomes, and this meant that naïve comparisons between studies could not be used to draw conclusions about the effectiveness of the bags. Moreover, the studies were of poor quality, meaning that the findings may not be reliable or representative of the outcomes that would be experienced by people with a colostomy using the same bags in clinical practice. Overall, there was insufficient evidence to say whether individual 1-piece closed bags for adults with a colostomy or bags that contain potentially innovative features offer greater benefits than bags without those features.

The EAG's economic analyses observed a large difference in price per bag on the NHS Drug Tariff (£1.85 to £3.84). Moreover, regression analysis found no statistically significant relationship between the bag features and price, except for flushable disposal for flat bags, which were associated with an increase in price of 95p (SE 28p). While this analysis was limited due to sample size, the EAG concluded that there was very little, if any, correlation between the presence of potentially innovative bag features and the price of 1-piece closed bags. Rather, the low R-squared suggested that other elements play a greater role in determining price. The EAG noted that bag prices in NHS Scotland were substantially below those in NHS England, and that a key difference between the two was that NHS Scotland did not allow sponsorship of NHS staff or stoma care services. However, the EAG was aware that such arrangements have both costs and benefits, and within the scope of this assessment it was unclear whether these represented a value for money to the taxpayer and/or a net benefit to NHS patients in England.

The EAG developed a decision model to estimate the maximum willingness to pay to eliminate a number of discrete bag-related complications experienced by adults with a colostomy, with the results expressed as a maximum eJP for a hypothetical bag that eliminated that complication. The total eJP was calculated by adding the willingness to pay for elimination of the complication

to the lowest cost basic bag (£1.85). The total eJPs ranged from £2.22 for a bag that completely eliminated odour to £4.24 for one that eliminated PSC. For a bag that reduced the impact of a complication (in terms of HRQoL and cost) by 50%, the eJPs ranged from £2.01 to £3.00. These eJPs can be compared to the current average bag price in NHS England, which was £3.02. As noted above, the EAG did not identify any robust data to determine how effective bag features were at reducing the impact of these complications. It was therefore not possible for the EAG to conclude whether the prices of current 1-piece closed bags was reasonable. Despite limitations with the clinical effectiveness evidence, as an exploratory analysis, the EAG selected three instances where bags evaluated in the included studies were associated with a difference in the risk of complications. In only one of the three exploratory analyses was the bag with the higher price associated with greater benefits to participants and in this case the price difference was higher than the difference explained by the additional health benefits. There were limitations with this approach, and these bags were not compared against a basic bag (i.e. comparisons were not being made along the 'efficient frontier' in cost-effectiveness terms). However, the EAG considered this analysis to provide further indication that the price of 1-piece closed bags was not closely aligned with expected clinical benefits.

The analyses conducted by the EAG as part of its assessment were the best available to meet the decision problem, given the paucity of evidence available. A broad range of evidence sources were sought to inform the analyses, including the conduct of a structured expert elicitation process to plug evidence gaps in, for example, estimates of disutility associated with experiencing complications. Analyses were also conducted using best practice approaches to decision modelling. However, the analysis also contained several limitations, almost exclusively driven by the lack of relevant data. In particular, there was a lack of data to quantify the clinical and economic benefits of specific features or types of bags. Effectiveness data were lacking with no studies identified that demonstrated a significant impact of any bag or feature on the two most impactful complications (PSC and leaks). The available data on the impact of bag-related complications on HRQoL and resource use generally came from a mixed population, with a higher proportion of ileostomy cases compared to colostomy cases. These studies often used methods that do not align with the NICE reference case, such as vignettes or the SF-6D for utilities or were poorly reported. Furthermore, no published data were available on the impact of many complications of interest on either resource use or HRQoL.

The EAG has highlighted evidence gaps and research priorities for understanding the benefits of 1-piece closed bags for adults with a colostomy and determining whether potentially

innovative features offer value for money to the NHS. In addition to studies that provide robust estimates of outcomes associated with 1-piece closed bags, these recommendations include research into real world outcomes and treatment use, the development of a core outcome set and validated patient-reported outcomes, research to understand unmet treatment needs, and research to further understanding into the criteria that determine the effectiveness of specific bag and feature types. In addition to providing understanding of whether 1-piece closed bags offer value to the NHS, the EAG considered that future research may also offer benefits to the wellbeing and treatment outcomes of adults with a colostomy.

References

1. NHS Supply Chain. Value Based Procurement. London: Supply Chain Coordination Limited; 2024. Available from: <https://www.supplychain.nhs.uk/programmes/value-based-procurement/>.
2. National Institute for Health and Care Excellence (NICE). GID-HTE10045 One-piece closed bags for adults with a colostomy. Late-stage assessment. Final scope. London: NICE; 2024. Available from: <https://www.nice.org.uk/guidance/indevelopment/gid-hte10045/documents>.
3. Farmer C, Santo V, Lovell A, Barnish MS, Abdelsabour A, Lowe J, et al. One-piece closed bags for adults with a colostomy [GID-HTE10045]. Final EAG protocol. Exeter: University of Exeter; 2024. Available from: <https://www.nice.org.uk/guidance/gid-hte10045/documents/final-protocol>.
4. NHS Business Services Authority (NHSBSA). Drug Tariff. Newcastle upon Tyne: NHSBSA. Available from: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>.
5. Bennett Institute for Applied Data Science. Oxford: Nuffield Dept of Primary Care Health Sciences, University of Oxford; 2024. Available from: <https://www.bennett.ox.ac.uk/>.
6. Rolls N, Gotfredsen JL, Vestergaard M, Hansen AS, Koblauch H. Importance of stoma care nurses in preparing patients for stoma surgery and adjustment to life with a stoma. Br J Nurs. 2023;32(16):S32-s41.
7. Bowles TM, Moses C, Perry-Woodford ZL. The voice of stoma care nurses: an exploration of stoma care in England. Br J Nurs. 2022;31(22):S14-s24.
8. Colostomy UK. What is a stoma? [online]. Wokingham Colostomy UK; 2022. Available from: <https://www.colostomyuk.org/information/what-is-a-stoma/>.
9. World Health Organization. Colorectal cancer. Key facts. Geneva: WHO; 2023 [updated 11 July 2023]. Available from: <https://www.who.int/news-room/fact-sheets/detail/colorectal-cancer#:~:text=Colorectal%20cancer%20is%20the%20third,people%20aged%2050%20and%20above>.
10. Juul K, Prieto L. Quality of Life with an Intestinal Stoma. Semin Colon Rectal Surg. 2008;19(3):167-73.
11. Coloplast A/S. Study Evaluating a New Ostomy Appliance With Regard to Leakage, Handling and Comfort. ClinicalTrials.gov ID NCT01243294. Bethesda (MD): National Library of Medicine; 2010 [updated 10 Jul 2011]. Available from: <https://clinicaltrials.gov/study/NCT01243294>.
12. Tenière P, Welser M, Martinet C. Ostomy pouch management: two comparative studies of one-piece pouches. WCET journal. 2007;27(2):10-6.
13. Virgin-Elliston T, Nonboe P, Boisen EB, Koblauch H. Evaluating the Performance and Perception of a Stoma Bag Full-Circle Filter in People with a Colostomy or an Ileostomy-Two Randomized Crossover Trials. Healthcare (Basel). 2023;11(3).
14. Voergaard LL, Vendelbo G, Carlsen B, Jacobsen L, Nissen B, Mortensen J, et al. Ostomy bag management: comparative study of a new one-piece closed bag. Br J Nurs. 2007;16(2):95-6, 8-101.
- 15.

16. National Institute for Health and Care Excellence (NICE). The guidelines manual. NICE process and methods [PMG6]. Appendix C: Methodology checklist: randomised controlled trials. London: NICE; 2012. Available from: <https://www.nice.org.uk/process/pmg6/resources/the-guidelines-manual-appendices-bi-2549703709/chapter/appendix-c-methodology-checklist-randomised-controlled-trials>.
17. [REDACTED]
18. Johnson S, Hoch JS, Halabi WJ, Ko J, Nolta J, Dave M. Mesenchymal Stem/Stromal Cell Therapy Is More Cost-Effective Than Fecal Diversion for Treatment of Perianal Crohn's Disease Fistulas. *Front Immunol*. 2022;13.
19. Economically Justifiable Price [online]. York: York Health Economics Consortium; 2016. Available from: <http://www.yhec.co.uk/glossary/economically-justifiable-price/>.
20. Andersen BD, Keizerswaard Pv, Castro MM, English E, Carter D. Introduction to the DialogueStudy: methods and baseline demographic findings. *Gastrointest Nurs*. 2011;9(Sup2):4-8.
21. Berger A, Inglese G, Skountrianos G, Karlsmark T, Oguz M. Cost-effectiveness of a Ceramide-Infused Skin Barrier Versus a Standard Barrier: Findings From a Long-Term Cost-effectiveness Analysis. *J Wound Ostomy Continence Nurs*. 2018;45(2):146-55.
22. Cawson M, Vestergaard M, Ajslev TA, Boisen E. EE281 Predicted UK Health Care Associated Cost-Savings and Health-Related Quality of Life Benefits of Introducing a Digital Leakage Notification System for People Living with a Stoma. *Value Health*. 2023;26(12, Supplement):S105.
23. Dale M, Morgan H, Carter K, White J, Carolan-Rees G. Peristeen Transanal Irrigation System to Manage Bowel Dysfunction: A NICE Medical Technology Guidance. *Appl Health Econ*. 2019;17(1):25-34.
24. Martins L, Tavernelli K, Sansom W, Dahl K, Claessens I, Porrett T, et al. Strategies to reduce treatment costs of peristomal skin complications. *Br J Nurs*. 2012;21(22):1312-5.
25. Meisner S, Lehur P-A, Moran B, Martins L, Jemec GBE. Peristomal Skin Complications Are Common, Expensive, and Difficult to Manage: A Population Based Cost Modeling Study. *PLOS ONE*. 2012;7(5):e37813.
26. Mockford K, Mthombeni F, Pannett S, Rethmeier L, Nottmeier M, Jayne D. Cost saving analysis of a community stoma care service [poster]. *Value Health*. 2018;21:S1-S481.
27. Neil N, Inglese G, Manson A, Townshend A. A Cost-Utility Model of Care for Peristomal Skin Complications. *J Wound Ostomy Continence Nurs*. 2016;43(1).
28. Nørtoft E, Mthombeni F, Håkan-Bloch J. PMD62 The association between stoma related complications and stoma appliance prescription spend. *Value Health*. 2019;22:S680.
29. Dossa F, Josse J, Acuna SA, Baxter NN. Health State Utility Values for Ileostomies and Colostomies: a Systematic Review and Meta-Analysis. *J Gastrointest Surg*. 2018;22(5):894-905.
30. Coloplast Professional. Ostomy Skin Tool. Assessing peristomal skin and obtaining a DET score. Peterborough: Coloplast Ltd; 2016. Available from: https://www.coloplastprofessional.co.uk/contentassets/9017a6c8003040f3bfdb9216df2507be/det_skintool_editable.pdf.
31. Martins L, Ayello EA, Claessens I, Steen Hansen A, Hentze Poulsen L, Sibbald RG, et al. The ostomy skin tool: tracking peristomal skin changes. *Br J Nurs*. 2010;19(15):960, 32-4.

32. Mohiuddin S, Reeves BC, Smart NJ, Hollingworth W, the Csg. A semi-Markov model comparing the lifetime cost-effectiveness of mesh prophylaxis to prevent parastomal hernia in patients undergoing end colostomy creation for rectal cancer. *Colorectal Dis.* 2021;23(11):2967-79.
33. National Institute for Health and Care Excellence (NICE). Peristeen Plus transanal irrigation system for managing bowel dysfunction. Medical technologies guidance [MTG36]. London: NICE; 2018 [updated 6 June 2022]. Available from: <https://www.nice.org.uk/guidance/mtg36>.
34. Geisler BP, Cao KN, Ryschon AM, Alavi K, Komen N, Pietzsch JB. Cost associated with diverting ostomy after rectal cancer surgery: a transnational analysis. *Surg Endosc.* 2023;37(10):7759-66.
35. Kettle J. StoMap Programme Baseline Report. Cambridge: East of England NHS Collaborative Procurement Hub. Integrated Care Team; 2019. Available from: <https://www.eoecph.nhs.uk/wp-content/uploads/2024/05/StoMap-Baseline-Report-FINAL-amended-11.12.19.pdf>.
36. Dossa F, Acuna SA, Baxter NN, Bayoumi AM. Optimal Operative Strategy for Hinchey III Sigmoid Diverticulitis: A Decision Analysis. *Dis Colon Rectum.* 2020;63(8).
37. de Buck van Overstraeten A, Brar MS, Khorasani S, Dossa F, Myrelid P. Ileorectal Anastomosis Versus IPAA for the Surgical Treatment of Ulcerative Colitis: A Markov Decision Analysis. *Dis Colon Rectum.* 2020;63(9).
38. Andeweg CS, Groenewoud J, van der Wilt GJ, van Goor H, Bleichrodt RP. A Markov Decision Model to Guide Treatment of Recurrent Colonic Diverticulitis. *Clin Gastroenterol Hepatol.* 2016;14(1):87-95.e2.
39. Fellows J, Voegeli D, Håkan-Bloch J, Herschend NO, Størling Z. Multinational survey on living with an ostomy: prevalence and impact of peristomal skin complications. *Br J Nurs.* 2021;30(16):S22-s30.
40. Jeppesen PB, Vestergaard M, Boisen EB, Ajslev TA. Impact of stoma leakage in everyday life: data from the Ostomy Life Study 2019. *Br J Nurs.* 2022;31(6).
41. Sandberg S, Asplund D, Bock D, Ehrencrona C, Ohlsson B, Park J, et al. Predicting life with a permanent end colostomy: A prospective study on function, bother and acceptance. *Colorectal Dis.* 2021;23(10):2681-9.
42. Sun V, Bojorquez O, Grant M, Wendel CS, Weinstein R, Krouse RS. Cancer survivors' challenges with ostomy appliances and self-management: a qualitative analysis. *Support Care Cancer.* 2020;28(4):1551-4.
43. Heerschap C, Duff V. The Lived Experience of Patients with an Ostomy: A Pilot Study on the Effect of Ostomy Pouch Opacity. *Adv Skin Wound Care.* 2021;34(12):662-6.
44. McKenzie F, White CA, Kendall S, Finlayson A, Urquhart M, Williams I. Psychological impact of colostomy pouch change and disposal. *Br J Nurs.* 2006;15(6):308-16.
- 45.
46. D'Ambrosio F, Pappalardo C, Scardigno A, Maida A, Ricciardi R, Calabrò GE. Peristomal Skin Complications in Ileostomy and Colostomy Patients: What We Need to Know from a Public Health Perspective. *Int J Environ Res Public Health* [Internet]. 2023; 20(1).
47. Centre for Health Economics. Structured expert elicitation resources (STEER) [homepage]. York: University of York; 2024. Available from: <https://www.york.ac.uk/che/research/teehta/elicitation/steer/> (accessed 21 Jun 2024).

48. Burch J. Choosing the correct accessory for each stoma type: an update. *Br J Nurs*. 2013;22(16):S10, s2-3.
49. Rolls N, de Fries Jensen L, Mthombeni F, Vardanega V, Håkan-Bloch J, van Hest N, et al. Healthcare resource use and associated costs for patients with an ileostomy experiencing peristomal skin complications. *Int Wound J*. 2023;20(7):2540-50.
50. de Fries Jensen L, Rolls N, Russell-Roberts P, Vestergaard M, Jensen ML, Boisen EB. Leakage of stomal effluent outside the baseplate leads to rise in product usage and health professional interactions. *Br J Nurs*. 2023;32(1):8-19.
51. Colwell JC, Pittman J, Raizman R, Salvadalena G. A Randomized Controlled Trial Determining Variances in Ostomy Skin Conditions and the Economic Impact (ADVOCATE Trial). *J Wound Ostomy Continence Nurs*. 2018;45(1):37-42.
52. Jones K, H W, Birch S, Castelli A, Chalkley M, Dargan A, et al. Unit Costs of Health and Social Care 2023. Manual. Canterbury: Personal Social Services Research Unit, University of Kent; 2023. Available from: https://kar.kent.ac.uk/105685/1/The%20unit%20costs%20of%20health%20and%20social%20care_Final2%20%282023%29.pdf.
53. NHS England. 2021/22 National Cost Collection Data Publication. London: NHS England; 2023 [updated 19 May 2023]. Available from: <https://www.england.nhs.uk/publication/2021-22-national-cost-collection-data-publication/>.
54. Department of Health and Social Care. Drugs and pharmaceutical electronic market information tool (eMIT). London: UK Government; 2011 [updated 5 Apr 2024]. Available from: <https://www.gov.uk/government/publications/drugs-and-pharmaceutical-electronic-market-information-emit>.
55. British National Formulary (BNF). London: BMJ Publishing Group Ltd and the Royal Pharmaceutical Society of Great Britain; 2024 [updated 1 May 2024]. Available from: <https://bnf.nice.org.uk/>.
56. Taneja C, Netsch D, Rolstad BS, Inglese G, Lamerato L, Oster G. Clinical and Economic Burden of Peristomal Skin Complications in Patients With Recent Ostomies. *J Wound Ostomy Continence Nurs*. 2017;44(4):350-7.
57. Rolls N, Yssing C, Bøgelund M, Håkan-Bloch J, de Fries Jensen L. Utilities associated with stoma-related complications: peristomal skin complications and leakages. *J Med Econ*. 2022;25(1):1005-14.
58. Bonnicksen O. Elicitation of ostomy pouch preferences: a discrete-choice experiment. *Patient*. 2011;4(3):163-75.
59. Jeong K, Cairns J. Systematic review of health state utility values for economic evaluation of colorectal cancer. *Health Econ Rev*. 2016;6(1):36.
60. Nichols TR, Inglese GW. The Burden of Peristomal Skin Complications on an Ostomy Population as Assessed by Health Utility and the Physical Component Summary of the SF-36v2®. *Value Health*. 2018;21(1):89-94.
61. Nichols T, Goldstine J, Inglese G. A multinational evaluation assessing the relationship between peristomal skin health and health utility. *Br J Nurs*. 2019;28(5):S14-S9.
62. Scheffel G, Boisen EB, Sternhufvud C, Jensen HH, Bøgelund M. Health-Related Quality of Life Associated with Common Stoma Complications – Peristomal Skin Complications and

Leakages Onto Clothes [poster]. 12-15 November 2023 ISPOR Europe; Copenhagen, Denmark; 2023.

63. Coronini-Cronberg S, Appleby J, Thompson J. Application of patient-reported outcome measures (PROMs) data to estimate cost-effectiveness of hernia surgery in England. *J R Soc Med*. 2013;106(7):278-87.

64. National Institute for Health and Care Excellence (NICE). NICE health technology evaluations: the manual. NICE process and methods [PMG36]. London: NICE; 2022 [updated 31 Oct 2023]. Available from: <https://www.nice.org.uk/process/pmg36>.

65. Rowen D, Brazier J, Wong R, Wailoo A. Measuring and valuing health-related quality of life when sufficient EQ-5D data is not available. Sheffield: School of Health and Related Research, University of Sheffield; 2020. Available from: <https://www.sheffield.ac.uk/media/34046/download?attachment>.

66. Taneja C, Netsch D, Rolstad BS, Inglese G, Eaves D, Oster G. Risk and Economic Burden of Peristomal Skin Complications Following Ostomy Surgery. *J Wound Ostomy Continence Nurs*. 2019;46(2):143-9.

67. Martin S, Claxton K, Lomas J, Longo F. The impact of different types of NHS expenditure on health: Marginal cost per QALY estimates for England for 2016/17. *Health Policy*. 2023;132:104800.

68. NHS England. Managing conflicts of interest in the NHS: Guidance for staff and organisations. London: NHS England; 2017 [updated 22 August 2017]. Available from: <https://www.england.nhs.uk/publication/managing-conflicts-of-interest-in-the-nhs-guidance-for-staff-and-organisations/>.

69. NHS Scotland. Stoma Appliance Service in the Community. Stoma Care Quality and Cost Effectiveness Review 2015. Edinburgh: The Scottish Government; 2016. Available from: <https://www.gov.scot/publications/stoma-appliance-service-community-stoma-care-quality-cost-effectiveness-review-2015/>.

70. NHS Scotland. National Stoma Quality Improvement SLWG (NSQIG). Final Report. Edinburgh: The Scottish Government; 2019. Available from: <https://www.nss.nhs.scot/media/3143/appendix-2-stoma-report-2020-final.pdf>.

71. OpenPrescribing.net. Oxford: Bennett Institute for Applied Data Science, University of Oxford; 2024. Available from: <https://openprescribing.net/>.

72. NHS Business Services Authority Statistics and Data Science. Prescription Cost Analysis – England – 2022-23. Newcastle upon Tyne: NHS Business Services Authority; 2023 [updated 27 Jul 2023].

73. Dispenser payments and prescription cost analysis. Financial year 2022 to 2023. Edinburgh: Public Health Scotland; 2023 [updated 19 September 2023]. Available from: <https://publichealthscotland.scot/publications/dispenser-payments-and-prescription-cost-analysis/dispenser-payments-and-prescription-cost-analysis-financial-year-2022-to-2023/>.

74. NHS Commissioning Support. Delivering Excellence in Stoma Care: A Guide to Implementation. Stoke on Trent: Midlands and Lancashire Commissioning Support Unit (MLCSU); 2020. Available from: https://medsopt.midlandsandlancashirecsu.nhs.uk/media/1058/aga_8653_nw-qipp-stoma-interactive-pdf_v8final.pdf.

75. Scottish Stoma Forum. Specialist Nurse and Patient Survey 2023 Briefing. London: British Healthcare Trades Association; 2024. Available from: <https://bhta.b-cdn.net/wp-content/uploads/2024/03/SSF-Nurse-Patient-Survey-2023.pdf>.
76. Coloplast A/S. Investigation of Heylo, a Novel App Driven Digital Supporting Ostomy Product. ClinicalTrials.gov ID NCT05200416. Bethesda (MD): National Library of Medicine; 2022 [updated 30 Jan 2023]. Available from: <https://clinicaltrials.gov/study/NCT05200416>.
77. Hollister Incorporated. Observational Study of Ostomy Consumers (OSO). ClinicalTrials.gov ID NCT03715179. Bethesda (MD): National Library of Medicine; 2018 [updated 7 May 2024]. Available from: <https://clinicaltrials.gov/study/NCT03715179>.
78. Zhende medical supplies co. l. A randomized, open, parallel, positive-controlled, multicenter, non-inferior clinical trial on the safety and effectiveness of deshutuo ostomy products in nursing patients with ostomy [protocol]. Registration number: ChiCTR2300072043 Chengdu, Sichuan: Chinese Clinical Trial Registry; 2023 [updated 28 Jul 2023]. Available from: <https://www.chictr.org.cn/showproj.html?proj=198166>.
79. Coloplast A/S. A Pilot Evaluation Exploring New Adhesive Materials and Their Ability to Adhere to Abdominal and Peristomal Skin. ClinicalTrials.gov ID NCT05641168. Bethesda (MD): National Library of Medicine; 2022 [updated 7 Dec 2022]. Available from: <https://clinicaltrials.gov/study/NCT05641168>.
80. BBraun Medical SAS. Safety and Performance of Flexima®/Softima® Stoma Appliances in Enterostomy Patients. ClinicalTrials.gov ID NCT05373888. Bethesda (MD): National Library of Medicine; 2022 [updated 13 May 2022]. Available from: <https://clinicaltrials.gov/study/NCT05373888>.
81. Richens A. Proof of efficacy trials: cross-over versus parallel-group. *Epilepsy Res.* 2001;45(1-3):43-7; discussion 9-51.
82. Welser M, Riedlinger I, Prause U. A comparative study of two-piece ostomy appliances. *Br J Nurs.* 2009;18(9):530, 2, 4 passim.
83. Arnaud JP, Poirier MR, Chaumier D, Langlois G, Lingesso F, Brulé I, et al. A randomised crossover study of a new two-piece ostomy appliance with an adhesive coupling [poster]. World Council of Enterostomal Therapists (WCET) Congress; June 15-19, 2008; Ljubljana, Slovenia; 2008.
84. Schröder K, Frankenberg H, Schmitz K, Lacroix B, Winkelmann K, Schrang T, et al. A comparative study of two adhesive coupling systems [poster]. European Council of Enterostomal Therapy (ECET) Conference; June 17-20, 2007; Salzburg, Austria; 2007.
85. [REDACTED]
87. Belfield-Cockings K. A new approach with a novel silicone adhesive stoma bag: a clinical study on peristomal skin and quality of life. *Br J Nurs.* 2022;31(6):S40-s7.
88. Sundberg W, Lindam AT, Knetsch H, Hoorntje G. Clinical evaluation of SenSura® Mio – a new elastic adhesive with unique fitting performance [poster]. Coloplast; 2012.
89. Rasmussen M, Martins L. NEW elastic 1-piece ostomy appliance (SenSura® Mio) improves peristomal skin condition and reduces costs of treatment [poster]. Coloplast; 2012.
90. Martins L, Samai O, Fernández A, Urquhart M, Hansen AS. Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. *Gastrointest Nurs.* 2011;9(Sup2):9-13.

91. Davis JS, Svavarsdóttir MH, Pudło M, Arena R, Lee Y, Jensen MK. Factors impairing quality of life for people with an ostomy. *Gastrointest Nurs.* 2011;9(Sup2):14-8.

92. Porrett T, Nováková S, Schmitz K, Klimekova E, Aaes H. Leakage and ostomy appliances: results from a large-scale, open-label study in clinical practice. *Gastrointest Nurs.* 2011;9(Sup2):19-23.

93. [REDACTED]

Appendix A – Evidence searches

Searches for clinical and economic evidence – summary

Database/search	Date	# hits
Clinical		
Medline clinical	19 Apr. 24	977
Embase clinical	22 Apr. 24	2191
Cochrane Reviews	22 Apr. 24	95
Cochrane Trials	22 Apr. 24	595
British Nursing Index	22 Apr. 24	193
CINAHL	22 Apr. 24	312
Deduped		3188
Economic		
Medline economic	22 Apr. 24	2566
Embase economic	22 Apr. 24	5420
HTA database	22 Apr. 24	18
CEA registry	23 Apr. 24	19
ScHARR HUD	23 Apr. 24	Website unavailable
NHS EED	23 Apr. 24	78
Deduped		5994
Protocols		
Cochrane Protocols	22 Apr. 24	13
ICTRP	23 Apr. 24	79
Clinicaltrials.gov	23 Apr. 24	270
Deduped		256
Other		
NICE		2
SIGN		0
MHRA (searched MDA & FSN)		4 (see links below)
FDA MAUDE		500+ (see below)
ASCN UK conferences	24 Apr. 24	6 (4 of which were added; 3 into the clinical review, 1 into the economic review)

Clinical searches

Ovid MEDLINE(R) ALL 1946 to April 18, 2024

#	Searches	Results
1	Surgical Stomas/	2521
2	Colostomy/ or ostomy/	11196
3	(stoma or stomas or colostom* or ostom*).ti,ab,kw.	22680
4	"stoma care".tw.	705
5	or/1-4	27536
6	(bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*).ab,ti,kw.	3044656
7	5 and 6	2769
8	randomized controlled trial.pt.	611008
9	controlled clinical trial.pt.	95517
10	randomized.ab.	642353
11	placebo.ab.	247483
12	clinical trials as topic.sh.	202061
13	randomly.ab.	431548
14	trial.ti.	307149
15	or/8-14	1593257
16	Epidemiologic Methods/	31618
17	exp Epidemiologic Studies/	3269376
18	Observational Studies as Topic/	9703
19	Clinical Studies as Topic/	830
20	(Observational Study or Validation Studies or Clinical Study).pt.	160381
21	(observational adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	241916
22	cohort*.ti,ab,kf.	935723
23	(prospective adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	562636
24	((follow up or followup) adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	178553
25	((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).ti,ab,kf.	368718
26	(retrospective adj7 (study or studies or design or analysis or analyses or data or review)).ti,ab,kf.	739772
27	((case adj control) or (case adj comparison) or (case adj controlled)).ti,ab,kf.	167294
28	(case-referent adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	642
29	(population adj3 (study or studies or analysis or analyses)).ti,ab,kf.	247453
30	((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	5301
31	(quasi adj (experiment or experiments or experimental)).ti,ab,kf.	22395
32	(interrupt* time* series or (segment\$2 adj3 regression) or (before adj2 after)).ti,ab,kf.	353979
33	("single-arm" or "single arm" or "non random*" or "non-random").ti,ab,kf.	42195
34	or/16-33	4674004

#	Searches	Results
35	7 and (15 or 34)	990
36	exp animals/ not humans.sh.	5213003
37	35 not 36	977

Embase 1974 to 2024 April 19

#	Searches	Results
1	Surgical Stomas/	12876
2	Colostomy/ or ostomy/	20500
3	(stoma or stomas or colostom* or ostom*).ti,ab,kw.	34027
4	"stoma care".tw.	890
5	or/1-4	43655
6	(bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*).ab,ti,kw.	3676658
7	5 and 6	4722
8	exp stoma bag/	625
9	7 or 8	5096
10	randomized controlled trial/	817807
11	controlled clinical trial/	472958
12	10 or 11	1012769
13	random\$.ti,ab.	2058522
14	randomization/	99185
15	intermethod comparison/	306118
16	placebo.ti,ab.	375816
17	(compare or compared or comparison).ti.	622915
18	((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.	2905585
19	(open adj label).ti,ab.	114803
20	((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.	281531
21	double blind procedure/	218122
22	parallel group\$1.ti,ab.	33403
23	(crossover or cross over).ti,ab.	127893
24	((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)).ti,ab.	431185
25	(assigned or allocated).ti,ab.	509541
26	(controlled adj7 (study or design or trial)).ti,ab.	469274
27	(volunteer or volunteers).ti,ab.	288658
28	human experiment/	658549
29	trial.ti.	421401
30	or/13-29	6403269
31	30 not 12	5553175

#	Searches	Results
32	(random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)	9930
33	Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group\$1.ti,ab.)	388276
34	((case adj control\$) and random\$) not randomi?ed controlled).ti,ab.	22269
35	(Systematic review not (trial or study)).ti.	282284
36	(nonrandom\$ not random\$).ti,ab.	19429
37	"Random field\$".ti,ab.	3066
38	(random cluster adj3 sampl\$).ti,ab.	1645
39	(review.ab. and review.pt.) not trial.ti.	1188861
40	"we searched".ab. and (review.ti. or review.pt.)	52447
41	"update review".ab.	140
42	(databases adj4 searched).ab.	67492
43	(rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/	1248690
44	Animal experiment/ not (human experiment/ or human/)	2625889
45	or/32-44	4511218
46	31 not 45	4800705
47	observational study/	369303
48	cohort analysis/	1150209
49	longitudinal study/	211195
50	follow up/	2176773
51	retrospective study/	1604298
52	exp case control study/	234559
53	cross-sectional study/	629235
54	quasi experimental study/	12419
55	prospective study/	914687
56	(observational adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	375931
57	cohort*.ti,ab,kf.	1572129
58	(prospective adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	854227
59	((follow up or followup) adj7 (study or studies or design or analysis or analyses)).ti,ab,kf.	283194
60	((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).ti,ab,kf.	520866
61	(retrospective adj7 (study or studies or design or analysis or analyses or data or review)).ti,ab,kf.	1228601
62	((case adj control) or (case adj comparison) or (case adj controlled)).ti,ab,kf.	221942
63	(case-referent adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	710
64	(population adj3 (study or studies or analysis or analyses)).ti,ab,kf.	372392
65	(descriptive adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	180391
66	((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	6159

#	Searches	Results
67	(cross adj sectional adj7 (study or studies or design or research or analysis or analyses or survey or findings)).ti,ab,kf.	623262
68	((natural adj experiment) or (natural adj experiments)).ti,ab,kf.	3889
69	(quasi adj (experiment or experiments or experimental)).ti,ab,kf.	27397
70	((non experiment or nonexperiment or non experimental or nonexperimental) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf.	2484
71	(interrupt* time* series or (segment\$2 adj3 regression) or (before adj2 after)).ti,ab,kf.	495125
72	("single-arm" or "single arm" or "non random*" or "non-random").ti,ab,kf.	70289
73	or/47-72	7153568
74	9 and (46 or 73)	2215
75	(exp animal/ or nonhuman/) not exp human/	7310075
76	74 not 75	2191

Cochrane

- #1 MeSH descriptor: [Surgical Stomas] explode all trees 150
- #2 MeSH descriptor: [Colostomy] explode all trees 259
- #3 MeSH descriptor: [Ostomy] explode all trees 2193
- #4 (stoma or stomas or colostom* or ostom*) 2516
- #5 #1 or #2 or #3 or #4 4254
- #6 (bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*) 186150
- #7 #5 and #6 in Cochrane Reviews, Cochrane Protocols, Trials 703

British Nursing Database

(MAINSUBJECT.EXACT("Ostomy") OR SUMMARY(stoma or stomas or colostom* or ostom*)) AND SUMMARY(bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*) AND SUMMARY(random* or control* or comparative* or trial* or observational or cohort* or prospective* or longitudinal or retrospective* or (before NEAR after) or (interrupt* NEAR time*) or (single NEAR arm))

CINAHL

#	Query	Results
S6	S3 and S4 and S5	312
S5	(S1 OR S2)	9,853

#	Query	Results
S4	AB ((random* or control* or comparative* or trial* or observational or cohort* or prospective* or longitudinal or retrospective* or (before N1 after) or (interrupt* N1 time*) or (single N1 arm))) OR TI ((random* or control* or comparative* or trial* or observational or cohort* or prospective* or longitudinal or retrospective* or (before N1 after) or (interrupt* N1 time*) or (single N1 arm)))	1,845,000
S3	AB ((bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*)) OR TI ((bag* or pouch* or product* or accessor* or appliance* or equip* or aid or aids or reservoir* or appliance* or filter*))	368,536
S2	AB ((stoma or stomas or colostom* or ostom*)) OR TI ((stoma or stomas or colostom* or ostom*))	7,867
S1	(MH "Colostomy") OR (MH "Ostomy Care+")	5,050

Economic searches

Ovid MEDLINE(R) ALL 1946 to April 19, 2024

#	Searches	Results
1	Surgical Stomas/	2523
2	Colostomy/ or ostomy/ or Ileostomy/	16852
3	(stoma or stomas or colostom* or ostom* or ileostom*).ti,ab,kw.	28420
4	"stoma care".tw.	705
5	or/1-4	35037
6	"Value of Life"/	5824
7	Quality of Life/	286722
8	quality of life.ti,kf.	124336
9	((instrument or instruments) adj3 quality of life).ab.	4044
10	Quality-Adjusted Life Years/	16291
11	quality adjusted life.ti,ab,kf.	18536
12	(qaly* or qald* or qale* or qtime* or life year or life years).ti,ab,kf.	30251
13	disability adjusted life.ti,ab,kf.	6085
14	daly*.ti,ab,kf.	5494
15	(sf36 or sf 36 or short form 36 or shortform 36 or short form36 or shortform36 or sf thirtysix or sfthirtysix or sfthirty six or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).ti,ab,kf.	31844
16	(sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or shortform6 or short form6).ti,ab,kf.	2766
17	(sf8 or sf 8 or sf eight or sfeight or shortform 8 or shortform 8 or shortform8 or short form8 or shortform eight or short form eight).ti,ab,kf.	647
18	(sf12 or sf 12 or short form 12 or shortform 12 or short form12 or shortform12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab,kf.	8087
19	(sf16 or sf 16 or short form 16 or shortform 16 or short form16 or shortform16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab,kf.	42
20	(sf20 or sf 20 or short form 20 or shortform 20 or short form20 or shortform20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab,kf.	468
21	(hql or hqol or h qol or hrqol or hr qol).ti,ab,kf.	25864
22	(hye or hyes).ti,ab,kf.	78
23	(health* adj2 year* adj2 equivalent*).ti,ab,kf.	48
24	(pqol or qls).ti,ab,kf.	482
25	(quality of wellbeing or quality of well being or index of wellbeing or index of well being or qwb).ti,ab,kf.	749
26	nottingham health profile*.ti,ab,kf.	1259
27	sickness impact profile.ti,ab,kf.	1101
28	exp health status indicators/	345600
29	(health adj3 (utilit* or status)).ti,ab,kf.	97166
30	(utilit* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or weight)).ti,ab,kf.	16901
31	(preference* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or instrument or instruments)).ti,ab,kf.	15293
32	disutilit*.ti,ab,kf.	673

#	Searches	Results
33	rosser.ti,ab,kf.	112
34	willingness to pay.ti,ab,kf.	9387
35	standard gamble*.ti,ab,kf.	922
36	(time trade off or time tradeoff).ti,ab,kf.	1718
37	tto.ti,ab,kf.	1488
38	(hui or hui1 or hui2 or hui3).ti,ab,kf.	2086
39	(eq or euroqol or euro qol or eq5d or eq 5d or euroqual or euro qual).ti,ab,kf.	24478
40	duke health profile.ti,ab,kf.	94
41	functional status questionnaire.ti,ab,kf.	134
42	dartmouth coop functional health assessment*.ti,ab,kf.	14
43	Ostomy-Q.ti,ab,kf.	3
44	Stoma Quality of Life Questionnaire.ti,ab,kf.	7
45	Ostomy Adjustment Inventory.ti,ab,kf.	29
46	or/6-45	784366
47	exp "Costs and Cost Analysis"/	269860
48	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	223724
49	(value adj2 (money or monetary)).ti,ab,kf.	3197
50	exp models, economic/	16281
51	economic model*.ab,kf.	4440
52	markov chains/	16100
53	markov.ti,ab,kf.	30635
54	monte carlo method/	32773
55	monte carlo.ti,ab,kf.	62856
56	exp Decision Theory/	13611
57	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	42302
58	or/47-57	562338
59	afghanistan/ or africa/ or africa, northern/ or africa, central/ or africa, eastern/ or "africa south of the sahara"/ or africa, southern/ or africa, western/ or albania/ or algeria/ or andorra/ or angola/ or "antigua and barbuda"/ or argentina/ or armenia/ or azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or "bosnia and herzegovina"/ or botswana/ or brazil/ or brunei/ or bulgaria/ or burkina faso/ or burundi/ or cabo verde/ or cambodia/ or cameroon/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cote d'ivoire/ or croatia/ or cuba/ or "democratic republic of the congo"/ or cyprus/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or egypt/ or el salvador/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or fiji/ or gabon/ or gambia/ or "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or independent state of samoa/ or exp india/ or indian ocean islands/ or indochina/ or indonesia/ or iran/ or iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libya/ or madagascar/ or malaysia/ or malawi/ or mali/ or malta/ or mauritania/ or mauritius/ or mekong valley/ or melanesia/ or micronesia/ or monaco/ or mongolia/ or montenegro/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nepal/ or nicaragua/ or niger/ or nigeria/ or oman/ or pakistan/ or palau/ or exp panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or qatar/ or "republic of belarus"/ or "republic of north macedonia"/ or romania/ or exp	1336655

#	Searches	Results
	russia/ or rwanda/ or "saint kitts and nevis"/ or saint lucia/ or "saint vincent and the grenadines"/ or "sao tome and principe"/ or saudi arabia/ or serbia/ or sierra leone/ or senegal/ or seychelles/ or singapore/ or somalia/ or south africa/ or south sudan/ or sri lanka/ or sudan/ or suriname/ or syria/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or uganda/ or ukraine/ or united arab emirates/ or uruguay/ or uzbekistan/ or vanuatu/ or venezuela/ or vietnam/ or west indies/ or yemen/ or zambia/ or zimbabwe/	
60	"Organisation for Economic Co-Operation and Development"/	600
61	australasia/ or exp australia/ or austria/ or baltic states/ or belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or exp denmark/ or estonia/ or europe/ or finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or exp japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or portugal/ or exp "republic of korea"/ or "scandinavian and nordic countries"/ or slovakia/ or slovenia/ or spain/ or sweden/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/	3543799
62	European Union/	17968
63	Developed Countries/	21524
64	or/60-63	3560093
65	59 not 64	1245954
66	58 not 65	528487
67	5 and (46 or 66)	2935
68	limit 67 to yr="1999 -Current"	2566

Embase 1974 to 2024 April 19

#	Searches	Results
1	Surgical Stomas/	12876
2	Colostomy/ or ostomy/ or ileostomy/ or exp stoma bag/	35388
3	(stoma or stomas or colostom* or ostom* or ileostom*).ti,ab,kw.	42708
4	"stoma care".tw.	890
5	or/1-4	57630
6	socioeconomics/	166395
7	exp Quality of Life/	690699
8	quality of life.ti,kf.	190099
9	((instrument or instruments) adj3 quality of life).ab.	5597
10	Quality-Adjusted Life Year/	37182
11	quality adjusted life.ti,ab,kf.	28162
12	(qaly* or qald* or qale* or qtime* or life year or life years).ti,ab,kf.	47473
13	disability adjusted life.ti,ab,kf.	7260
14	daly*.ti,ab,kf.	7028
15	(sf36 or sf 36 or short form 36 or shortform 36 or short form36 or shortform36 or sf thirtysix or sfthirtysix or sfthirty six or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).ti,ab,kf.	51736

#	Searches	Results
16	(sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or shortform6 or short form6).ti,ab,kf.	3083
17	(sf8 or sf 8 or sf eight or sfeight or shortform 8 or shortform 8 or shortform8 or short form8 or shortform eight or short form eight).ti,ab,kf.	1064
18	(sf12 or sf 12 or short form 12 or shortform 12 or short form12 or shortform12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab,kf.	12785
19	(sf16 or sf 16 or short form 16 or shortform 16 or short form16 or shortform16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab,kf.	72
20	(sf20 or sf 20 or short form 20 or shortform 20 or short form20 or shortform20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab,kf.	544
21	(hql or hqol or h qol or hrqol or hr qol).ti,ab,kf.	41566
22	(hye or hyes).ti,ab,kf.	195
23	(health* adj2 year* adj2 equivalent*).ti,ab,kf.	56
24	(pqol or qls).ti,ab,kf.	779
25	(quality of wellbeing or quality of well being or index of wellbeing or index of well being or qwb).ti,ab,kf.	926
26	nottingham health profile*.ti,ab,kf.	1698
27	nottingham health profile/	680
28	sickness impact profile.ti,ab,kf.	1301
29	sickness impact profile/	2406
30	health status indicator/	3576
31	(health adj3 (utilit* or status)).ti,ab,kf.	127350
32	(utilit* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or weight)).ti,ab,kf.	26918
33	(preference* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or instrument or instruments)).ti,ab,kf.	20195
34	disutilit*.ti,ab,kf.	1346
35	rosser.ti,ab,kf.	146
36	willingness to pay.ti,ab,kf.	13993
37	standard gamble*.ti,ab,kf.	1232
38	(time trade off or time tradeoff).ti,ab,kf.	2481
39	tto.ti,ab,kf.	2352
40	(hui or hui1 or hui2 or hui3).ti,ab,kf.	3310
41	(eq or euroqol or euro qol or eq5d or eq 5d or euroqual or euro qual).ti,ab,kf.	40746
42	duke health profile.ti,ab,kf.	121
43	functional status questionnaire.ti,ab,kf.	181
44	dartmouth coop functional health assessment*.ti,ab,kf.	14
45	dartmouth coop functional health assessment*.ti,ab,kf.	14
46	Ostomy-Q.ti,ab,kf.	5
47	Stoma Quality of Life Questionnaire.ti,ab,kf.	10
48	or/6-47	1047629
49	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	307933
50	(value adj2 (money or monetary)).ti,ab,kf.	4286

#	Searches	Results
51	Statistical Model/	177038
52	economic model*.ab,kf.	6629
53	Probability/	153818
54	markov.ti,ab,kf.	40216
55	monte carlo method/	53322
56	monte carlo.ti,ab,kf.	66474
57	Decision Theory/	1867
58	Decision Tree/	24191
59	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	56905
60	or/49-59	745934
61	afghanistan/ or africa/ or "africa south of the sahara"/ or albania/ or algeria/ or andorra/ or angola/ or argentina/ or "antigua and barbuda"/ or armenia/ or exp azerbaijan/ or bahamas/ or bahrain/ or bangladesh/ or barbados/ or belarus/ or belize/ or benin/ or bhutan/ or bolivia/ or borneo/ or exp "bosnia and herzegovina"/ or botswana/ or exp brazil/ or brunei darussalam/ or bulgaria/ or burkina faso/ or burundi/ or cambodia/ or cameroon/ or cape verde/ or central africa/ or central african republic/ or chad/ or exp china/ or comoros/ or congo/ or cook islands/ or coted'ivoire/ or croatia/ or cuba/ or cyprus/ or democratic republic congo/ or djibouti/ or dominica/ or dominican republic/ or ecuador/ or el salvador/ or egypt/ or equatorial guinea/ or eritrea/ or eswatini/ or ethiopia/ or exp "federated states of micronesia"/ or fiji/ or gabon/ or gambia/ or exp "georgia (republic)"/ or ghana/ or grenada/ or guatemala/ or guinea/ or guinea-bissau/ or guyana/ or haiti/ or honduras/ or exp india/ or exp indonesia/ or iran/ or exp iraq/ or jamaica/ or jordan/ or kazakhstan/ or kenya/ or kiribati/ or kosovo/ or kuwait/ or kyrgyzstan/ or laos/ or lebanon/ or liechtenstein/ or lesotho/ or liberia/ or libyan arab jamahiriya/ or madagascar/ or malawi/ or exp malaysia/ or maldives/ or mali/ or malta/ or mauritania/ or mauritius/ or melanesia/ or moldova/ or monaco/ or mongolia/ or "montenegro (republic)"/ or morocco/ or mozambique/ or myanmar/ or namibia/ or nauru/ or nepal/ or nicaragua/ or niger/ or nigeria/ or niue/ or north africa/ or oman/ or exp pakistan/ or palau/ or palestine/ or panama/ or papua new guinea/ or paraguay/ or peru/ or philippines/ or polynesia/ or qatar/ or "republic of north macedonia"/ or romania/ or exp russian federation/ or rwanda/ or sahel/ or "saint kitts and nevis"/ or "saint lucia"/ or "saint vincent and the grenadines"/ or saudi arabia/ or senegal/ or exp serbia/ or seychelles/ or sierra leone/ or singapore/ or "sao tome and principe"/ or solomon islands/ or exp somalia/ or south africa/ or south asia/ or south sudan/ or exp southeast asia/ or sri lanka/ or sudan/ or suriname/ or syrian arab republic/ or taiwan/ or tajikistan/ or tanzania/ or thailand/ or timor-leste/ or togo/ or tonga/ or "trinidad and tobago"/ or tunisia/ or turkmenistan/ or tuvalu/ or uganda/ or exp ukraine/ or exp united arab emirates/ or uruguay/ or exp uzbekistan/ or vanuatu/ or venezuela/ or viet nam/ or western sahara/ or yemen/ or zambia/ or zimbabwe/	1756981
62	"organisation for economic co-operation and development"/	2942
63	exp australia/ or "australia and new zealand"/ or austria/ or baltic states/ or exp belgium/ or exp canada/ or chile/ or colombia/ or costa rica/ or czech republic/ or denmark/ or estonia/ or europe/ or exp finland/ or exp france/ or exp germany/ or greece/ or hungary/ or iceland/ or ireland/ or israel/ or exp italy/ or japan/ or korea/ or latvia/ or lithuania/ or luxembourg/ or exp mexico/ or netherlands/ or new zealand/ or north america/ or exp norway/ or poland/ or exp portugal/ or scandinavia/ or sweden/ or slovakia/ or slovenia/ or south korea/ or exp spain/ or switzerland/ or exp united kingdom/ or "turkey (republic)"/ or exp united states/ or western europe/	3860991
64	european union/	32101
65	developed country/	36213

#	Searches	Results
66	or/62-65	3895579
67	61 not 66	1599284
68	60 not 67	694633
69	5 and (48 or 68)	5726
70	limit 69 to yr="1999 -Current"	5420

HTA database

colostomy or stoma or ostomy or ileostomy

NHS EED

colostomy or stoma or ostomy or ileostomy
(any field)

CEA registry

Colostomy (methods) n = 5

Ostomy (methods) n = 6

Stoma (methods) n = 8

Trial protocols

ICTRP + Clinical trials.gov

Term	ICTRP	Clinicaltrials.gov
Colostomy bag	7	16
Ostomy bag	14	16
Stoma bag	12	37
Colostomy pouch	3	14
Ostomy pouch	2	12
Stoma pouch	9	32
Colostomy product	8	60
Ostomy product	26	50
Stoma product	26	106
Colostomy appliance	3	16
Ostomy appliance	9	35
Stoma appliance	8	31
Total (deduped)	79	270

Other sources

MHRA

Colostomy = 0

Stoma = 1

Ostomy = 4

Maude

Pouch, colostomy = 500+ (1999 - present)

NICE & SIGN

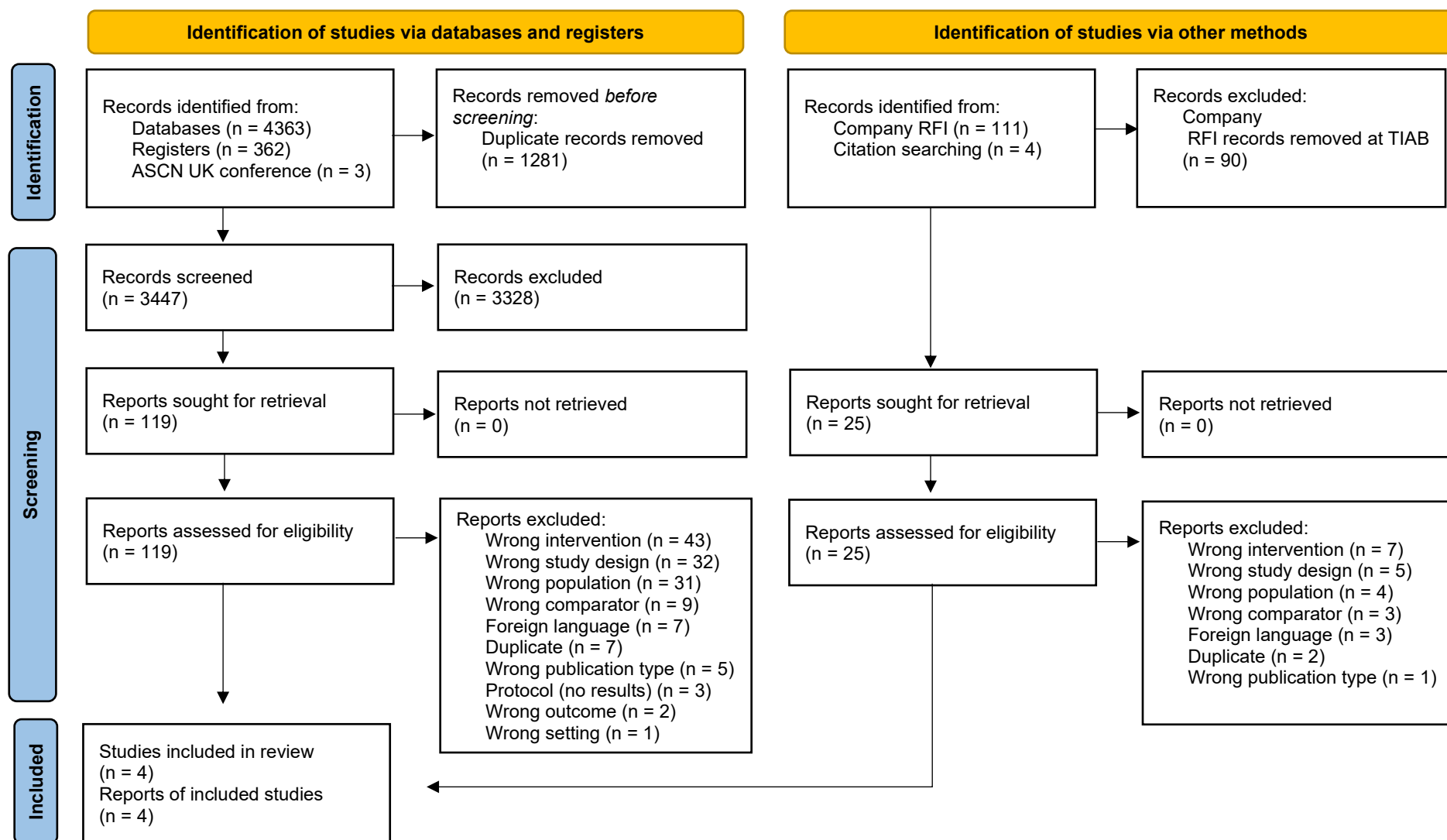
colostomy or stoma or ostomy or ileostomy

ASCN UK conferences

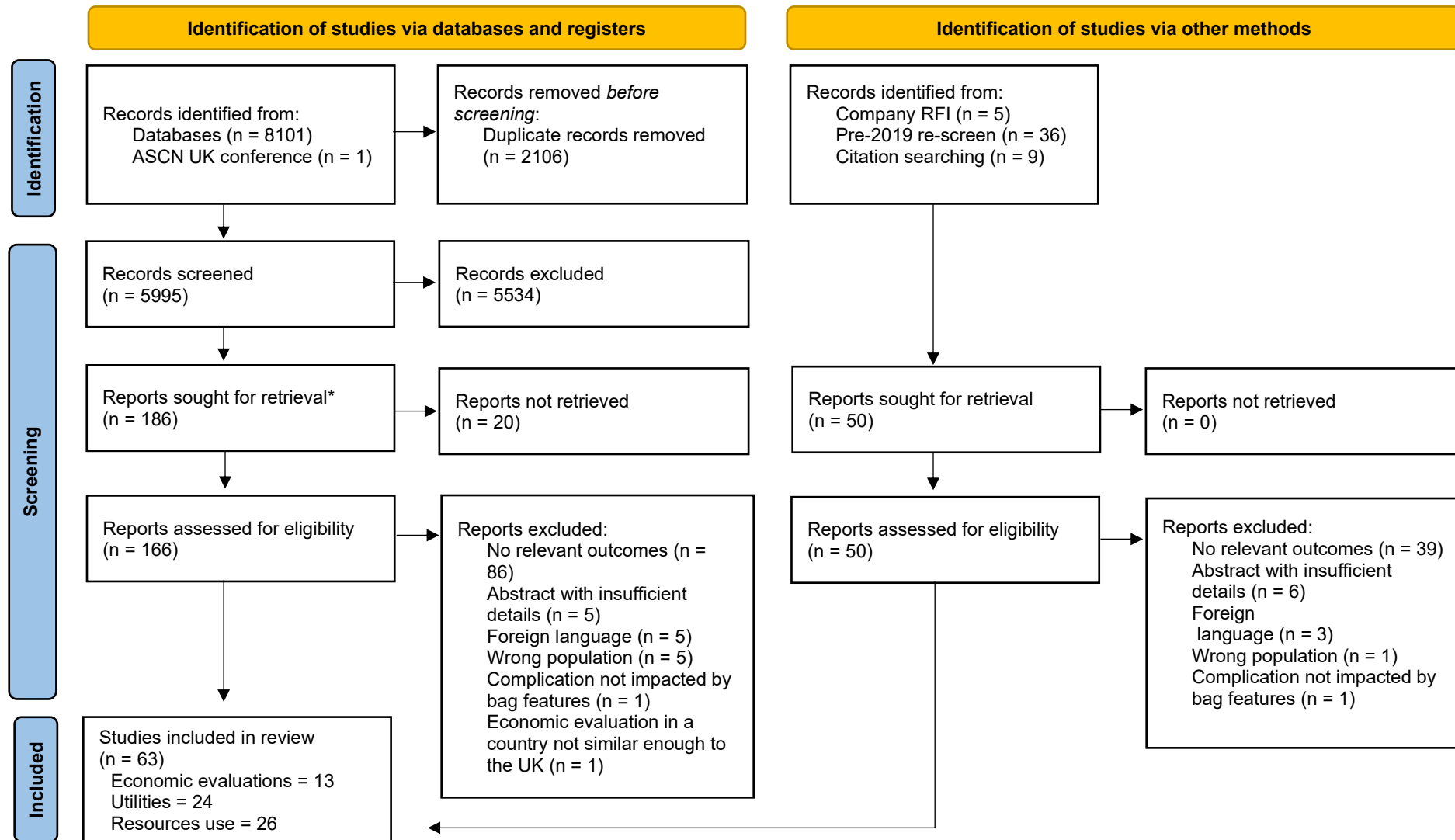
Year	Book of abstracts	# relevant abstracts
2023	Abstracts available	2
2022	Abstracts not available	–
2021	Abstracts not available	–
2020	No conference	–
2019	Abstracts available	1
2018	Abstracts available	1
2017	Abstracts available	2
2016	Abstracts not available	–
2015	Abstracts not available	–
2014	Abstracts not available	–
2013	Abstracts not available	–

Appendix B – PRISMA diagrams

PRISMA diagram. Clinical



PRISMA diagram. Economic



Appendix C – Excluded studies

Studies excluded at full text: clinical

Authors	Year	Reason for exclusion
Alberto Lado del et al.	2022	Wrong population (pooled ileostomy and colostomy)
Andersen et al.	2022	Wrong population (type of stoma not reported), wrong publication type
Andersen et al.	2011	Wrong outcome (methods and baseline paper)
Belcher	2013	Wrong study design (commentary paper)
Belfield-Cockings	2022	Wrong study design (single arm trial vs mixed comparator bag)
Belum et al.	2014	Wrong study design (general study, not about specific products)
Ber	2021	Wrong study design (single arm trial with mixed comparator plus case studies)
Berger et al.	2021	Wrong study design (budget impact analysis. The original trial evaluated 2-piece bags)
Bloemen et al.	2020	Wrong intervention (not listed in the drug tariff)
Boaden	2003	Wrong population (ileostomy)
Brady et al.	2023	Wrong intervention (unclear 'notification system' intervention. Also pooled ileostomy and colostomy)
Brady et al.	2022	Wrong intervention type (intervention is Heylo, a digital add-on product)
Burt-McAliley et al.	1994	Wrong intervention (not listed in the drug tariff)
Cabrejas & Clancy	2003	Wrong population (urostomy)
Calara et al.	2017	Wrong intervention (compared stoma bag companies based on high or low patent activities, not bag features)
Campo Cascon et al.	2000	Duplicate
Campo Cascon et al.	2000	Foreign language
Caroppo et al.	2019	Wrong intervention (add-on product - pastes and treatments for people with dermatitis)
Cawson et al.	2023	Wrong publication type (poster abstract of an economic evaluation of a digital product)
Centellas Morral	2000	Foreign language
Centellas Morral et al.	2000	Foreign language
Charousaei et al.	2011	Wrong intervention (treatment for peristomal skin complications")
ChiCTR and Hefei First People's Hospital	2023	Foreign language
ClinicalTrials.gov	2022	Protocol
ClinicalTrials.gov	2018	Protocol

Authors	Year	Reason for exclusion
Coloplast	2021	Wrong comparator (mixed comparator – a company, not a specific product)
Coloplast	2021	Wrong comparator (mixed comparator – a company, not a specific product)
Coloplast	2021	Wrong comparator (mixed comparator – any extended wear product)
Coloplast, A. S.	2018	Wrong intervention, wrong population (pooled stoma population; no named products)
Coloplast, A. S.	2013	Wrong intervention, wrong population (pooled stoma population; no named products)
Coloplast, A. S.	2014	Wrong intervention, wrong population (pooled stoma population; no named products)
Coloplast, A. S.	2013	Wrong population (ileostomy)
Coloplast, A. S.	2015	Wrong comparator (mixed comparator at baseline)
Coloplast, A. S.	2015	Wrong intervention (company responded at clarification to say products were never commercialised)
Coloplast, A. S.	2017	Wrong population (Ileostomy)
Coloplast, A. S.	2021	Protocol
Coloplast, A. S.	2017	Wrong population (ileostomy)
Coloplast, A. S.	2017	Wrong population (healthy volunteers)
Coloplast, A. S.	2017	Wrong population (ileostomy)
Coloplast, A. S.	2020	Wrong intervention, wrong population (pooled stoma population; no named products)
Coloplast, A. S.	2021	Wrong intervention (intervention is a digital leakage notification system)
Coloplast, A. S.	2022	Wrong intervention (intervention is Heylo, a digital add-on product)
Coloplast, A. S.	2021	Wrong intervention (intervention is Heylo, a digital add-on product)
Coloplast, A. S.	2016	Wrong population (pooled stoma population)
Coloplast, A. S.	2012	Wrong comparator (mixed comparator and mixed baseline)
Coloplast, A. S.	2013	Wrong population (ileostomy)
Colwell et al.	2018	Wrong intervention (intervention and control used 2-piece systems) and wrong population (mixed population)
ConvaTec Inc	2010	Wrong population (healthy volunteers)
ConvaTec Inc,	2013	Wrong publication type (company confirmed this was a protocol for an evaluation which had since been superseded)
ConvaTec Inc,	2012	Wrong intervention (intervention was an accessory)
Duluklu et al.	2019	Wrong intervention (mixed interventions – any bag, to which lavender oil was added)
Durnal et al.	2011	Wrong intervention (intervention was a plug)

Authors	Year	Reason for exclusion
Erwin-Toth et al.	2012	Wrong intervention (intervention was mixed 1- and 2-piece bags)
Evans	2018	Wrong population (pooled stoma population)
Evans & White	2020	Wrong study design (case series/survey)
Feddern et al.	2015	Wrong study design (general survey – not on specific products)
Forsmark et al.	2023	Wrong publication type (abstract with insufficient detail and no available full text)
González et al.	2021	Wrong intervention (not listed in the drug tariff)
Grove et al.	2019	Wrong population (healthy volunteers)
Grove et al.	2019	Duplicate
Guyot	1996	Wrong study design (literature review that did not cover specific products)
Hoeflok et al.	2009	Wrong intervention (intervention was 2-piece bag)
Hollister	2023	Wrong publication type (statistical analysis plan for an ongoing study)
Hollister	2023	Wrong study design (single arm study with mixed comparator bags at baseline)
Hueso-Montoro et al.	2023	Wrong intervention (intervention was an add-on product)
Kalayci et al.	2022	Wrong study design (study did not evaluate specific products)
Krogsgaard et al.	2022	Wrong study design (survey did not evaluate specific products)
Kruse et al.	2015	Wrong population (pooled ileostomy and colostomy)
Laboratoires Coloplast, S. A. S.	2020	Wrong publication type (trial protocol with no results posted)
Lager & Loxdale	2021	Wrong study design (review and survey with no relevant comparison)
Leece & Inglese	2017	Wrong study design (economic study)
Lindholm et al.	2013	Wrong study design (study did not evaluate specific products)
Liu et al.	2017	Wrong intervention (intervention was a skin barrier for 2-piece bags)
Lyon et al.	2000	Wrong study design (study did not evaluate specific products)
Malandrino et al.	2022	Wrong population (pooled stoma population)
Marks et al.	1978	Wrong population (healthy volunteers)
Marks et al.	1979	Wrong population (healthy volunteers)
Marques et al.	2022	Wrong intervention (intervention was an essential oil added to various bag types)
Maxwell et al.	2010	Wrong intervention (intervention was a plug)
Maydick-Youngberg	2017	Wrong population, wrong study design (QoL survey of a pooled population of ileostomy and colostomy)
McKenzie et al.	2006	Wrong study design (study did not evaluate specific products)

Authors	Year	Reason for exclusion
McPhail et al.	2018	Wrong intervention (intervention was an add-on product)
Mihalopoulos et al.	1994	Wrong study design (evaluated surgery rather than products)
Miller et al.	2020	Wrong study design (study did not evaluate specific products)
Mockford et al.	2019	Wrong study design (study did not evaluate specific products)
Mrak et al.	2011	Wrong intervention (evaluated surgery rather than products)
Murrell et al.	2009	Wrong study design (study did not evaluate specific products)
NCT01103466	2010	Wrong population (ileostomy)
NCT01243294	2010	Duplicate
NCT01245413	2010	Wrong population (pooled healthy and colostomy populations)
NCT01272869	2010	Wrong intervention, wrong population (not listed in the drug tariff. Also, ileostomy only)
NCT01273038	2010	Wrong intervention (not listed in the drug tariff)
NCT01513330	2012	Wrong comparator (mixed comparator – multiple different bags)
NCT01691729	2012	Wrong population (pooled stoma population)
NCT01799239	2013	Wrong population (ileostomy)
NCT01957488	2013	Wrong population (ileostomy)
NCT02043782	2014	Wrong population (pooled ileostomy and colostomy)
NCT02351817	2015	Wrong intervention (company responded at clarification to say products were never commercialised)
NCT02675634	2016	Wrong population (pooled stoma population)
NCT03154944	2017	Wrong population (ileostomy)
NCT04101318	2019	Wrong intervention (intervention was open bags)
NCT04868617	2021	Wrong intervention (intervention was open bags)
NCT05200416	2022	Wrong intervention (intervention was a digital add-on product)
Nichols et al.	2019	Wrong population (healthy volunteers)
Nichols et al.	2019	Duplicate
NI, Omon and Coloplast, A. S.	2020	Wrong population (ileostomy)
Nørtoft et al.	2019	Wrong outcome (no outcomes relevant to clinical review)
Nørtoft et al.	2019	Duplicate
Nørtoft et al.	2019	Duplicate
Nørtoft et al.	2019	Wrong study design (study did not evaluate specific products)
Nugent et al.	1999	Wrong study design (study did not evaluate specific products)
Omura et al.	2010	Wrong study design (study did not evaluate specific products)
Persson et al.	2010	Wrong study design (study did not evaluate specific products)
Pieper & Mikols	1996	Wrong study design (study did not evaluate specific products)

Authors	Year	Reason for exclusion
Rat et al.	2018	Wrong comparison (not listed in the drug tariff)
Ratliff	2014	Wrong study design (a cross sectional survey looking for predictors of leakage. No analysis of any bags or bag features)
Ratliff et al.	2005	Wrong study design (study did not evaluate specific products)
Redmond et al.	2013	Wrong study design (study did not evaluate specific products)
Reis et al.	2022	Wrong intervention (not listed in the drug tariff)
Richbourg et al.	2007	Wrong study design (study did not evaluate specific products)
Richbourg et al.	2011	Wrong study design (study did not evaluate specific products)
Rivas	2012	Foreign language
Rouholiman et al.	2018	Wrong intervention (intervention was a digital add-on product)
Roveron	2017	Wrong population (pooled stoma population)
Rubbini & Bertuzzi	1996	Foreign language
Sánchez et al.	2023	Wrong intervention (2-piece bag)
Saetre et al.	2023	Wrong intervention, wrong population (pooled ileostomy and colostomy. Intervention was limited to open bags)
Sanchez	1998	Foreign language
St-Cyr et al.	2022	Wrong comparator (comparators were unnamed)
Summa et al.	2021	Wrong intervention, wrong population (pooled ileostomy and colostomy. Intervention was a barrier for 2-piece bags)
Sundberg et al.	2012	Wrong comparator (mixed comparators)
Szewczyk et al.	2014	Wrong population (ileostomy and colostomy)
Tielemans et al.	2016	Wrong intervention (add-on product – a “skin protector”)
Vertical, Evamed, B. Braun Medical S.A.S.	2017	Wrong intervention (2-piece bag)
Virgin-Elliston et al.	2023	Wrong comparator (mixed comparators at baseline)
Voergaard et al.	2007	Duplicate
Watson	1982	Wrong intervention (not listed in the drug tariff)
White & Evans	2019	Wrong study design (survey with no clear baseline and no information about the products used)
Yilmaz et al.	2021	Wrong study design (population profile post-surgery)
Zamarripa et al.	2024	Wrong setting [REDACTED]

Studies excluded at full text: economic

Authors	Year	Reason for exclusion
Acevedo-ibarra et al.	2021	No relevant outcomes
Acquati et al.	2021	No relevant outcomes
Alharbi et al.	2023	No relevant outcomes
Alrubaiy et al.	2022	No relevant outcomes
Anonymous et al.	2024	Wrong population: urostomy or ileostomy for QoL
Arhip et al.	2023	No relevant outcomes
Augustad et al.	2020	Wrong population: urostomy or ileostomy for QoL
Ayaz-Alkaya et al.	2019	No relevant outcomes
Aylon et al.	2019	No relevant outcomes
Babazada et al.	2023	Not in English
Babazada et al.	2020	Abstract with insufficient details
Barnwell et al.	2015	No relevant outcomes
Belfield-Cockings et al.	2022	No relevant outcomes
Bennett et al.	2024	No relevant outcomes
Ber et al.	2021	No relevant outcomes
Bianchi et al.	2022	No relevant outcomes
Black et al.	2018	No relevant outcomes
Blackwell et al.	2022	No relevant outcomes
Boisen et al.	2017	No relevant outcomes
Bozkul et al.	2024	No relevant outcomes
Brady et al.	2022	No relevant outcomes
Brandsma et al.	2021	No relevant outcomes
Bulkley et al.	2022	No relevant outcomes
Burch et al.	2021	No relevant outcomes
Burch et al.	2016	No relevant outcomes
Cauley et al.	2018	No relevant outcomes
Cengiz et al.	2020	No relevant outcomes
Cheng et al.	2021	Not in English
Clark et al.	2023	No relevant outcomes
Collado-Boira et al.	2021	No relevant outcomes
Colwell et al.	2018	No relevant outcomes

Authors	Year	Reason for exclusion
Cronin et al.	2023	No relevant outcomes
Dapper et al.	2020	No relevant outcomes
Della Valle et al.	2022	No relevant outcomes
Di Re et al.	2023	No relevant outcomes
Di Re et al.	2021	Abstract with insufficient details
Diniz et al.	2021	No relevant outcomes
Dourado et al.	2024	No relevant outcomes
Drury et al.	2020	No relevant outcomes
Duluklu et al.	2019	No relevant outcomes
Eid et al.	2022	No relevant outcomes
Elfeki et al.	2018	No relevant outcomes
Faury et al.	2020	No relevant outcomes
Feddern et al.	2019	No relevant outcomes
Fellows et al.	2021	No relevant outcomes
Ferreira et al.	2023	No relevant outcomes
Ferreira et al.	2021	No relevant outcomes
Fish et al.	2017	Wrong population: urostomy or ileostomy for QoL
Foster et al.	2015	Abstract with insufficient details
Golpazir-Sorkheh et al.	2022	No relevant outcomes
Goodman et al.	2022	No relevant outcomes
Groom et al.	2010	No relevant outcomes
Guo et al.	2023	No relevant outcomes
Habib et al.	2020	No relevant outcomes
Haviland et al.	2015	Abstract with insufficient details
Hernandez-Marin et al.	2022	Not in English
Heydari et al.	2023	No relevant outcomes
Huang et al.	2021	No relevant outcomes
Hubbard et al.	2021	No relevant outcomes
Hubbard et al.	2019	No relevant outcomes
Indrebo et al.	2020	No relevant outcomes
Jiang et al.	2022	No relevant outcomes
Jiang et al.	2019	No relevant outcomes
Jiao et al.	2020	No relevant outcomes
Juul et al.	2008	No relevant outcomes

Authors	Year	Reason for exclusion
Kanabolo et al.	2023	Wrong population: urostomy or ileostomy for QoL
Kanabolo et al.	2019	Wrong population: urostomy or ileostomy for QoL
Kasperek et al.	2023	Not in English
Khalilzadeh Ganjalikhani	2019	No relevant outcomes
Koeter et al.	2019	No relevant outcomes
Kowalski et al.	2022	No relevant outcomes
Kristensen et al.	2019	No relevant outcomes
Krogsgaard et al.	2022	No relevant outcomes
Krogsgaard et al.	2021	Complication cannot be impacted by bag features
Kugler et al.	2021	No relevant outcomes
Lahnaoui et al.	2024	No relevant outcomes
Lahnaoui et al.	2019	No relevant outcomes
Lambrichts et al.	2020	No relevant outcomes
LeBlanc et al.	2023	No relevant outcomes
Leimkuhler et al.	2020	No relevant outcomes
Li et al.	2023	No relevant outcomes
Liu et al.	2021	No relevant outcomes
Liu et al.	2019	No relevant outcomes
Liu et al.	2017	No relevant outcomes
Luo et al.	2019	Not in English
Maalouf et al.	2023	Abstract with insufficient details
MacDonald et al.	2023	No relevant outcomes
Madbouly et al.	2022	No relevant outcomes
Maguire et al.	2022	No relevant outcomes
Malandrino et al.	2022	No relevant outcomes
Malcolm et al.	2019	Abstract with insufficient details
Malgina et al.	2021	No relevant outcomes
Marcus et al.	2020	No relevant outcomes
Martin-Gill et al.	2024	No relevant outcomes
Mayadevi et al.	2019	No relevant outcomes
McPhail et al.	2017	Abstract with insufficient details
Miller et al.	2022	Complication cannot be impacted by bag features
Mo et al.	2022	No relevant outcomes
Munro et al.	2023	No relevant outcomes

Authors	Year	Reason for exclusion
Munro Jaws et al.	2024	No relevant outcomes
Nain et al.	2022	No relevant outcomes
NasiriZiba et al.	2020	No relevant outcomes
Natalia et al.	2019	Not in English
Naverlo et al.	2019	No relevant outcomes
Neuberger et al.	2022	No relevant outcomes
Nieuwenhuyzen-De Boer et al.	2022	No relevant outcomes
Ohta et al.	2022	No relevant outcomes
Oxenham et al.	2014	No relevant outcomes
Pang et al.	2021	No relevant outcomes
Pappou et al.	2022	No relevant outcomes
Paquette et al.	2013	Wrong population: urostomy or ileostomy for QoL
Park et al.	2024	No relevant outcomes
Park et al.	2023	No relevant outcomes
Petralia et al.	2020	No relevant outcomes
Pietzsch et al.	2019	Abstract with insufficient details
Pittman et al.	2022	No relevant outcomes
Pochopien et al.	2015	Abstract with insufficient details
Qaderi et al.	2021	No relevant outcomes
Razon-Gonzalez et al.	2018	No relevant outcomes
Redmond et al.	2013	Abstract with insufficient details
Rierner et al.	2019	No relevant outcomes
Rivera Garcia et al.	2023	No relevant outcomes
Rodriguez et al.	2023	Abstract with insufficient details
Saetre et al.	2023	No relevant outcomes – RCT of open bags, does not look specifically at the impact of complications on HRQoL
Santos et al.	2021	No relevant outcomes
Scheele et al.	2022	No relevant outcomes
Segura-González et al.	2023	Not in English
Semi et al.	2022	No relevant outcomes
Shannon et al.	2023	No relevant outcomes
Shao et al.	2020	No relevant outcomes
Sheikh et al.	2022	No relevant outcomes
Shin et al.	2021	Not in English

Authors	Year	Reason for exclusion
Simoens et al.	2009	No relevant outcomes
Sivero et al.	2022	No relevant outcomes
Skibsted et al.	2022	No relevant outcomes
Skipper et al.	2016	No relevant outcomes
Sodergren eP527 et al.	2018	No relevant outcomes
Sodergren eP528 et al.	2018	No relevant outcomes
Swiatkowski et al.	2022	No relevant outcomes
Tan et al.	2020	No relevant outcomes
Thomas et al.	2021	No relevant outcomes
Tolentino et al.	2015	No relevant outcomes
van der storm et al.	2024	No relevant outcomes
van ginkel et al.	2021	No relevant outcomes
Walming et al.	2020	No relevant outcomes
Weledji et al.	2022	No relevant outcomes
Wilkinson et al.	2014	No relevant outcomes
Wurschi et al.	2024	Economic evaluation in a country not similar enough to the UK
Xia et al.	2020	No relevant outcomes
Xu et al.	2020	No relevant outcomes
Yacir et al.	2022	No relevant outcomes
Zewude et al.	2021	No relevant outcomes
Zhang et al.	2020	No relevant outcomes

Appendix D – Structured Expert Elicitation

Stoma care LSA - structured expert elicitation protocol

Rationale

Given the scarcity of evidence found in the available literature on some of the parameters that are likely to be important for the decision model the EAG plans to conduct a structured expert elicitation exercise to inform the following parameters:

- The disutility of ballooning
- The disutility of pancaking
- The disutility of bad odour
- The utility gain from preferred appearance and discreteness of stoma bags
- The probability of switching to a different bag if a patient experiencing complications with their current bag rather than using supporting products
- The probability of more serious complications such as hospitalisation or stoma resiting happening due to peristomal skin complications

Description of elicited parameters

The objective of the elicitation exercise is not to seek a 'single best answer' or point estimate from each expert, but to elicit a probability distribution representing their judgement about the relative likelihood of different values. That is, the distribution represents an expert's uncertainty based upon their existing knowledge. We are looking to understand the uncertainty around the average (mean) value and not to understand individual patient heterogeneity. The probability distributions are aggregated and used as an input into the decision model for the unknown parameter.

The EAG will seek to understand the expected utility for people with an ostomy with one piece closed bags experiencing different complications and the cost associated with them in UK practice.

The EAG plans to provide experts with the demographics of the population to be estimated to reduce the potential for variation driven by patient characteristics.

The Stomap 2019 report on stoma care by the East of England integrated care board revealed that 70% of people with an ostomy are aged 60 or above, with 70-79 age range having the biggest proportion (27.8%). Although the data includes a diverse group of patients with both colostomies and ileostomies, it offers the advantage of representing a substantial number of UK patients (12,341). This is especially valuable, as many studies have difficulty recruiting patients with a colostomy. Additionally, the report presents data from the perspective of the health service provider, which could explain the higher median age observed compared to smaller studies that may have limited representation of older age groups in their sample.

According to a Coloplast report (Ostomy life review 2018/2019), 68% of people with a colostomy have skin issues. 85% of all people with a stoma experience 'common problems' (skin issues, leakage, difficulty using their bag) (STOMAP). Half of all people with a stoma have even skin around the stoma. Of the rest, ~35% have an outward shape and the rest ~15% have a sink in the skin around the stoma [Coloplast report]. Approximately 13,500 individuals get stoma surgery annually in the UK. With the primary reason being colorectal cancer. The majority of patients get their prescriptions from a DAC (Stomap 2019).

We will ask the experts the following questions:

For an average person with a colostomy one year following their surgery, what's the **disutility** associated with experiencing the following complications for a period of one year:

- Regular (daily) ballooning
- Regular (daily) pancaking
- Regular (daily) issues with bad odour
- What's the **utility gain** from a discreet bag design with preferred for an average person with a colostomy one year after surgery?

For an average person with a colostomy one year following their surgery, what's the **probability** they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:

- Leakage onto clothes 4 times per month
- Leakage onto clothes once a month
- Leakage onto clothes once every 6 months
- Peristomal skin complications - mild level of pain, itching and burning (2/10); no bleeding or ulcers
- Peristomal skin complications - moderate level of pain, itching and burning (5/10); no bleeding or ulcers
- Peristomal skin complications - weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers
- Peristomal skin complications - bleeding or ulcers and a moderate level of pain, itching and burning (5/10)
- Peristomal skin complications - bleeding or ulcers and a severe level of pain, itching and burning (8/10)
- Regular (daily) ballooning
- Regular (daily) pancaking
- Regular (daily) issues with bad odour

For an average person with a colostomy one year following their surgery, what's the probability they would:

- Be hospitalised if they were to experience peristomal skin complications
- Have their stoma resited if they were to experience peristomal skin complications

The definitions for skin complications and leakage come from a published paper where quality of life data were collected from a survey of 758 members of the UK general public based on these definitions which were produced by a group of stoma nurses for use in the survey. The definitions for ballooning, pancaking and issues with bad odour were produced by the project team and cross-checked with the participating stoma nurses (4 responses received). There was some disagreement on what constituted regular: 2 nurses considered this to be daily, one to be anything from daily to more than once a week and one to be 2-3 times/week; given this we included the more frequent definition of regular with the expectation that this would have a higher impact on quality of life.

For all of the estimates provided the EAG will ask the experts to provide the rationale for their answers and any comments.

Protocol for elicitation

The following sections describe the details of the elicitation exercise, according to the elements as described in the MRC elicitation guidance.

Selecting the quantities (preparation and design stage)

The choice of quantity considered the following three objectives: fitness for purpose; directly observable and homogeneity in the quantities elicited. Eliciting the same summaries, where possible, will reduce the burden of training.

Methods to encode judgements (preparation and design stage)

Either the Chips and Bins method or a Bisection method have been shown to work equally well in health care elicitation. The Chips and Bins approach however, is viewed as less complex and easier to complete by health care professionals, and so this method will be used here.

Experts will be first asked to express the range for their judgements, the minimum, which is the value such that the expert believes that there is a 1% probability that the proportion is less than that value, and the maximum, a value such that the experts believe that there is a 1% probability that the proportion is more than that value. Grids are then generated based on this range and experts were asked to place 'chips' on this grid to represent their beliefs about the relative likelihood of different values.

Validation (preparation and design stage)

At the end of each task, experts are given a qualitative summary of their responses. If experts feel that these did not represent their views, they are encouraged to revise their responses. We will not seek feedback from experts on the aggregated results, however, where answers have been provided which appear to be outliers the team will make contact with the expert to check that the answers provided are as intended.

Selecting experts (preparation and design stage)

NICE have already recruited ten clinical experts (primarily CNS in stoma care) to participate in this assessment (Table 39). We will invite these experts to take part in this exercise. These

experts cover a mix of geographical areas across England and have declared any relevant conflicts to NICE already per NICE's policy.

Table 39: Clinical experts included in the expert elicitation exercise

Title	Name	Profession	Organisation
Ms	Emma Gaunt	Practice Development Lead	Continence, Urology and Colorectal Service (CUCS)
Dr	Gabriella Thorpe	Associate Professor of Nursing Sciences	University of East Anglia
Ms	Heather Ilett	Lead Stoma Nurse	Pharmacy & Medicines Optimisation Team, Herts & West Essex Integrated Care Board
Mrs	Jennifer Louise Burch	Head of gastrointestinal nurse education	St Mark's Hospital
Mrs	Natasha Rolls	Lead Stoma Care Nurse Specialist	University Hospital Bristol and Weston Foundation Trust
Ms	Rali Marinova	Nurse practitioner (stoma and internal pouch care)	St Mark's Hospital
Mrs	Rebecca Wootton	Colorectal Clinical Nurse Specialist	Sheffield Teaching Hospitals
Miss	Petya Marinova	Lead Nurse Practitioner – Pouch & Stoma Care	St Mark's Hospital
Mrs	Amelia Palmer	Stoma Care Clinical Nurse Specialist	Kingston Hospital NHS Foundation
Dr	Michelle Boucher	Lead Stoma Care Clinical Nurse Specialist	Salisbury NHS Foundation Trust

NICE's recruitment was focused on substantive skills rather than normative skills. This aligns with the recommendations for structured expert elicitation. An expert is said to be a substantive expert if they possess skills/knowledge pertaining to a particular domain or subject within that domain whereas normative expertise is the expert's ability to accurately assess and clearly communicate their beliefs in probabilistic form.

The planned inclusion criteria for experts are:

- A clinical expert registered with NICE for the stoma late stage assessment
- Willing and able to participate within the elicitation exercise

We will ask experts for the following details when they complete the survey to determine their level of experience and what area they represent:

- Years of experience as a stoma nurse
- Type of facility in which you practice [Community Health, Primary care, Secondary care, Tertiary care, Other (please specify)]
- Band of nurse
- Average number of colostomy patients you manage per week

Training and preparation for experts (preparation and design stage)

A narrated PowerPoint training session will be delivered to experts prior to the task at the end of the second user preference workshop if time allows. If there is not time to do this the training session will focus on piloting the intended questions and a recorded version of the more general training will be sent after the workshop.

The training session describes the objectives of the elicitation exercise, clarifies concepts such as uncertainty, familiarises the experts with the quantities elicited, describes and explains the impact of bias and heuristics, and trains experts on the methods of elicitation used.

A recorded version of the training slides will be sent to the experts following the workshop regardless of whether it was able to be conducted live, and guidance will be repeated within the task itself. We will adapt the PowerPoint slides available within the STEER tools for this purpose.

Experts will be reminded within the instructions for the SEE that they are to provide uncertainty on their estimate rather than thinking about variability across this heterogeneous group of patients.

Level of elicitation (elicitation stage)

Each expert elicits their judgements individually without interaction with other experts. Eliciting judgements individually reduces the risk of estimates being biased by a subset of experts. In the SEE elicitation literature, there are concerns that experts may not feel confident in eliciting judgements individually, however, the experts in this SEE process elicited their beliefs on a condition that they encounter regularly in general practice. Concerns regarding individual level

elicitation and lower confidence amongst experts generally arises when dealing with problems/technologies or conditions that are new or unknown to the experts.

Mode of administration (elicitation stage)

The elicitation exercise will be administered via an application in SHINY using the STEER R tool. The task will be delivered remotely. Experts will be offered the opportunity to complete the exercise remotely alongside one of the team. Email contacts will be given to provide any support needed.

Feedback to experts and revision (elicitation stage)

Once experts have expressed their beliefs and completed each question, they will be presented with graphical feedback of what their estimates looked like. Experts will be able to see how the grid looks once they have placed all of their chips on it. In addition, once experts have completed the grid, a summary of their answers will be relayed to them. This provides the following information:

Your answers imply that (example quantities given)

- There is a 17% probability that the disutility of this complication is between 0.08 and 0.1
- There is a 50% probability that the disutility of this complication is between 0.05 and 0.08
- There is a 33% probability that the disutility of this complication is between 0.03 and 0.05

Opportunity for interaction (elicitation stage)

As experts will complete the exercise individually, there will be no opportunity for interaction between the experts.

Feedback from experts on process (elicitation stage)

Qualitative feedback on the elicitation process will be collected from the experts, including rationales for their responses. This will be collected during the task using free text boxes. This form of validation helps to highlight if experts understood the task and responded as best they could.

If/how to aggregate (aggregation, analysis and post-elicitation)

As an individual level of elicitation was chosen, mathematical aggregation will be applied to generate the distributions, specifically linear opinion pooling using equal weighting of experts. First a probability distribution will be fitted to each expert's beliefs from the histogram. Then these will be pooled, assuming that each expert contributed equally to the group overall distribution. The MRC protocol advises the use of linear pooling with equal weights for mathematical aggregation for simplicity and due to a lack of research on how to generate appropriate weights.

Fit to distribution (aggregation, analysis and post-elicitation)

The statistical best fit distribution will be selected from Normal, Student t, Skew Normal, Gamma, Log Normal, Log Student t, and Beta distributions. Distributions were fitted for each expert individually, with the best fitting distribution determined by the smallest sum of squared errors, in accordance with the recommendations provided in the Sheffield Elicitation Framework (SHELF). Once the best fit distribution was identified for each expert, the fitted distributions were linearly pooled to produce the aggregated distribution.

Data Protection and Anonymity (aggregation, analysis and post-elicitation)

Experts will be asked to give their opinions individually (not in groups). The information provided, including personal details, will be kept anonymous and confidential, stored securely and only accessed by those carrying out the study.

Evidence pack to be provided to experts

Description of an average patient

	Value	Source
Time since surgery	One year or more after surgery A one-year mark was chosen so patients have largely healed from surgery, have a well-defined stoma shape, and have gained some experience with the use of stoma bags	Stomap 2019 report on stoma care by the East of England integrated care board
Cause of stoma	The most common conditions resulting in stoma surgery are: Colorectal cancer Bladder cancer Ulcerative colitis Crohn's disease	Stomap 2019 report on stoma care by the East of England integrated care board
Age	Above 60 (70% of patients) 70-79 (highest group 27.8%)	Stomap 2019 report on stoma care by the East of England integrated care board
Sex	We don't have exact data on the proportion of males and females, but the fact that colon cancer, which has a higher incidence in males, is the main cause of colostomy surgery suggests a higher percentage of male patients.	
Frequency of complications	85% of all people with a stoma experience 'common problems' (skin issues, leakage, difficult using bags)	Stomap 2019 report on stoma care by the East of England integrated care board
Frequency of skin complications	68% of people with a colostomy experience some level of skin issues	Ostomy life review 2018/2019
Skin around the stoma	50% Even 35% Outward shape 15% Sunken	Coloplast report
Hospitalisation due to peristomal skin complications	While we lack precise data on patients one year post-surgery, a study showed a 14% chance of hospitalisation due to PSC within 120 days following surgery. Therefore, we expect a lower chance of hospitalisation in patients one year after surgery	Burch (2013) ⁴⁸

Definitions

Peristomal skin complications	PSC describes a variety of complications that result in damage to the skin surrounding the stoma. For consistency with other patient-reported outcomes in the model, PSC is defined as the presence of dermatitis, pain, itching, burning, weeping, bleeding, or ulcers. ⁵⁷
Leakage	Stoma effluent reaching beyond the baseplate (leading to, e.g. the soiling of clothes or bedsheets) or spreads underneath the baseplate. ⁵⁷
Pancaking	Pancaking occurs when, instead of dropping to the bottom of the bag, poo collects around the stoma and may seep between the flange/baseplate and the skin. This can happen because there is not enough air in the bag and so the two sides stick together.
Ballooning	Gas expelled through the colon collects inside the bag and is not dispersed by the filter causing it to inflate
Odour	Offensive odour due to the filter deodoriser being ineffective for any reason other than leakage (to avoid double counting)
Discreetness & appearance	The property of a bag that comes in the users preferred colour and shape; is less obtrusive and visible, such as a bag with a low profile that reduces dragging when filling, less bulky material and material that doesn't become see through when wet. A bag that is made of material that makes minimal noise when moving

What is a disutility / utility gain?

Utilities are a generic measure of health-related quality of life which can be used in all disease areas. Use of utilities allows comparison across diseases which then allows the decision maker to determine if the health gains or loss prevention is worth the money companies wish to charge the NHS.

Utilities are measured from 0 to 1 with 1 being perfect health and 0 being death or in a coma. The same change means the same irrespective of the part of the scale being considered (e.g. a change in health from 0.3 to 0.2 is equivalent to a change from 0.9 to 0.8).

The average utility for a person aged 65 - 75 is around 0.85 in the general population, as most people of this age will have already some health loss due to comorbidities or the natural aging process.

The loss in quality of life caused by having a particular complication is called a 'disutility.' So if you think a patient loses one tenth of their health from perfect health status due to a

complication then the disutility is 0.1. A utility gain is an improvement in quality of life and operates on the same scale.

We provide below the information we have found on disutilities for leaks and skin complications for patients with a stoma for comparison.

Disutilities for comparison

We conducted a literature review to identify any available published evidence on the impact on health-related quality of life of different stoma complications in the form of utilities. The below presents the evidence we were able to identify for you to use when considering the impact of the other complications on health-related quality of life.

Complication	Disutility	Source	Quality of data collection
Peristomal skin complications: mild level of pain, itching and burning (2/10); no bleeding or ulcers	0.025	Rolls et al., 2022 ⁵⁷	
Peristomal skin complications: weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers	0.112	Rolls et al., 2022 ⁵⁷	
Peristomal skin complications: bleeding or ulcers and a moderate level of pain, itching and burning (5/10)	0.161	Rolls et al., 2022 ⁵⁷	
Peristomal skin complications: bleeding or ulcers and a severe level of pain, itching and burning (8/10)	0.287	Rolls et al., 2022 ⁵⁷	
Leakage onto clothes: 4 events/month	0.114	Rolls et al., 2022 ⁵⁷	
Leakage onto clothes: 1 event/month	0.057	Rolls et al., 2022 ⁵⁷	
Leakage onto clothes: 1 event/ 6 months	0.022	Rolls et al., 2022 ⁵⁷	
Disutility of symptomatic peristomal hernia	0.086	Mohiuddin et al., 2021 ³²	
Disutility of hospital stay after peristomal hernia surgery (equal to the average hospital stay after hernia surgery in England)	0.083	Mohiuddin et al., 2021 ³²	
Disutility of long-term complications such as bowel obstruction, bowel perforation, infection, haematoma and nonhealing wound may occur following bowel surgery and stoma creation for 22 days	0.090	Mohiuddin et al., 2021 ³²	

PSC Mild Mild skin irritation: characterised by occasional reddening and irritation caused by stomal discharge or adhesives	0.0480	Nichols et al., 2019 ⁶¹	
PSC Moderate Moderate skin irritation: characterised by always being reddened or irritated by stoma discharge or adhesives, and occasional but slight blistering	0.0940	Nichols et al., 2019 ⁶¹	
PSC Severe Severe skin irritation: characterised by skin that is always blistered or damaged, where blistering often results in denuded skin caused by the mechanical process of repeated application and removal of an ostomy appliance	0.1240	Nichols et al., 2019 ⁶¹	
Mild PSC a Discoloration, Erosion, Tissue overgrowth [DET] instrument score <4)	0.0570	Berger et al., 2018 ²¹	
Moderate PSC Discoloration, Erosion, Tissue overgrowth DET score >4 and <7	0.1070	Berger et al., 2018 ²¹	
Severe PSC Discoloration, Erosion, Tissue overgrowth DET score ≥7	0.1650	Berger et al., 2018 ²¹	

Common cognitive biases to think about when completing the survey



Cognitive biases

1. Anchoring bias

- Fixing on an initial value and failing to sufficiently adjust estimates away from it
- Challenging to eliminate
- Asking for plausible limits before the median minimizes anchoring bias

2. Availability bias

- Basing judgement about the probability of an event on how easily examples of an outcome come to mind
- Judgement may be biased towards more recent or prominent experiences
- Evidence brief aims to minimize this by summarizing key evidence



Motivation biases

1. Confirmation bias

- Focusing on and being less critical of information that is consistent with existing beliefs and preference

2. (Un)desirability bias

- Overestimating the likelihood of positive outcomes (wishful thinking) or negative outcomes (precautionary thinking)

- Cognitive and motivational biases often lead to **overconfidence** (probability distributions that are too narrow)
- Keeping these biases in mind during the exercise can help you to reduce their impact

APPENDIX E – CLINICAL EFFECTIVENESS EVIDENCE IN PEOPLE WITH AN ILEOSTOMY

Given the low number of studies identified for inclusion in the clinical evidence review, the EAG asked CNS in stoma care about whether the decision to restrict the evidence review to studies reporting data for a population with colostomies only (or, in effect, studies that included a population of at least 80% colostomy) was appropriate. This was done to determine whether there should be a deviation from the review protocol to include studies with a mixed population (i.e. a mixed population of people with a stoma, where fewer than 80% of participants had a colostomy) or an ileostomy only population. SCMs were emailed for their feedback on the following questions:

- How are people with an ileostomy similar or different to people with a colostomy in relation to key outcomes?
- Would the features of 1-piece closed bags have similar or different effectiveness in people with an ileostomy as for people with a colostomy?

These questions were intended to determine whether baseline characteristics for outcomes in the NICE scope are different between those with an ileostomy and a colostomy (i.e. would people with an ileostomy start studies with different health than those with a colostomy) and whether effect estimates associated with 1-piece closed bags be as comparable in an ileostomy population as in a colostomy population.

The results of the feedback received from SCMs is summarised in the following tables. All respondents were CNS in stoma care. In sum, several SCMs highlighted differences between people with an ileostomy and a colostomy that would make it challenging to generalise evidence from studies with people with an ileostomy to those with people with a colostomy. While there were mixed views from some respondents, there was no one outcome or bag feature that respondents universally agreed would be comparable between populations. Given this feedback, the EAG decided not to change the protocol for the review. The implications of this feedback from CNS in stoma care for the economic analysis, where data from ileostomy and mixed populations were used, are discussed in section 7. The implications of this issue for future research are discussed in section 8.

Table 40: Are people with an ileostomy similar to people with a colostomy on key outcomes? – CNS in stoma care feedback

Are outcomes in people with an ileostomy similar to people with a colostomy? Number of CNS who responded yes, no, or unsure/no response				
Outcome	Yes	No	Unsure or no response	Reasoning
Leakage	1	1	5	People with an ileostomy have a higher risk of leakage than people with a colostomy because their poo is more liquid. On the other hand, people with a colostomy experience pancaking, which can lead to leakage, so the risk is the same.
Peristomal skin complications	2	7	0	There is a higher risk of skin complications (up to ten times the risk) for people with an ileostomy due to the type of poo they have and the different enzymes in their poo. Their poo is particularly corrosive to the skin and causes more peristomal problems. On the other hand, skin health is still treated the same way for both people with an ileostomy and with a colostomy. People with an ileostomy generally keep their bags on longer, so the risks of irritation or complications increase accordingly. However, people with a colostomy may experience a higher risk of skin complications due to more frequent bag changes.
Psychological wellbeing	4	3	0	The type and unpredictability of the looser poo with an ileostomy makes it harder to adapt. People with ileostomy are concerned about leakage and access to the toilet, especially when they are out. On the other hand, both stoma groups are affected psychologically – different individual patients will have difference experiences.
Social functioning	3	4	0	People with an ileostomy are more worried about their social activities. There is no option to irrigate or wear a stoma cap and diet and fluid intake is a bigger consideration. On the other hand, A new stoma of any kind affects social functioning. If the stoma bag has good adherence, social functioning should be similar for people both with an ileostomy and a colostomy.
Quality of life	6	1	0	People with ileostomies face a greater impact on their QoL because ileostomies are more problematic than colostomies, due to their erratic and unpredictable poo. On the other hand, how well a person adjusts to having a stoma depends a lot on why they needed it. For example, a patient that has had long standing ulcerative colitis can, and often do, have a much better QOL after having their ileostomy compared to others. A patient that has been diagnosed with a cancer, say, may view their stoma differently.

Are outcomes in people with an ileostomy similar to people with a colostomy? Number of CNS who responded yes, no, or unsure/no response				
Use of medicines to improve bag outcomes and manage complications	1	6	0	People with ileostomies are more likely to need rehydration solutions, accessories, and skin protectors due to the type of poo with an ileostomy. Loperamide/codeine or other medications may be required to thicken poo. On the other hand, complications with stomas occur with both types: poo thickeners for ileostomy, whether that's in the bag or medication, and laxatives for colostomy. Use of steroid applications for sore/ulcerated skin is often the same for both.
Use of supporting products to improve bag outcomes	2	4	1	Due to their poo, poor spouts, and creases, life is more challenging with an ileostomy. More accessories are often required. On the other hand, with any stomas, ultimately it is necessary to find the correct bag that fits well around the stoma. The correct bag means you do not have to use so many supporting products, and hence the use of supporting products can often be similar.
Length of time before switching bags/ frequency of bag change	1	6	0	Typically, ileostomy every 1-2 days, colostomy 1-3 times daily.
Patient-reported ease of use of bag and acceptability	4	3	0	Ileostomies often cause more problems. People with ileostomies often trial a variety of bags before settling on one – they need to empty their bag, whereas people with colostomy change the whole appliance. Lifestyle changes are generally deemed greater for ileostomy. On the other hand, most patients have only experience of one stoma, so their ability to adapt/accept is the same for both – it's not really stoma specific.
Number of or time to ballooning events	3	5	0	People with colostomies struggle with ballooning more, especially with a closed bag. Also, people with ileostomies usually empty their bag frequently so they can avoid the ballooning. Ballooning may be the same for both, as this may be highly influenced by diet and personal circumstances. However, one expert noted that more wind can arise in the large bowel, which may increase the risk of ballooning for people with a colostomy. When ballooning does happen, the experience is the same for both, regardless of cause.
Pancaking	0	7	0	This is most often a colostomy problem. Pancaking is less likely in ileostomy although can still happen (especially for people with cystic fibrosis).
Number of appointments	1	5	1	Ileostomies usually require more input and visits from stoma care nurses, due to the nature of the stoma and their poo – also in making sure the peristomal skin does not get damaged.

Are outcomes in people with an ileostomy similar to people with a colostomy? Number of CNS who responded yes, no, or unsure/no response				
with GPs and clinical nurse specialists in stoma care				On the other hand, the follow up pathway is often the same for both people with an ileostomy and people with a colostomy.
Odour control	3	3	1	People with ileostomies tend not to have an odour issue, particularly when the bag is adhered to the skin and not being emptied. On the other hand, it can be problematic with both stomas. Looser poo appears to wet the filter, making it less effective, and so emptying is an odour producing activity for people with an ileostomy.

Table 41: Would the features of 1-piece closed bags have similar or different effectiveness in people with an ileostomy as for people with a colostomy? – SCM feedback

Would the feature affect people with an ileostomy differently to people with a colostomy? Number of CNS who responded yes, no, unsure or no response				
Feature	Yes	No	Unsure or no response	Reasoning
Baseplate additives	2	2	3	People with a colostomy generally get less benefit from baseplate additives than people with an ileostomy. This is because leaking from an ileostomy is more likely to cause skin damage, due to the digestive enzymes in their poo. On the other hand, additives such as ceramide and vitamin E promote skin health and healing are necessary and used by all people with a stoma in the same way people use skin care products. These additives ensure correct care of the skin under the baseplate.
Different baseplate shapes	0	7	0	These are useful for both people with colostomies and ileostomies as body shapes differ.
Different baseplate adhesive types	2	4	1	Longer wear time is required for people with an ileostomy. People with colostomies change their bags approximately 1-3 times daily, compared to people with ileostomies every 1-2 days. Therefore, the adhesive needs to be stronger for ileostomies. Also, ileostomy poo is more corrosive on the skin and on the adhesive. On the other hand, all baseplates need to adhere to the skin for both stomas to prevent skin damage.

Would the feature affect people with an ileostomy differently to people with a colostomy? Number of CNS who responded yes, no, unsure or no response				
Different bag shapes	1	6	0	People may experience the same issues for both types of stoma. All people will have preferences regarding the look, feel and function of bags. On the other hand, the bags for people with an ileostomy tend to be bigger/longer than bags for people with a colostomy. Therefore, different shapes would benefit people with ileostomies.
Different types of filters	2	5	2	The filter needs to be effective for both stomas, although it needs to last longer for an ileostomy as the bag stays on the body for longer (approximately 1-2 days). Also, the filter might get clogged more often with solid rather than loose poo, and people with a colostomy may have a higher risk of wind. On the other hand, ileostomy poo is more liquid and may damage the filter after 12 to 24 hours
Different bag material	1	6	0	Important for both stoma types. On the other hand, more experienced people with a stoma will make changes based on their activities (although they still would largely be driven by baseplate fit and feel).
Bags that are flushable	4	2	0	In some respects, it was considered that this feature would be as meaningful for either population – if this is what the person wants, then the features would be similar. On the other hand, a flushable bag would not be recommended for a person with ileostomy. The nature of the liquid poo can affect the materials in these bags, which could cause odour whilst the bag is on.

Appendix F – Quality appraisal checklists of included clinical effectiveness evidence

Table 42: NICE checklist results for RCTs*

	Teniere 2007	Voorgaard 2007	Virgin-Elliston 2023
A. Selection bias.			
A1. An appropriate method of randomisation was used to allocate participants to treatment groups (which would have balanced any confounding factors equally across groups).	Unclear	Unclear	Unclear
A2. There was adequate concealment of allocation (such that investigators, clinicians and participants cannot influence enrolment or treatment allocation).	No	No	Yes
A3. The groups were comparable at baseline, including all major confounding and prognostic factors.	Unclear	Unclear	Unclear
Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect? Low, unclear, or high.	Unclear	Unclear	Unclear
Likely direction of effect	Unclear	Unclear	Unclear
B. Performance bias			
B1. The comparison groups received the same care apart from the intervention(s) studied.	Unclear	Unclear	Yes
B2. Participants receiving care were kept 'blind' to treatment allocation.	No	No	No
B3. Individuals administering care were kept 'blind' to treatment allocation.	No	No	No
Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect? Low, unclear, or high	High	High	High
Likely direction of effect	Unclear	Unclear	Unclear
C. Attrition bias			
C1. All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up).	Unclear	Unclear	Yes

	Teniere 2007	Voorgaard 2007	Virgin-Elliston 2023
C2a. How many participants did not complete treatment in each group?	5 participants – not specified from which arms	1 dropout (plus one exclusion) – doesn't specify arms	2 dropouts while using full-circle filter after crossover – one due to patient choice one to an adverse event
C2b. The groups were comparable for treatment completion (that is, there were no important or systematic differences between groups in terms of those who did not complete treatment).	Unclear	Unclear	Unclear
C3a. For how many participants in each group were no outcome data available?	Unclear	Unclear	Unclear
C3b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available).	Unclear	Unclear	Unclear
Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect? Low, unclear, or high.	High	High	High
Likely direction of effect	Unclear	Unclear	Unclear
D. Detection bias			
D1. The study had an appropriate length of follow-up.	Unclear	Unclear	Yes
D2. The study used a precise definition of outcome	No	No	Yes
D3. A valid and reliable method was used to determine the outcome	No	No	Yes, although relied self-reporting
D4. Investigators were kept 'blind' to participants' exposure to the intervention	No	No	No
D5. Investigators were kept 'blind' to other important confounding and prognostic factors.	No	No	No
Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect? Low, unclear, or high	High	High	Low

	Teniere 2007	Voorgaard 2007	Virgin-Elliston 2023
Likely direction of effect	In favour of intervention	In favour of intervention	In favour of intervention
E. Other bias: Crossover design	Moderate risk	Moderate risk	Moderate risk

[illegible]

Appendix G – Comparing the DET score and the PIB score

The literature identified for utility scores and resource use for PSC measures PSC in a variety of ways. Two scales are presented in a number of papers: the discolouration, erosion and tissue overgrowth ([DET score](#)) and the pain itching and bleeding (PIB) score. Both are based on the validated [Ostomy Skin Tool 2.0](#). When using the DET score mild, moderate and severe PSC were defined as a score of <4, 5 or 6, and 7 and over respectively. When using the PIB score 5 levels were presented in Rolls et al. (2022)⁵⁷:

- Mild: Peristomal skin complications - mild level of pain, itching and burning (2/10); no bleeding or ulcers
- Moderate: Peristomal skin complications - moderate level of pain, itching and burning (5/10); no bleeding or ulcers
- Moderate: Peristomal skin complications - weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers
- Severe: Peristomal skin complications - bleeding or ulcers and a moderate level of pain, itching and burning (5/10)
- Severe: Peristomal skin complications - bleeding or ulcers and a severe level of pain, itching and burning (8/10)

Expert advice was sought from Natasha Rolls on how these two scales compare in order to implement sensitivity analysis which used the Rolls 2022 study for utilities.

The DET score measures visual symptoms, so mild, moderate and severe represented as changes in the skin integrity and health that can be viewed on the skin physiology. The percentage of skin area affected which sits under the baseplate is measured, there is also an assessment of depth of erosion and then degree of granulation so a person may have a small area but score high because the erosion is a deep ulcer or the granulation is high, equally a person may have a wide spread area of visible 'sore/red' skin but this is not accompanied by erosion through the layers of skin so therefore 'superficial and lower score.

The PIB score was based upon the Ostomy Skin Tool using DET but with the inclusion of 'felt', perceived and experienced skin symptoms. So, the skin may present as healthy because it is visually intact but the patient experiences symptoms that impact their day-to-day life. A clinician

may mark as 'no treatment required' or healthy but there will be an impact for the patient. The Ostomy Skin Tool 2.0 was devised to ensure the patient experience symptoms were measured.

An expert was asked to provide their subjective opinion of how the two scores relate to each other (Table 44 – see Appendix H for details of CNS feedback on impact of PSC on bag use). This was used within the economic model to relate the PIB score used in Rolls 2022 to the DET score used in the majority of the other sources when conducting scenario analysis.

Table 44: Expert opinion of the correlation between DET and PIB scores

	DET ≤4	DET 5 - 6	DET 7+
Mild level of pain, itching and burning (2/10); no bleeding or ulcers	95%	5%	
Moderate level of pain, itching and burning (5/10); no bleeding or ulcers	95%	5%	
Weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers	85%	15%	
Bleeding or ulcers and a moderate level of pain, itching and burning (5/10)	20%	50%	30%
Bleeding or ulcers and a severe level of pain, itching and burning (8/10)	10%	50%	40%

Appendix H – CNS in stoma care feedback on impact of PSC on bag use

Clinical experts were asked to provide input on the number of bags that would be used per day by people according to whether or not they had PSC and level of severity following input from one SCM that the initial values chosen following input from experts were too high.

The initial estimates can be found in Table 45 and were supplied to the experts for comment. Six experts responded.

- One expert stated that the numbers were accurate and that they had encountered colostomy patients needing to change as frequently as 6 times a day and that they see far more complications and bag changes with ileostomy than colostomy
- One expert stated that the numbers were accurate and that increasing PSC severity would increase the number of bags required
- One expert stated that they would suggest changing to a 2-piece rather than increasing the level of bag use and that the usual for a patient with no PSC is 1-3 bags per day
- One expert stated that needing to change more than 3 times a day is not normal and would initiate a request to review
- One expert stated that they wouldn't expect the number of bag changes to increase or decrease depending on the level of PSC and that people without complications may change once a day or even less often up to 3 times a day; if a person's poo is so loose that it request more bag changes a day they would be switched to a drainable bag
- One expert stated that the bag numbers seemed high and that some people who poo less frequently need only one change per day with maybe one extra for severe skin damage, however, if someone poos a lot and has skin damage it could be many bags; they considered that on average they would expect one bag less per category than the data presented

Given the wide range of estimates presented the EAG amended the base case to align with the final experts' opinion of one fewer bag per day on average per health stated but tested

scenarios using the original estimates and assuming no change in bag requirements per day across the health states.

Estimates were also compared with a rough estimate of the mean number of bags used per day across England based upon there being 146,256,349 one-piece bags sold in 2023 using the data from the Bennett institute⁵ and 176,824 people with a stoma in England in 2019 from the StoMap report³⁵ the mean number of bags used per day is 2.26 $[146,256,349 / (365.25 * 176,824)]$. Data was not available on the number of people using one-piece bags relative to two-piece bags. However, we understand that the vast majority of people in 2023 used one-piece bags. This means the mean number reported here is likely to be something of an underestimate. Survey data submitted by Colostomy UK indicates that 44% of people with a stoma have PSC, meaning that our new estimates for bag usage according to PSC are broadly aligned with the overall population data.

Table 45: Initial estimates of bag use according to PSC

Cost / resource use item	EAG base case input	Source
Number of 1-piece closed bags per day	No PSC: 2.5 Mild: 4 Moderate: 5.5 Severe: 6.5	Clinical expert opinion (2 CNS in stoma care)

APPENDIX I – MODEL INPUTS

Complication	Parameter type	Health State	Value	Source
PSC	Utilities & Disutilities	No PSC	0.80	Rolls (2022)
PSC	Utilities & Disutilities	Mild: PIB2	0.77	Rolls (2022)
PSC	Utilities & Disutilities	Moderate: PIB5	0.69	Rolls (2022)
PSC	Utilities & Disutilities	Moderate: PIB5 + weeping skin	0.69	Rolls (2022)
PSC	Utilities & Disutilities	Severe: PIB5	0.64	Rolls (2022)
PSC	Utilities & Disutilities	Severe: PIB8	0.52	Rolls (2022)
PSC	Utilities & Disutilities	No PSC	0.80	Rolls (2022) adjusted to expert input
PSC	Utilities & Disutilities	Mild	0.67	Rolls (2022) adjusted to expert input
PSC	Utilities & Disutilities	Moderate	0.58	Rolls (2022) adjusted to expert input
PSC	Utilities & Disutilities	Severe	0.56	Rolls (2022) adjusted to expert input
PSC	Utilities & Disutilities	No PSC	0.97	Scheffel (2023)
PSC	Utilities & Disutilities	Mild: PIB2	0.94	Scheffel (2023)
PSC	Utilities & Disutilities	Moderate: PIB5	0.93	Scheffel (2023)
PSC	Utilities & Disutilities	Moderate: PIB+ weeping skin	0.89	Scheffel (2023)
PSC	Utilities & Disutilities	Severe: PIB5	0.83	Scheffel (2023)
PSC	Utilities & Disutilities	Severe: PIB8	0.71	Scheffel (2023)
PSC	Utilities & Disutilities	No PSC	0.73	Nichols (2019)
PSC	Utilities & Disutilities	Mild	0.69	Nichols (2019)
PSC	Utilities & Disutilities	Moderate	0.64	Nichols (2019)
PSC	Utilities & Disutilities	Severe	0.61	Nichols (2019)
PSC	Utilities & Disutilities	No PSC	0.75	Berger (2018)
PSC	Utilities & Disutilities	Mild	-0.06	Berger (2018)
PSC	Utilities & Disutilities	Moderate	-0.11	Berger (2018)
PSC	Utilities & Disutilities	Severe	-0.17	Berger (2018)
PSC	Supportive All Products Monthly Costs EAG	All Health States	■	Nørtoft (2019) subgroup analysis ■

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Complication	Parameter type	Health State	Value	Source
PSC	HCP costs – CNS visits	All Health States	119.05	Rolls (2023)
PSC	HCP costs - CNS telephone consultations	All Health States	19.04	Rolls (2023)
PSC	HCP costs - CNS home care visits	All Health States	71.44	Rolls (2023)
PSC	HCP costs – Dermatology	All Health States	121.01	Rolls (2023)
PSC	HCP costs - Gastroenterology	All Health States	145.33	Rolls (2023)
PSC	HCP costs - GP	All Health States	184.00	Rolls (2023)
PSC	HCP costs - Surgeon	All Health States	122.00	Rolls (2023)
PSC	HCP costs - SCN Costs PSC Mild	All Health States	167.13	NHS Reference costs inflated to 2023, SCN opinion
PSC	HCP costs - SCN Costs PSC Moderate	All Health States	250.91	NHS reference costs, Rolls (2023)
PSC	HCP costs - SCN Costs PSC Severe	All Health States	310.76	NHS reference costs, Rolls (2023)
PSC	HCP costs - CNS visits	All Health States	76.80	PSSRU cost per consultation
PSC	HCP costs – Dermatology	All Health States	174.88	PSSRU cost per consultation
PSC	HCP costs - Gastroenterology	All Health States	230.40	PSSRU cost per consultation
PSC	HCP costs - GP	All Health States	56.00	PSSRU cost per consultation
PSC	HCP costs - Surgeon	All Health States	231.59	PSSRU cost per consultation
PSC	HCP costs	Mild	286.91	Rolls (2023)
PSC	HCP costs	Moderate	435.96	Rolls (2023)
PSC	HCP costs	Severe	546.11	Rolls (2023)
PSC	HCP costs	Mild	11.87	Rolls (2023)
PSC	HCP costs	Moderate	26.75	Rolls (2023)
PSC	HCP costs	Severe	49.41	Rolls (2023)
PSC	Health state costs	All Health States	289.63	Mockford (2018)
PSC	Health state costs	No PSC	0.00	Martins (2012)
PSC	Health state costs	Mild	149.04	Martins (2012)
PSC	Health state costs	Moderate	188.31	Martins (2012)
PSC	Health state costs	Severe	377.87	Martins (2012)
PSC	Cost of Pharma Products	Mild	0.35	Rolls (2023), Drug Tariff
PSC	Cost of Pharma Products	Moderate	1.82	Rolls (2023), BNF 2024

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Complication	Parameter type	Health State	Value	Source
PSC	Cost of Pharma Products	Severe	2.43	Rolls (2023), Drug Tariff
PSC	Cost of Pharma Products	Mild	0.50	Rolls (2023)
PSC	Cost of Pharma Products	Moderate	0.45	Rolls (2023)
PSC	Cost of Pharma Products	Severe	1.11	Rolls (2023)
PSC	1-piece bag cost (No PSC)	No PSC	21.14	EAG calculation
PSC	Resource use increased cost by Health state	No PSC	7.00	Berger (2018)
PSC	Resource use increased cost by Health state	Mild	11.48	Berger (2018)
PSC	Resource use increased cost by Health state	Moderate	10.43	Berger (2018)
PSC	Resource use increased cost by Health state	Severe	10.43	Berger (2018)
PSC	Resource use increased cost by Health state	No PSC	4.59	Rolls (2023)
PSC	Resource use increased cost by Health state	Mild	5.40	Rolls (2023)
PSC	Resource use increased cost by Health state	Moderate	9.68	Rolls (2023)
PSC	Resource use increased cost by Health state	Severe	10.82	Rolls (2023)
PSC	RU number bags wasted due to bag change (weekly)	All Health States	15.85	EAG calculation
PSC	Number of bags by health state	No PSC	10.50	Expert opinion
PSC	Number of bags by health state	Mild	21.00	Expert opinion
PSC	Number of bags by health state	Moderate	31.50	Expert opinion
PSC	Number of bags by health state	Severe	38.50	Expert opinion
PSC	CNS Resource use	Mild	3.14	Berger (2018)
PSC	CNS Resource use	Moderate	3.17	Berger (2018)
PSC	CNS Resource use	Severe	3.00	Berger (2018)
PSC	HCP resource use	Mild	0.04	Berger (2018)
PSC	HCP resource use	Moderate	0.08	Berger (2018)
PSC	HCP resource use	Severe	0.00	Berger (2018)

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Complication	Parameter type	Health State	Value	Source
PSC	Source of resource use for PSC	All Health States		EAG consultation with CNS experts, Martins (2012), Mockford (2018), Berger (2018), Rolls (2023)
PSC	Number of bags	All Health States		Berger (2018), Rolls (2023), EAG
PSC	Number of supportive care products	All Health States		EAG consultation with CNS experts, Rolls (2023)
PSC	Hospitalisation	All Health States		D'Ambrosio 2023, Expert Elicitation
PSC	Proportion of patients undergoing resit - Severe Health only	All Health States		Expert Elicitation, Rolls (2023)
PSC	Medicinal Products source	All Health States		Rolls (2023), EAG consultation with CNS experts
PSC	Source of information for nurse consultations (from Rolls)	All Health States		HCP survey, Patient survey
PSC	Dermatologist Resource use	Mild	0.00	Rolls (2023)
PSC	Dermatologist Resource use	Moderate	0.04	Rolls (2023)
PSC	Dermatologist Resource use	Severe	0.08	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Mild	0.01	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Moderate	0.01	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Severe	0.03	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Mild	0.01	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Moderate	0.02	Rolls (2023)
PSC	Proportion Pts Referred to Gastroenterologist	Severe	0.07	Rolls (2023)
PSC	Proportion of patients expected to undergo stoma revision/re-surgery	Mild	0.01	Rolls (2023)
PSC	Proportion of patients expected to undergo stoma revision/re-surgery	Moderate	0.01	Rolls (2023)
PSC	Proportion of patients expected to undergo stoma revision/re-surgery	Severe	0.01	Rolls (2023)
PSC	Proportion of patients expected to undergo stoma revision/re-surgery	Severe	0.02	Expert Elicitation

Complication	Parameter type	Health State	Value	Source
PSC	Treatment duration (weeks)	Mild	1.67	Rolls 2023 HCP survey
PSC	Treatment duration (weeks)	Moderate	2.63	Rolls 2023 HCP survey
PSC	Treatment duration (weeks)	Severe	3.61	Rolls 2023 HCP survey
PSC	Treatment duration (weeks)	Mild	0.82	Rolls 2023 PT survey
PSC	Treatment duration (weeks)	Moderate	0.54	Rolls 2023 PT survey
PSC	Treatment duration (weeks)	Severe	2.1	Rolls 2023 PT survey
PSC	Treatment Times (weeks) & Source - PSC	All Health States		Rolls (2023) PT Survey, or Rolls (2023) HCP Survey
PSC	Chance of hospitalisation for PSC	All Health States	13.4%	Expert elicitation
PSC	Chance of hospitalisation for PSC	All Health States	14.0%	D'Ambrosio 2023
PSC	Proportion of PSC by severity	Mild	44%	ADVOCATE study
PSC	Proportion of PSC by severity	Moderate	48%	ADVOCATE study
PSC	Proportion of PSC by severity	Severe	8%	ADVOCATE study
PSC	Proportion of Moderate PSC with PIB = 5	Moderate	0.5	Assumption
PSC	Proportion of Severe PSC with PIB = 5 and bleeding skin	Severe	0.5	Assumption
PSC	Number of PSC episodes		2.41	Colwell (2018); ADVOCATE RCT SoC arm
Leakage	Utility Health States	No PSC (Leakage group)	0.81	Rolls (2022)
Leakage	Utility Health States	No PSC (Leakage group)	0.99	Scheffel (2023)
Leakage	Disutility Health States	No leakage	0.00	Rolls (2022)
Leakage	Disutility Health States	Mild leakage	-0.02	Rolls (2022)
Leakage	Disutility Health States	Moderate leakage	-0.06	Rolls (2022)
Leakage	Disutility Health States	Severe leakage	-0.11	Rolls (2022)
Leakage	Disutility Health States	No leakage	0.00	Scheffel (2023)
Leakage	Disutility Health States	Mild leakage	-0.01	Scheffel (2023)
Leakage	Disutility Health States	Moderate leakage	-0.05	Scheffel (2023)
Leakage	Disutility Health States	Severe leakage	-0.10	Scheffel (2023)
Leakage	Weekly cost of leaks	All Health States	9.27	EAG calculation
Leakage	Resource use Leakage	All Health States		Nortoft (2019),De Fries Jensen (2023)
Leakage	Treatment Times (weeks) & Source - Leakage			

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Complication	Parameter type	Health State	Value	Source
Leakage	Treatment time: two leakage events per year (mild)	All Health States	52.00	CNS in stoma care assumption
Leakage	Treatment time: one leakage event per month (moderate)	All Health States	3.00	CNS in stoma care assumption
Leakage	Treatment time: 4 leakage events per month (severe)	All Health States	3.00	CNS in stoma care assumption
Leakage	CNS contacts cost	Mild leakage	0.00	EAG calculation
Leakage	CNS contacts cost	Moderate leakage	19.05	EAG calculation
Leakage	CNS contacts cost	Severe leakage	84.54	EAG calculation
Odour	Treatment Times (weeks) & Source - Odour	All Health States	3.00	CNS in stoma care assumption
Odour	Cost of supporting products	All Health States	0.92	EAG calculation
Odour	Disutility	All Health States	-0.08	Expert elicitation
Odour	Cost all types of visits to CNS for Odour	All Health States	121.97	NHS cost reference (inflation to 2023), Expert opinion
Ballooning	Cost of supporting products	All Health States	■	Nørtoft2019 subgroup analysis (CIC)
Ballooning	Weekly bag use increase	All Health States	3.75	Change added during the night for 50% of patients
Ballooning	Cost all types of visits to CNS for Ballooning	All Health States	90.33	NHS cost reference (inflation to 2023), Expert opinion
Pancaking	Cost of supporting products	All Health States	■	Nørtoft 2019 subgroup analysis (CIC)
Pancaking	Bag use increase	All Health States	5.25	50% of patients doubling the use
Pancaking	Cost all types of visits to CNS for Pancaking	All Health States	167.13	NHS cost reference (inflation to 2023), Expert opinion
Discreetness, appearance and comfort	Cost all types of visits to CNS for discreetness, appearance and comfort	All Health States	167.13	NHS cost reference (inflation to 2023), Expert opinion
Hospitalisation	QALY decrement due to hospitalization	All Health States	0.00	Mohiuddin 2021
Hospitalisation	QALY decrement for re-operation	All Health States	-0.25	Dossa 2020
All indications	Cost of average 1 piece bag	All Health States	3.02	Average cost bag for a colostomy from the Bennet Institute
All indications	Cost of cheapest 1 piece flat bag	All Health States	1.85	Alliance Opus NaturFit bag
All indications	Cost of cheapest 1 piece convex bag	All Health States	2.30	Alliance Opus NaturFit convex bag

Complication	Parameter type	Health State	Value	Source
Other inputs	Willingness-to-pay threshold (£ per QALY)	All Health States	20000	Assumption
Other inputs	Number of episodes reduction (intervention vs comparator)	All Health States	0-100%	Assumption
Other inputs	Treatment Times (weeks) & Source			
Other inputs	Discreetness, appearance and comfort	All Health States	3.00	CNS in stoma care assumption
Other inputs	Ballooning	All Health States	3.00	CNS in stoma care assumption
Other inputs	Pancaking	All Health States	3.00	CNS in stoma care assumption
Other inputs	Cost per CNS consultation	All Health States		Berger (2018), EAG consultation with CNS in stoma care, Rolls (2023)
Other inputs	Cost per bag for comparator (cheapest bag)	All Health States		Bennett Institute 2023, Lowest cost 2023, Scotland cost 2023
Other inputs	Cost per bag for wastage (average bag)	All Health States		Bennett Institute 2023, Lowest cost 2023, Scotland cost 2023

Abbreviations: CIC, commercial in confidence; CNS, Clinical nurse specialist; EAG, external assessment group; HCP, health-care professional; PIB, pain, itching and bleeding; PSC, peristomal skin complication; QALY, quality-adjusted life-year; RCT, randomised controlled trial; RU, resource use

APPENDIX J – EXPANDED CLINICAL EVIDENCE BASE

Introduction

Due to the paucity of evidence identified for the effectiveness of 1-piece closed bags for adults with a colostomy and as part of its assessment, the EAG considered some evidence that did not meet the clinical review inclusion criteria but may be considered to be useful to decision-making. This included:

- Evidence from patient-reported outcomes (PROs) that did not appear to have been externally validated
- [REDACTED]
[REDACTED] Evidence from a study that was only available as an abstract without any accompanying slides or poster, where results and additional information was available from the clinicaltrials.gov.uk website.

The limitations of this evidence are discussed within the main body of the report.

Due to a paucity of evidence identified that evaluated 1-piece closed bags for adults with a colostomy in line with the NICE scope for this assessment, the EAG explored several additional sources of evidence that were not included in the initial evidence review:

- Evidence for the effectiveness of 2-piece closed bags for adults with a colostomy.
- Studies comparing mixed interventions (i.e. outcomes with a 1-piece closed bag compared to outcomes for a mix of different 1-piece bags).

As these evidence types were not selected during screening in the clinical effectiveness review, a decision was taken to identify this evidence from company RFIs. As companies were asked at the time to provide all of the evidence for both 1- and 2-piece bags, it was expected that the RFIs would therefore be a reasonable method for identifying the key evidence.

This section reports the expanded evidence base for 2-piece closed bags and studies with mixed comparators identified from company RFIs to this assessment. As the EAG report was largely complete at the time that the evidence was included, the findings are reported separately in this appendix.

In the sections below, the EAG first presents feedback from CNS in stoma care about the generalisability of evidence from 2-piece closed bags for adults with a colostomy to the NICE scope for this assessment. Following this, a summary is provided of how evidence from studies with mixed comparators may be interpreted, since the results of these studies and their relevance to the decision problem is particularly complex. The EAG then presents the results of the expanded evidence base and its conclusions about this evidence as relates to this assessment.

Feedback from CNS in stoma care

In 1-piece closed bags, the baseplate that attaches to the skin and the bag are combined into one, whereas these are separate for 2-piece closed bags. People with a 2-piece closed bag will leave a baseplate attached to their skin and change their bag several times before changing the baseplate, while people with a 1-piece closed bag change their baseplate every time they change their bag.

CNS in stoma care were asked about the generalisability of the evidence for 2-piece bags in relation to bag features and whether there was a difference between the populations in relation to baseline risk.

Responses from CNS in stoma care about the populations, both from the EAG's experts and as additional comments from SCMs, suggested that there may be some differences between the people who choose 1- and 2-piece closed bags. Mostly, however, these were more about lifestyle choice and personal preferences. For example, feedback from CNS in stoma care was that someone may prefer a 2-piece bag because it allowed for faster bag changes when in public, and that there were benefits for sleeping, intimacy, work and travel. The responses suggested that there may be some clinical differences between people using 1- and 2-piece closed bags, such that people with visual or dexterity impairments may prefer 2-piece bags, and that they may also be preferred in people who are supported by carers in changing their bag. In addition, people who need to change their bags more frequently may prefer 2-piece bags, due to them being easier to change. Overall, the EAG did not consider that there were major population differences between the people choosing 1- and 2-piece closed bags. Moreover, one CNS in stoma care noted that, in her service, they were encouraging more people with a colostomy to consider a 2-piece bag, due to some of the practical benefits these offer. If this trend is observed more broadly, then evidence in a 2-piece population may therefore become more applicable in the target population.

CNS in stoma care did, however, note some ways in which baseline risk for scoped outcomes and the effectiveness of bag features may vary across the populations using 1- and 2-piece closed bags. In some cases, feedback was conflicting across experts and was therefore considered to be inconclusive. In brief:

Differences in baseline risk between adults with a colostomy using 1- and 2-piece closed bags

CNS in stoma care noted that people using 1-piece closed bags may have a higher risk of PSC due to the impact of more frequent bag changes on the skin surrounding their stoma. There were inconclusive views on the risk of leakage: some respondents suggested that leakage would be comparable, but one expert suggested that people using a 2-piece closed bag may have a higher risk of leakage, due to the 2-pieces of the bag being incorrectly connected or the baseplate sitting on the skin for longer. They further noted that any increased risk of leakage would have consequences for skin health.

Experts considered that the risk of ballooning and pancaking was likely to be the same in people using 1- and 2-piece closed bags, although two experts discussed how these complications may be easier to manage with a 2-piece bag and so may have a reduced impact on the lives of people using 2-piece closed bags.

It was noted that people using a 2-piece closed bag may have more positive views about the acceptability of their bag and may have a higher quality of life, due to the reduced impact of bag changes on their lives. Although a caveat to this, mentioned by one expert, was that some people may not like the way that 2-piece bags protrude more as compared to the 1-piece bags.

Differences in the effectiveness of bag features between adults with a colostomy using 1- and 2-piece closed bags:

While the baseplate of a 2-piece bag is changed less frequently, the EAG was unsure whether people with a 2-piece bag would change the bag component with the same frequency as people with a 1-piece bag. Evidence on this was not sought as part of the main assessment. One expert noted that any difference in the frequency of bag change between the two populations may impact on their similarity in effectiveness for some features (e.g. filters that are more effective when the bag is first applied)..

- *Baseplate additives* (e.g. alginate, ceramide, manuka honey, vitamin E): **inconclusive**. Two experts considered effectiveness to be the same, while two experts suggested that they may be more effective as they sit on the skin for longer.
- *Different baseplate shapes* (e.g. flower shaped, oval shaped, tapered): **inconclusive**. One expert considered this feature to be as effective in a 1- or 2-piece bag while one thought that it would have different effectiveness due to the more frequent baseplate changes with 1-piece bags.
- *Different baseplate adhesives*: **inconclusive**. One expert considered that the adhesive would have the same effectiveness while two experts considered that adhesives would have different effectiveness due to the more frequent baseplate changes with 1-piece bags.
- *Different bag shapes*: **no difference**. Two experts said that bag shape would be as effective in 1- and 2-piece bags.
- *Different types of filters*: **no difference**. Two experts said that the filters should be as effective in 1- and 2-piece bags, while one expert said that this would only be the case if the bags were changed as frequently.
- *Different type of bag material*: **no difference**. Two experts considered that a different type of bag material would be as effective in 1- and 2-piece bags, although one noted that this would be dependent on whether people with each bag type were changing their bags as frequently.
- *Flushable disposal*: **no difference**. Two experts considered that flushable devices would have the same effects for 1- and 2-piece bags.

Conclusion of the feedback from CNS in stoma care

The EAG considered that the issue of whether adults with a colostomy using 1- or 2-piece closed bags have comparable baseline risk for scoped outcomes and will have similar outcomes from bags with the same feature is complicated and challenging for experts to provide detailed advice.

Based on the responses from experts, the EAG considered that evidence for bag shape, filters, bag material and flushable disposal may be largely comparable between 1- and 2-piece closed bags. However, the EAG noted that there may be differences in the impact of ballooning and

pancaking arising from filter function, which may lead to poorer generalisability between outcomes (e.g. measures of the impact of ballooning).

The EAG considered that evidence for baseplate additives, baseplate adhesives, and baseplate shapes may or may not be comparable between people with 1- and 2-piece closed bags. Specifically, there may be a lack of generalisability for the following outcomes, largely due to the different frequency with which people with 2-piece closed bags change their baseplate: PSC, leakage, use of medicines to manage complications, and supporting product use.

Finally, the EAG considered the feedback to suggest that people using 2-piece closed bags may have higher perceived acceptability and satisfaction with their devices, and potentially higher HRQoL at baseline. This should be considered when interpreting evidence on study outcomes relating to these outcomes.

Direct comparability of 1- and 2-piece closed bags for adults with a colostomy

CNS in stoma care said that many features of 1-piece closed bags were also included in 2-piece closed variations of the same bag. However, as 2-piece closed bags were not included in the final scope for this assessment, companies were requested to provide information about the potentially innovative features of their 2-piece closed bags in RFIs but were not asked additional questions by the EAG during the assessment. For this reason, and due to difficulties in determining the potentially innovative features of 1-piece closed bags for people with a colostomy from published materials (more information on this is provided in Section 2), the EAG did not have a record of the innovative features of 2-piece closed bags evaluated in the expanded evidence base. One of the 2-piece closed bags (SenSura, Coloplast) evaluated in the included evidence used the same branded name as a 1-piece closed bag. The Coloplast RFI states that the 2-piece version has the same features, except for the addition of the mechanical coupling components. The EAG also considered it plausible that there are variations between 1- and 2-piece closed bags to account for the baseplate sitting on the skin for longer. Other 2-piece closed bags evaluated in the included evidence did not share brand names with the 1-piece closed bags listed on the NHS Drug Tariff (or were variations on the brand names for 1-piece closed bags). The EAG was therefore uncertain to what extent evidence for these bags was generalisable to the effectiveness of 1-piece closed bags for people with a colostomy.

Of the three studies included that evaluated 2-piece closed bags for adults with a colostomy, two studies were designed with the aim to evaluate specific features of 2-piece closed bags

(modified adhesive). In these cases, the EAG considered that the evidence may be generalisable to understanding the effectiveness of the same feature in a 1-piece closed bag, when accounting for the potential impact of other variations in features between 1- and 2-piece bags. However, the EAG was uncertain to what extent the features evaluated were relevant to features present in any 1-piece closed bags available on the NHS Drug Tariff.

Interpreting evidence from studies with mixed comparators

Studies with a mixed comparator were not included in the initial review. The key rationale for this was that where studies include a range of different bags as comparators, they cannot generate relative effect estimates that can be associated with a specific feature or set of features. Examples of these studies excluded from the initial review include:

- Studies that compared outcomes from a 1-piece closed bag with a mix of other 1-piece closed bags that were not named. Examples included single-arm studies that measured participants outcomes at baseline with their usual bag and compared these with outcomes following the same 1-piece closed bag. In these cases, it appeared as if the participants were using many different types of bags at baseline, and the bags used were not named or were listed by company name only.
- Studies that compared outcomes from a 1-piece closed bag with two or more closed bags that were named but where these differed from each other. Examples included crossover studies where participants could use one of several different bags during the comparator phase, presumably based on prior use or patient preference, and the comparator bags had different features from each other.

[REDACTED]

The expanded evidence base presented herein includes the two types of studies (studies evaluating 2-piece closed bags and studies with a mixed comparator) previously excluded from

the evidence review. The EAG considered the evidence base from these studies could be interpreted as follows:

Absolute data in these studies (i.e. outcomes reported specifically for each bag) could be compared with the same outcomes for 1-piece closed bags in the main evidence review. It should be noted that when analysing absolute data, you use the scores for each bag separately, and compare these with outcomes that were reported in different studies, using potentially different study designs and populations. Differences in study designs and populations between studies would be expected to influence the comparability of the outcomes, and this should be taken into consideration in addition to noting the differences between 1- and 2-piece bags.

Relative data in these studies (i.e. outcomes that compare the effectiveness of bags with the mixed comparator) would be unable to determine the magnitude or direction of effect of any bag or bag feature, as this may vary according to the different bags included in the comparator arm. For example, the bag being evaluated may be more effective than some bags used in the comparator arm and less effective than other bags in the comparator arm, and the relative effect would only provide an average of these differences. Depending on the comparator, however, it may be possible to draw some tentative conclusions from the evidence. For example, when compared with a mixed comparator of bags that participants had been prescribed and were continuing to use (i.e. it could be assumed that the previous bags were considered by CNS in stoma care to be appropriate for the participant and that participants were reasonably content with them), it may be possible to identify whether a new bag offers any additional benefits to these circumstances. The EAG cautioned that most studies with mixed comparisons did not provide this level of detail about the comparator arms, and whether any such comparisons would provide any meaning would depend on whether the populations in the studies were identifiable and relevant to clinical practice in the NHS.

Expanded evidence base clinical results

Consistent with the review protocol, risk of bias assessment was not conducted for the expanded evidence base, as these studies did not directly address the appraisal decision problem.

There were eight studies included in the expanded evidence base, including studies that evaluated 2-piece closed bags and studies that evaluated 1- or 2-piece closed bags in comparison with a mixed comparator.

Three of the eight studies were comparisons of 2-piece closed bags (Section 0), followed by five mixed comparator studies (Section 0). Within each section, studies are ordered by date (most recent first). Of the mixed comparator studies, ■ used a 1-piece closed bag, while the other ■ used a combination of 1- and 2-piece closed bags. Intervention and comparator bag names and manufacturers are listed in Table 46.

Table 46: intervention and comparator bags used in the expanded evidence base

Author and year	Reason for inclusion in expanded evidence base	Intervention and comparator bags
Welser 2009	2-piece closed bag	SenSura (Coloplast) Combihesive Natura (ConvaTec)
Arnaud 2008	2-piece bag (unclear if closed or drainable)	SenSura Flex (Coloplast) Esteem Synergy (ConvaTec)
Schröder 2007	2-piece closed bag	Easiflex (Coloplast) Esteem Synergy (ConvaTec)
■■■■■	■■■■■	■■■■■
■■■■■	■■■■■	■■■■■
Belfield-Cockings 2022	Mixed comparator	Genii flat (Trio Healthcare)
Sundberg 2012, and Rasmussen and Martins 2012	Mixed comparator	Sensura Mio (Coloplast)
DialogueStudy 2011	Mixed comparator	SenSura (Coloplast)

Evidence for 2-piece closed bags

Three studies were included in the expanded evidence base that evaluated 2-piece closed bags in adults with a colostomy. Key results for these studies are provided in this section.

SenSura vs Combihesive Naturea with Natura baseplate (Welser 2009)

Welser et al. (2009)⁸² was a crossover RCT performed in Germany (across eight centres). The 73 included participants were adults with a colostomy who normally used a flat 2-piece closed bag. Participants were excluded if they irrigated, were pregnant or breast-feeding, had been treated with chemotherapy or radiation therapy in the two months before the study or during the study, or were suffering from skin complications (bleeding or broken skin) around the stoma.

The aim of the study was to evaluate a 2-piece closed bag (SenSura by Coloplast) by comparing its performance to the Combihesive Natura® and Stomahesive® bag (ConvaTec). This appliance used the Natura® baseplate and standard opaque Natura® closed bags (maxi size) with carbon filter. The study was sponsored by Coloplast.

Follow up was 4 weeks. There were five reported dropouts: one due to pain when changing; one due to leakage; one did not like the coupling, and two not reported. Source data could not be verified for a further eight participants. Therefore, 60 of the 73 participants completed the study.

A variety of outcomes were reported in the study – these are summarised in Table 47. Ninety-eight percent of participants reported preferring the SenSura bag to the comparator bag (although it was not clear how the question was asked).

Limitations of this study included that more than two-thirds of the participants were already using SenSura at baseline, meaning that they were familiar with the bag and may be more likely to have a positive view of it. Randomisation and allocation procedures were not described, neither was the study blinded. Attrition rates were relatively high, and information was not available on the reasons given for some of the people who dropped out of the study. Finally, outcomes were often poorly reported, with the frequent use of bar charts without the concomitant reporting of numerical results in tables.

Table 47: Summary of results for Welser et al 2009

Outcome category	Definition of outcome	Results
Leakage	Poo under the flange	Significantly less seepage of poo under the flange was experienced with SenSura than with Combihesive Natura (p<0.05)
Length of time before switching baseplate *	Wearing time <i>Mean (SD) hours</i>	SenSura 55 (13) hours Natura 45 (20) hours
Number of or time to ballooning events	Frequency of ballooning	27% of participants experienced ballooning with SenSura

Outcome category	Definition of outcome	Results
	<i>Percentage of participants who experienced ballooning</i>	54% of participants experienced ballooning with Natura
Odour control	Odour <i>Percentage of participants bothered by odour problems</i>	13% of participants bothered by odour problems with SenSura 76% of participants bothered by odour problems with Natura
Intervention-related adverse events	Measured on a 6-point scale from 1 ('broken and bleeding skin') to 6 ('normal skin without redness')	Peristomal skin complications (PSC) 0–2cm from the stoma were significantly improved after using SenSura compared to Natura ($p<0.05$). There were no differences in skin conditions 2–4cm from the stoma after using the two appliances ($p=0.2$).

* This outcome was not in the scope, but comparable to a scoped outcome and considered useful to understand general wear time of the baseplate.

SenSura Flex vs Esteem Synergy (Arnaud 2008)

Arnaud et al. (2008)⁸³ was a crossover RCT of 46 patients (56.5% male with an average age of 68 years), reported as a conference abstract. Participants were eligible if they had a colostomy (≥ 3 months duration), normally wore 2-piece bags, did not have PSC and did not irrigate. It compared SenSura® Flex 2-piece stoma bag (with a 50 mm adhesive coupling [Coloplast]) with Esteem® Synergy 2-piece (with a 48 mm adhesive coupling [ConvaTec]). No information was given on whether bags were closed or drainable. The objective was to compare the performance and safety of the new SenSura adhesive coupling to that of a reference adhesive coupling. The study was sponsored by Coloplast.

The trial took place across 13 centres in France and had a follow up time of one week. Three of the 46 participants dropped out of the trial: one due to feeling that Esteem Synergy 2-piece was insecure; one due to withdrawal of consent, and one due to a serious adverse event (nephritic colic). It was unclear which device was being worn at the time of the serious adverse event.

The main outcomes were regarding odour control, adverse events and acceptability. The abstract reported that the Sensura Flex was associated with improved odour control compared to Esteem synergy: measured on a scale from 1 (not at all) to 5 (very much), 3 participants (7%) reported bad odour "much" or "very much" with Sensura Flex while 15 participants (33%) reported as such with Esteem Synergy 2-piece. Three participants reported device-related PSC while testing Esteem Synergy (skin irritation due to leakages; itching/redness; and a burning sensation) while none were reported with Sensura Flex. Finally, 74% participants reported preferring Sensura Flex over 26% who preferred Esteem synergy.

As this study was presented as a poster, limited details of the methods were available. Randomisation, allocation concealment and any attempt at blinding procedures were not described, and no information was given on the types of bags used (closed or drainable). Non-validated outcome scales were used for many outcomes (e.g. “very poor” to “very good”), which were challenging to interpret.

Easiflex vs Esteem Synergy (Schröder 2007)

Schröder et al. (2007)⁸⁴ was a crossover RCT of 66 participants (60.6% male with an average age of 62 years), reported as a conference abstract with an accompanying poster. Participants were eligible if they normally wore 2-piece closed bags, did not have PSCs and did not irrigate. None of the participants were pregnant or breast-feeding, nor had they been treated with chemo or radiation therapy during the study or in the two months before the study. The trial compared Easiflex 2-piece closed bags (Coloplast) vs. Esteem Synergy 2-piece closed bags (ConvaTec). The objective of the study was to compare the performance of the Easiflex adhesive coupling system to the adhesive coupling of a reference system. This comparison is therefore likely to be less relevant to understanding the effectiveness of 1-piece closed bags, due to using an adhesive coupling system rather than a mechanical coupling system.

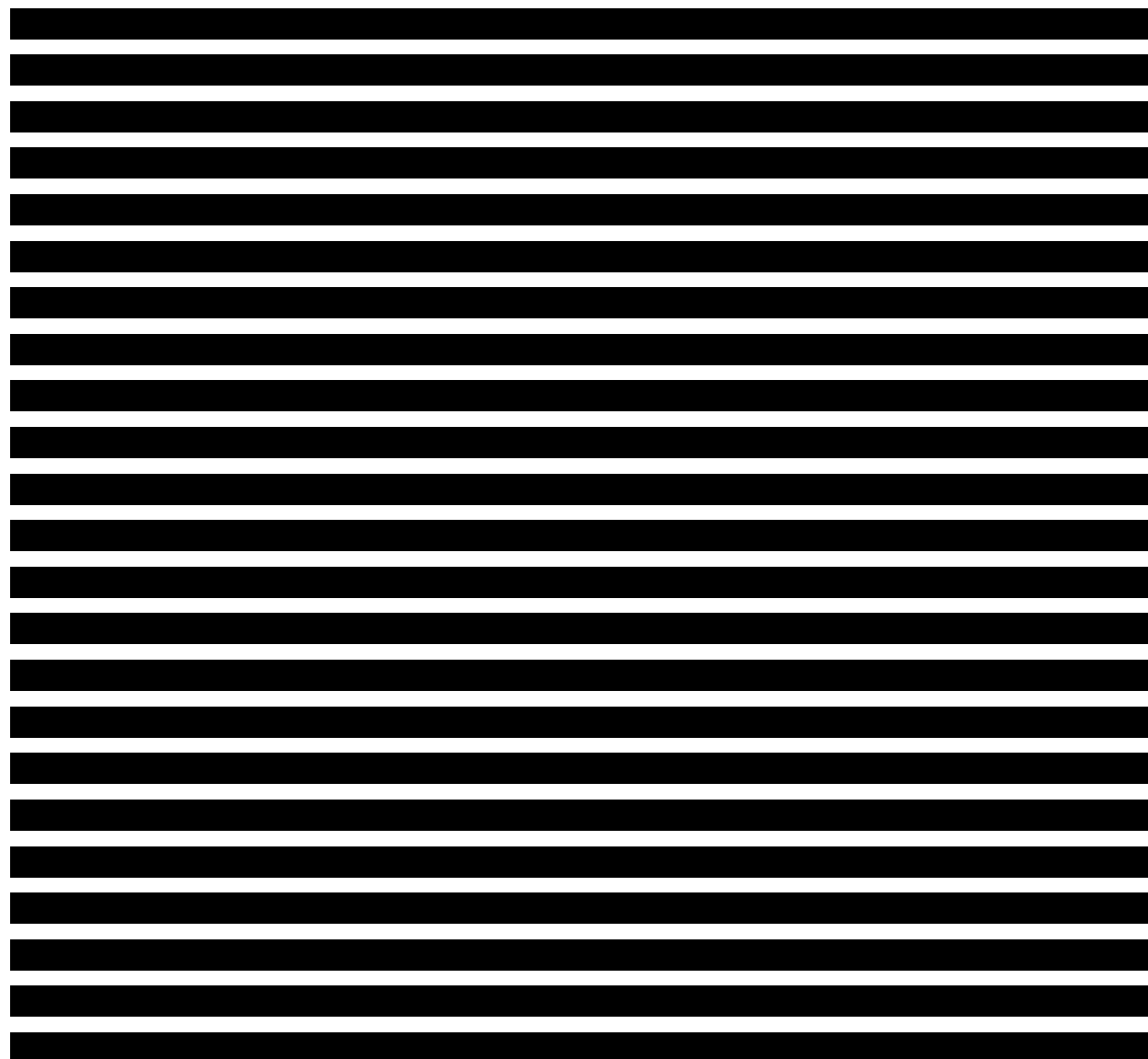
The trial took place in Germany. The follow up period was not stated, although each participant continued with each bag until five baseplates had been changed, in accordance with their normal changing frequency. The number of participants who did not complete the study was not reported.

The main outcomes were leakage, length of time before switching, and participants' acceptability for the bags. It was reported that Easiflex 2-piece closed bags were associated with reduced risk of leakage in the coupling (9% of participants) than Esteem Synergy 2-piece closed bags (21% of participants) and reduced risk of leakage under the baseplate (41% of participants with Easiflex 2-piece closed bags vs 57% of participants using Esteem Synergy 2-piece closed bags). The average wear time of the baseplate increased slightly for Easiflex 2-piece closed bags than for Esteem Synergy 2-piece closed bags (54 hours vs 48 hours), while the average wear time of bags was similar (9.5 hours for Easiflex 2-piece closed bags and 10 hours for Esteem Synergy 2-piece closed bags). Finally, 89% of the participants preferred using the Easiflex 2-piece closed bags to Esteem Synergy 2-piece closed bags (although it was not clear how the question was asked).

As this study was presented as a poster, limited details of the methods were available. Limitations included that randomisation and allocation were not described, and the study was not blinded. Study follow up was short – only for five baseplate changes. Finally, non-validated outcome scales were used for many outcomes (e.g. “very poor” to “very good”), which were challenging to interpret.

Mixed comparators

Five studies that evaluated 1- or 2-piece closed bags in comparison with mixed comparators were included in the expanded evidence base. Results for these studies are provided in this section.



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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Genii stoma bag vs mixed comparator (Belfield-Cockings 2022)

Belfield-Cockings (2022)⁸⁷ was a 6-week before and after study. The study was carried out and funded by Trio Healthcare. Sixty-four adults who had a colostomy (for at least nine months) were initially recruited for the study; although two dropped out before the trial began and one withdrew at week 4. Results were reported for 61 participants, all of whom were living in the UK. Participants were people who used a 1-piece closed bag (either flat or soft convex), had a protruding stoma (not bigger than 60mm), and did not have broken or bleeding skin.

The primary objective of the study was to investigate the effects of the Genii flat 1-piece closed bag on peristomal skin, compared with baseline. Secondary objectives included impact on quality of life and satisfaction with the bag. Bag use at baseline was not reported.

By the end of the study, 36% of participants experienced an improvement in their peristomal skin condition, 57% reported that their skin remained the same, and 6% reported a worsening of their skin. Forty nine percent of participants reported having a normal peristomal skin condition at the start of the trial (the remaining participants had “normal-to-mild”, “mild” or “mild to severe” soreness – none report “severe” soreness). The percentage of participants reporting “normal” skin improved to 69% by the end of the 6 weeks using the Genii 1-piece closed bag.

The authors reported that most study participants “*reflected an overall positive experience*” when using the stoma bag.

Limitations of the study included the use of a case series design. This may have limited validity and reliability, as case series are based on a small and non-representative sample, which may not be replicable or generalisable to other settings or populations. It was unclear how participants were identified and recruited. Non-validated outcome scales were used for many outcomes, including quality of life (e.g. “not at all” to “very much”), which were challenging to

interpret. Further to this, baseline scores for quality of life were not reported, hence without that context there were difficult to interpret.

SenSura Mio vs mixed comparator (Sundberg 2012 and Rasmussen & Martins 2012)

Sunberg et al. (2012)⁸⁸ and Ramussen and Martins (2012)⁸⁹ are two posters that report outcomes for the same trial. The Sundberg et al poster described the four-week, randomised (by country) crossover study of the Sensura Mio 1-piece closed bag vs. standard care, a mixed comparator of 1-piece closed bags, including SenSura (Coloplast), Nova 1 (Dansac), Moderma/Moderma Flex (Hollister), Esteem (Convatec) or Softima (B. Braun). The trial was sponsored by Coloplast. The study was conducted in four countries: Germany (n=33), Netherlands (n=43), France (n=22), and Norway (n=24). Participants (N=144) were adults with a colostomy who currently wore 1-piece closed bags. Peristomal skin condition was assessed at three visits using the DET score. Overall, there was an improvement in DET score when using SenSura Mio and a significant difference when compared with standard care (-0.277, p<0.05).

Ramussen and Martins (2012)⁸⁹ used data from Sunberg et al. to report on the effect of treatment costs of the SenSura Mio 1-piece closed bag compared with standard care. Ramussen and Martins reported that 44% of participants in Sunberg et al. went from having a PSC to normal skin (measured as DET = 0) after using SenSura Mio. In comparison, 22% of standard care users went from having a PSC to normal skin. At study end, the authors reported that mean DET score was improved after use of SenSura Mio (mean DET = 1.4) whereas it was worsened after use of standard care (mean DET = 1.6). From this, the authors calculated that using the SenSura Mio 1-piece closed bag translated into a 33% decrease in cost associated with treating PSCs. However, the difference in DET score was small, no minimal clinically important difference in DET score was stated, and no standard deviation or other range was provided. The EAG was therefore uncertain whether the change represented a meaningful difference or that it could be used to justify the proposed cost reduction.

As this study was presented as a poster, limited details of the methods were available. Limitations noted included that randomisation was by country and the study was not blinded. Non-validated outcome scales were used for some outcomes (e.g. “very poor” to “very good”), which were challenging to interpret.

SenSura vs mixed comparator (DialogueStudy 2011)

The DialogueStudy (2011)^{20,90-92} was an open label, non-comparative, study set up to document real-world experience of the SenSura stoma bag (Coloplast) with a focus on HRQoL and PSCs. The study was large, with 3017 participants with a stoma (2015 of which, 67%, had a colostomy), across 379 centres in a variety of countries – at least one centre was in the UK. Participants were included if they were adults, at least 18 years of age, with a stoma for at least six months. Results were reported for the subgroup of people with a colostomy. People were excluded if they had more than one stoma, used a plug, irrigated, were pregnant or breast feeding, or participating in another study. The mean age of participants was 63.2 years, and 49% were male. The study compared participants outcomes at baseline with a follow-up of six to eight weeks (± 4 days). The model and make of bags used at baseline bag was not reported. Sponsorship was not formally stated but a Coloplast employee was a co-author, acknowledgements were made to Coloplast employees, and it was noted in the text that some investigators will have received sponsorship or payment from Coloplast in relation to activities such as conference attendance or consultancy outside the DialogueStudy.

Outcomes reported for the DialogueStudy were on HRQoL, PSC, leakage, and intervention-related adverse events. Results were provided separately for people with a colostomy. Mean stoma-QoL score improved during the study period: it was approximately (estimated from Figure 1 in the report) 45.5 at baseline and approximately 49 at visit 2 (no SDs were estimable). PSCs improved between baseline and follow-up, as the DET score fell by 0.95 ($p < 0.001$), and the proportion of participants with a colostomy reporting that they had leakage 'always', 'often' or 'sometimes' fell from approximately 55% at baseline to approximately 35% at follow-up.

Adverse events were only reported for the entire pool of participants – i.e. not reported only for participants with a colostomy. Overall, 74 participants (2.5%) reported an adverse event, of which 17 were judged to be serious. None of the serious adverse events were related to the use of the double-layer adhesive used in the SenSura bag. Of the remaining non-serious events, 49 were considered to be 'possibly related' or 'related' to the double-layer adhesive used in SenSura. Most of these events (47%) were irritant contact dermatitis.

The authors acknowledged that the real-life setting in a number of countries may have led to a variation in the populations recruited. Also, that country differences in stoma care standards were likely to have affected baseline parameters, and that the study did not distinguish between the effect of the stoma care nurses and the use of the bag under investigation. The lack of

information on the model and make of bags used at baseline bag meant that little could be interpreted from the study about the relative clinical effectiveness of the SenSura bag.

Concluding remarks

Due to a paucity of evidence identified that evaluated 1-piece closed bags for adults with a colostomy in line with the NICE scope for this assessment, the EAG explored several additional sources of evidence that could be useful to decision-making. This appendix includes evidence for 2-piece closed bags evaluated in adults with a colostomy and evidence for 1 or 2-piece closed bags evaluated in comparison with mixed comparators.

Three studies were included that evaluated the effectiveness of 2-piece closed bags. All studies were head-to-head comparisons of 2-piece closed bags produced by Coloplast (SenSura, SenSura Flex, Easiflex) in comparison with bags produced by ConvaTec (Combihesive Natura and Esteem Synergy). All three studies were sponsored by Coloplast. Formal quality assessment was not conducted, as per the review protocol, although the EAG informally noted limitations in the studies. All studies were identified as having limitations that would suggest a risk of bias and limitations with generalisability of the evidence. Many of these issues were similar to those identified in the main evidence base, discussed in Section 5.3. All three studies reported differences in clinical and participant-reported outcomes between bags, with bags produced by Coloplast showing greater benefits. The three crossover RCTs of 2-piece closed bags reported improvements with the intervention bag in leakage,^{82,84} ballooning,⁸² odour control,^{82,83} and PSC.^{82,83} As noted in Section 0, companies provided information about their 2-piece bags in their RFIs but were not asked for further clarification about the features of their 2-piece bags by the EAG during the initial assessment. Due to this, the EAG did not have a record of the potentially innovative features of the evaluated 2-piece closed bags, the EAG was unable to draw conclusions about the associated between bag features and outcomes. As stated in Section 0, the EAG was also uncertain to what extent the evaluated 2-piece closed bags share similarities with 1-piece closed bags available on the NHS Drug Tariff for adults with a colostomy. Feedback from CNS in stoma care also suggested that there may be differences in baseline risk between people using 1- and 2-piece bags and that the effectiveness of features may not be the same between these bag types. Absolute outcomes for 2-piece closed bags were broadly comparable with absolute outcomes for 1-piece closed bags evaluated in the evidence review, where these comparisons could be made (this was often hindered by the fact that outcomes were often measured slightly differently between studies). Overall, the EAG

considered that there were uncertainties around the generalisability of this additional evidence to the decision problem.

The studies with mixed comparators consisted of [REDACTED]. All studies were sponsored by companies that produce stoma bags (Coloplast [REDACTED], [REDACTED] Trio Healthcare). As with studies evaluating 2-piece closed bags, formal quality assessment was not conducted, however limitations in outcome assessment were noted. In most cases, the performance of the evaluated bag was compared with the bag that participants were typically using prior to the study. This is a limitation because participants were using a variety of different bags prior to the study, meaning that the study is not a direct comparison between two different bags. In one study,⁸⁷ all participants were experiencing PSC at baseline and the objective of the study was to determine outcomes after participants were changed to the Genii 2-piece closed bag. However, as the study did not report which bag or bag features participants were using prior to the start of the study, it was unclear what change in bag feature(s) was driving any difference in PSC after using the Genii 2-piece closed bag.

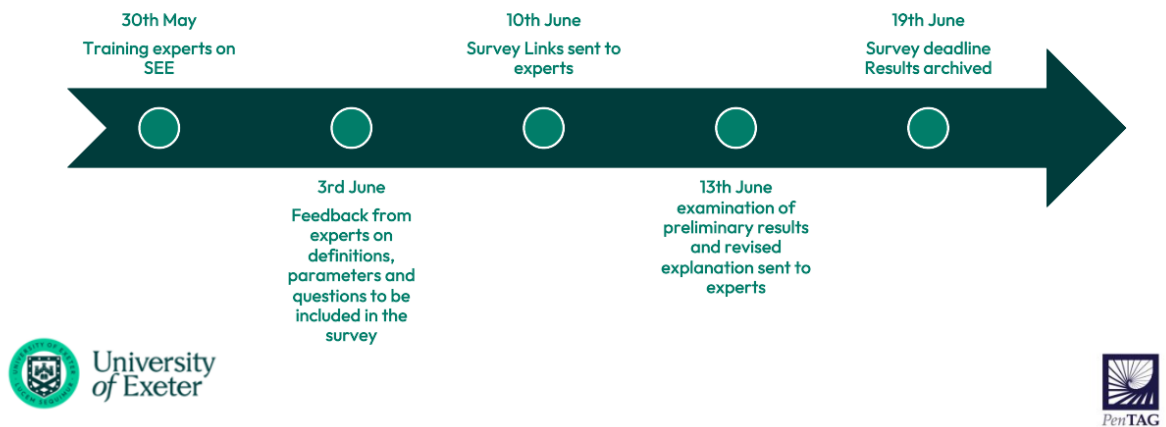
[REDACTED]

[REDACTED]. As the evaluated 2-piece bags were not compared to a known or fixed counterpoint, the EAG was unable to draw conclusions about the likely direction or magnitude of benefit that the evaluated bags could have for people with a colostomy in clinical practice.

Appendix K – Additional Information from Structured Expert Elicitation

The following appendix includes the pooled data from the first stage of structured expert elicitations, along with the rationales provided by the experts during the elicitation exercise before receiving additional explanations in the meeting to discuss the additional results. In the second stage additional explanation was provided and the EAG asked the experts to review their initial values to determine if they were still satisfied with them. Specifically, we sought to confirm whether the values they provided aligned with their rationales and whether these values truly represent where they believe the true value lies

Timeline



Experts

- Seven of the nine experts invited completed the exercise
- Those who completed the exercise had 11.5 years of experience on average
- Two of our experts worked in tertiary care, two worked in secondary care, one in community health, and one in higher education.
- Three of our experts are band 8 nurses, three are band 7, and one chose not to answer
- Our experts manage an average of 13 colostomy patients per week
- We excluded the answers from two of the seven experts for the disutility questions as they provided very high estimates and did not respond when contacted with a revised explanation of disutility



Patient population and evidence pack

- We provided you with data that we believe best represents the characteristics of a typical colostomy patient in the UK, based on information from published sources.
- The factors to be considered are the duration since the surgical procedure, the reasons for patients requiring a colostomy, their age, and the frequency of complications and skin complications. The anatomy of the skin around a stoma and the likelihood of hospitalisation resulting from peristomal skin complications
- The negative impact (disutility) associated with to different frequencies of leakage and the severity level of peristomal skin problems



Disutilities in the literature

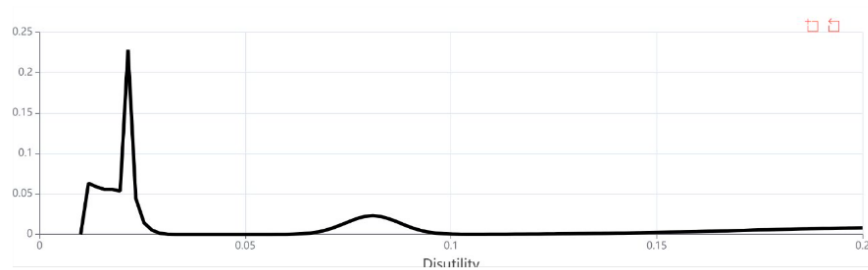
Complication	Disutility
Peristomal skin complications: mild level of pain, itching and burning (2/10); no bleeding or ulcers	0.025
Peristomal skin complications: weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers	0.112
Peristomal skin complications: bleeding or ulcers and a moderate level of pain, itching and burning (5/10)	0.161
Peristomal skin complications: bleeding or ulcers and a severe level of pain, itching and burning (8/10)	0.287
Leakage onto clothes: 4 events/month	0.114
Leakage onto clothes: 1 event/month	0.057
Leakage onto clothes: 1 event/ 6 months	0.022
Disutility of symptomatic peristomal hernia	0.086
Disutility of hospital stay after peristomal hernia surgery (equal to the average hospital stay after hernia surgery in England)	0.083



Disutility of long-term complications such as bowel obstruction, bowel perforation, infection, haematoma and nonhealing wound may occur following bowel surgery and stoma creation for 22 days	0.090
PSC Mild Mild skin irritation: characterised by occasional reddening and irritation caused by stomal discharge or adhesives	0.0480
PSC Moderate Moderate skin irritation: characterised by always being reddened or irritated by stoma discharge or adhesives, and occasional but slight blistering	0.0940
PSC Severe Severe skin irritation: characterised by skin that is always blistered or damaged, where blistering often results in denuded skin caused by the mechanical process of repeated application and removal of an ostomy appliance	0.1240
Mild PSC a Discoloration, Erosion, Tissue overgrowth [DET] instrument score <4)	0.0570
Moderate PSC Discoloration, Erosion, Tissue overgrowth DET score >4 and <7	0.1070
Severe PSC Discoloration, Erosion, Tissue overgrowth DET score ≥7	0.1650

Ballooning disutility

The average disutility of Regular (daily) ballooning for an average patient one year post surgery is 0.058 (SE = 0.0019)



Question: Happy with final figure given other available utilities? We have one outlier, but responses justify this

Rationales given

- Expert 1 “Ballooning has a lower impact on QoL”
- Expert 2 “I do not think this problem will cause people to report a significant reduction in their perceived quality of life”
- Expert 3 “Ballooning is embarrassing potentially as it makes the stoma bag visible by bulging on the abdomen but at home this might not be an issue or with certain clothing it might be less visible”
- Expert 4 “Ballooning is not a concern that my cohort of patients presents with often, it is more likely an issue that is secondary to other issues such as pancaking but on its own is mildly concerning for some”
- Expert 5 “Ballooning may occur quite often, and it affects patient quality of life as they worry about clothing, diet, the bag being visible”



Pancaking disutility

The average disutility of Regular (daily) Pancaking for an average patient one year post surgery is 0.162 (SE = 0.0039)

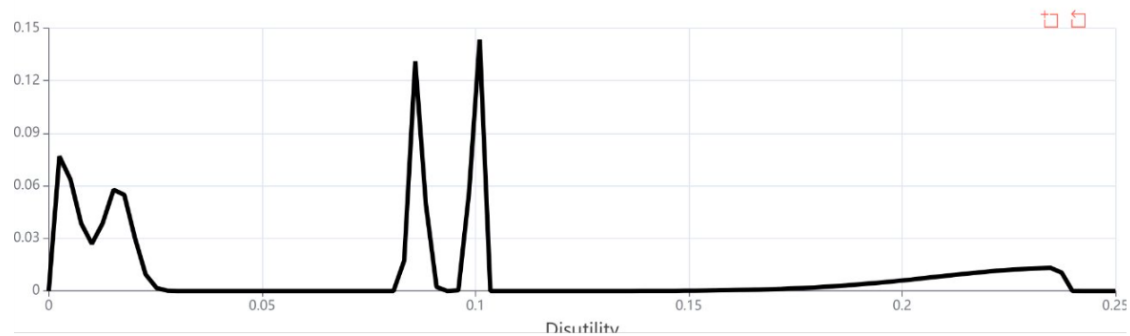


Rationales given

- Expert 1 “Pancaking daily could cause a small disutility, but this will vary”
- Expert 2 “There are degrees of pancaking, sometimes it causes leaks which would be distressing, sometimes it doesn't cause any further problem and is only a nuisance”
- Expert 3 “pancaking can lead to poo on the skin which can irritate/damage the skin and risk of smell”
- Expert 4 “Pancaking is a huge and under-resourced or solvable issue which affects most colostomates”
- Expert 5 “pancaking may be very debilitating to patients as it may cause leakages, skin damage “

Bad odour disutility

The average disutility of Regular (daily) bad odour for an average patient one year post surgery is **0.082 (SE = 0.002)**



Question: Happy with final figure given other available utilities? There appear to be two schools of thought here in terms of impact

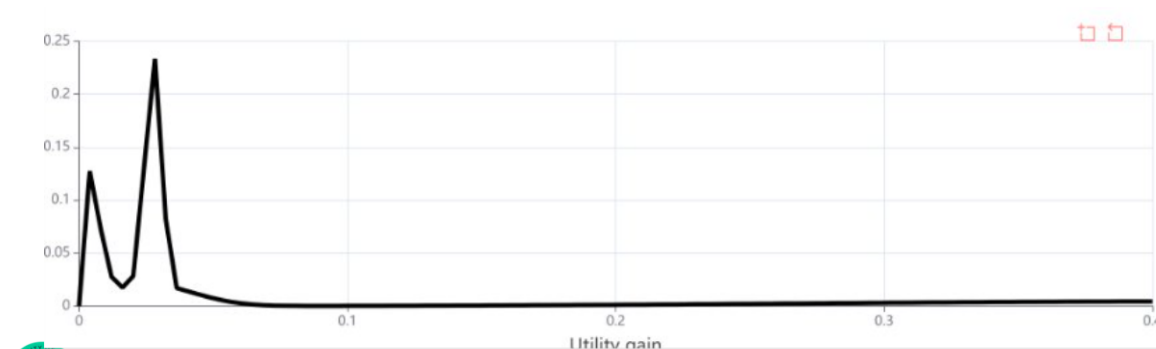
Rationales Given

- Expert 1 “Daily bad odour will small loss of QOL but will also vary “
- Expert 2 “I think odour is likely to cause a reduction in health utility”
- Expert 3 “smell is a big issue unless living alone”
- Expert 4 “Again odour is often associated with pancaking, and/or leaks, so the disutility is lower and as colostomy patients change their pouches more often filter malfunction should be less. that is not to say the idea or chance that there is odour is not enormously impactful but not something established patients present with”
- Expert 5 “odour is likely one of the complications that may affect patients QOL and wellbeing the most, as they constantly worry about it, thinking that others will know they have a stoma, and therefore, they may isolate from people “



Discreet bag / preferred appearance utility gain

The average utility gain from a discreet bag design with preferred appearance for an average person with a colostomy one year after surgery is **0.077 (SE = 0.004)**



Question: Again, two schools of thought here. Additionally, could this be extended to comfort?

Rationales given

- Expert 1 “I expect a small gain with discreet pouch”
- Expert 2 “I think this will have relatively low impact on healthy utility, but I think this may be related to other factors such as patient age and whether they work, relationship status etc”
- Expert3 “there are potential ways to disguise a bag”

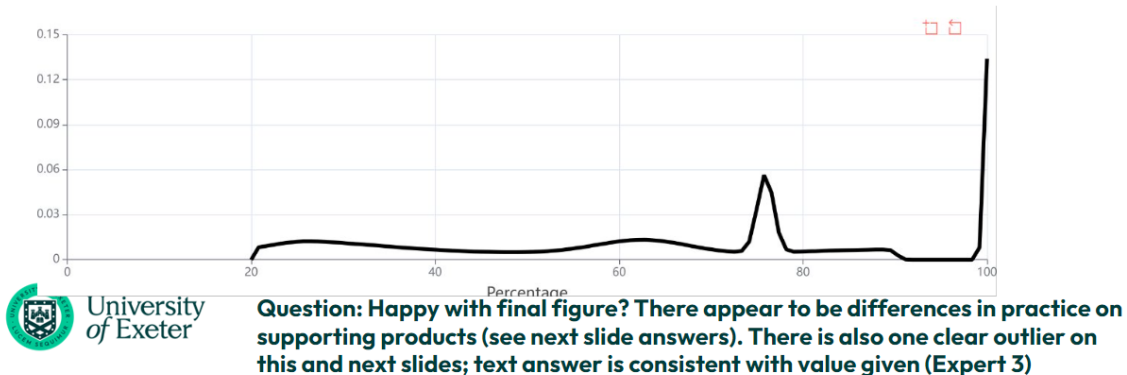
Expert4 “The value of choice and the perception of 'preferred' appearance cannot be underestimated. Once established and competent the patient will wish to make choices about pouches that they feel affords them the added QOL and aspirational elements, but the utility gained is not significant in health terms”

Expert 5 “patients fear non discreet bags as they worry others will know they have a bag”



Switching: Leakage onto clothes

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Leakage onto clothes 4 times per month is 61.7%



Rationales given

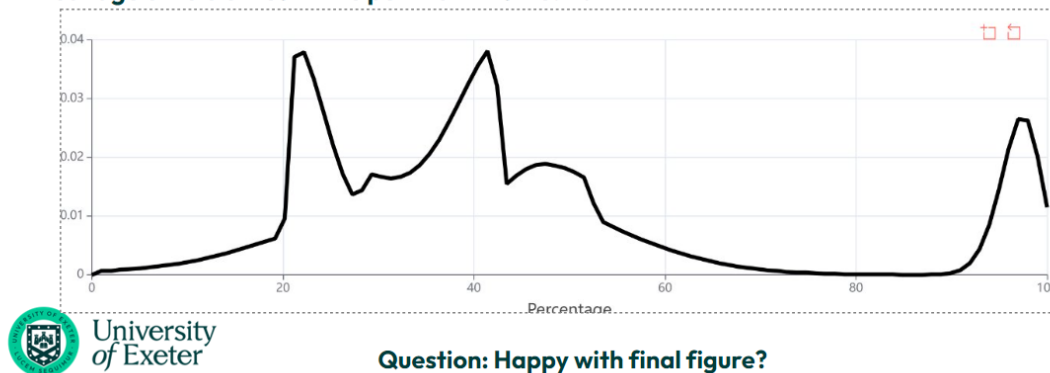
- Expert 1 "It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag"
- Expert 2 "Larger percentage likely to add in an accessory if familiar and happy with current bag"
- Expert 3 "A high chance (75%) of patients changing bag due to leaks of 4 times per month"
- Expert 4 "This is challenging, leakage is enormously impactful so patients would seek active measures to address this, but equally patients are often very trusting of existing pouches and may not wish to change so would add products or try alternative steps"
- Expert 5 "leakages may have devastating affect on patients QOL, psychosocial health, wellbeing, as well as overall peristomal skin health"

Rationales given

- Expert 6 “i think that the first option would be to choose an add on product or change to convex (depending on issue), changing to a new bag maybe if want different size, two-piece etc”
- Expert 7 “Leakage this often is likely to be a significant problem to the person and will impact on many areas of life”

Switching: Leakage onto clothes

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Leakage onto clothes 1 time per month is 43.9%



Rationales Given

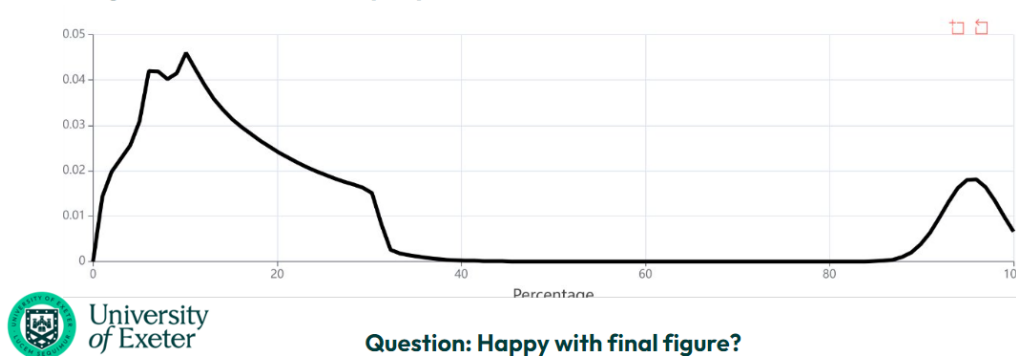
- Expert 1 “It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag.”
- Expert 2 “Less likely to change than with increased leakage events”
- Expert 3 “Most people would find this unacceptable, but may be contingent on age, work/relationship status and other factors”
- Expert 4 “i think less chance of changing bag if less leakage”
- Expert 5 “Patients used to and trusting a pouch would be unlikely to change that for leakage this 'infrequently’”

Rationales Given

- Expert 6 “it is less likely for patients to switch if leakages happen less often”
- Expert 7 “A lot of stoma patients would put up with leaks of once monthly and would remain on the same bag.”

Switching: Leakage onto clothes

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Leakage onto clothes 2 times per year is 25.1%



Rationales given

- Expert 1 "It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag"
- Expert 2 "Less likely to switch bag"
- Expert 3 "Even infrequent leaks will impact on mental health and fear of a leak."
- Expert 4 "Low change due to infrequency."
- Expert 5 "i don't think people would often choose a new bag over an add on"

Rationales given

- Expert 6 “This level of leakage is sadly accepted by many ostomates and would unlikely lead to seeking help or change”
- Expert 7 “if a bag leaks a patient would like to change it, though it may be less likely if leakages occur less often”

Bag switching PSC

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change: Peristomal skin complications - **mild level of pain, itching and burning (2/10); no bleeding or ulcers 29.9%**



Rationales given

- Expert 1 "It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag"
- Expert 2 "More likely to add accessory for mild"
- Expert 3 "Many people live with mild symptoms"
- Expert 4 "Fairly equal"
- Expert 5 "it is difficult to say- if the cause of the skin irritation was determined to be a reaction to the stoma bag then 100% change the bag but more likely related to poo so I dont think they would change unless due to pancaking maybe"

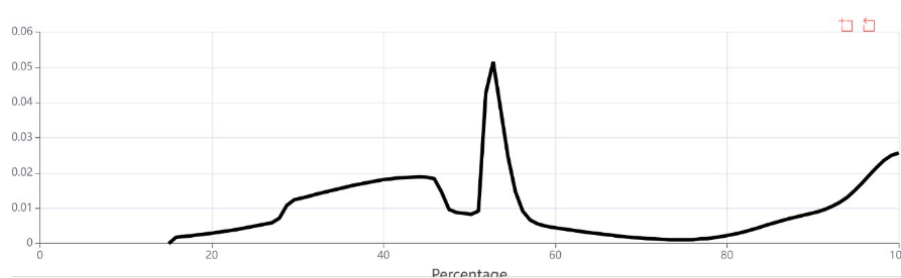


Rationales given

- Expert 6 "Again patients tolerate a lot for various reasons and have trust in a product so change or seeking help would be low on their agenda"
- Expert 7 "it is more likely to happen as the pain and complication level increases"

Bag switching PSC

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Peristomal skin complications - **Peristomal skin complications - moderate level of pain, itching and burning (5/10); no bleeding or ulcers 58.2%**



University
of Exeter

Question: Happy with final figure?

Rationales given

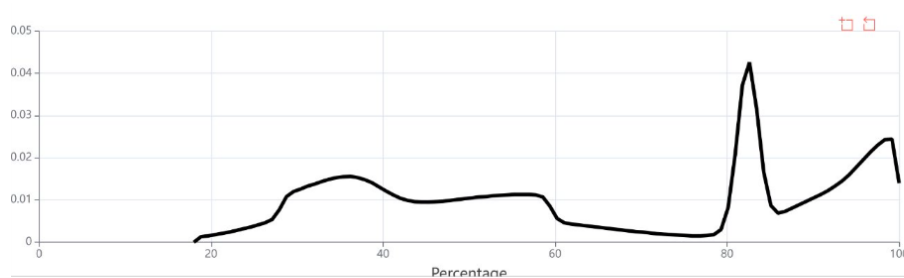
- Expert 1 "It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag"
- Expert 2 "More likely to change type of bag pain with these peristomal skin issues"
- Expert 3 "60/40 probability"
- Expert 4 "it is possible they might change if there is the need for convexity"
- Expert 5 "Some people put up with these issues rather than seek help."
- Expert 6 "Moderate PSC elicits seeking solutions but still less likely to change product but seek alternative/add on solutions."
- Expert 7 "Moderate PSC elicits seeking solutions but still less likely to change product but seek alternative/add on solutions"



University
of Exeter

Bag switching PSC

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Peristomal skin complications - bleeding or ulcers and a moderate level of pain, itching and burning (5/10) 63.25%



University
of Exeter

Question: Happy with final figure? Very little difference in impact between bleeding/ulcers and weeping skin for the same pain level

Rationales given

- Expert 1 "It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag"
- Expert 2 "Likely to try a new bag with these skin issues"
- Expert 3 "Most people would seek help with this issue"
- Expert 4 "Closer to 80% due to severity."
- Expert 5 "ulcers might be due to many different issues"



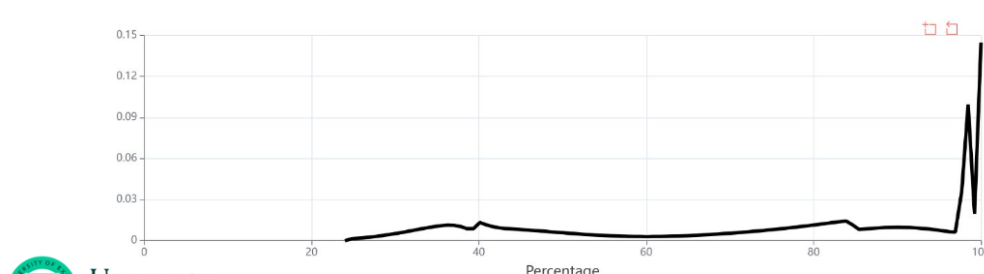
University
of Exeter

Rationales given

- Expert 6 “Bleeding and ulceration causes pouches to fail, patients seek help then and might elect to change their pouch. But some solution seeking may not be through a [SCN](#) and so additional products may be added but most people would seek help”
- Expert 7 “it is more likely to happen as the pain and complication level increases”

Bag switching severe PSC

- For an average person with a colostomy one year following their surgery, what's the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change: **Peristomal skin complications - bleeding or ulcers and a severe level of pain, itching and burning (8/10) 73.5%**



University
of Exeter

Question: Happy with final figure? Most consider a bag change would be required at this point

Rationales given

- Expert 1 “It is more likely a patient will add accessories or change to same brand but different baseplate or size of bag”
- Expert 2 “This would be an incapacitating issue requiring help”
- Expert 3 “High probability due to severity of the problem”
- Expert 4 “Very likely to change bag type”
- Expert 5 “it might not be first choice before the add ons”



Rationales given

- Expert 6 “The impact on QOL and managing everyday activities is much greater and so patients are likely to seek solutions and are more open to making the change, even if that is temporary, although some will still use additional products”
- Expert 7 “it is more likely to happen as the pain and complication level increases”

Bag switching: Ballooning

- For an average person with a colostomy one year following their surgery, the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Regular (daily) ballooning 59%

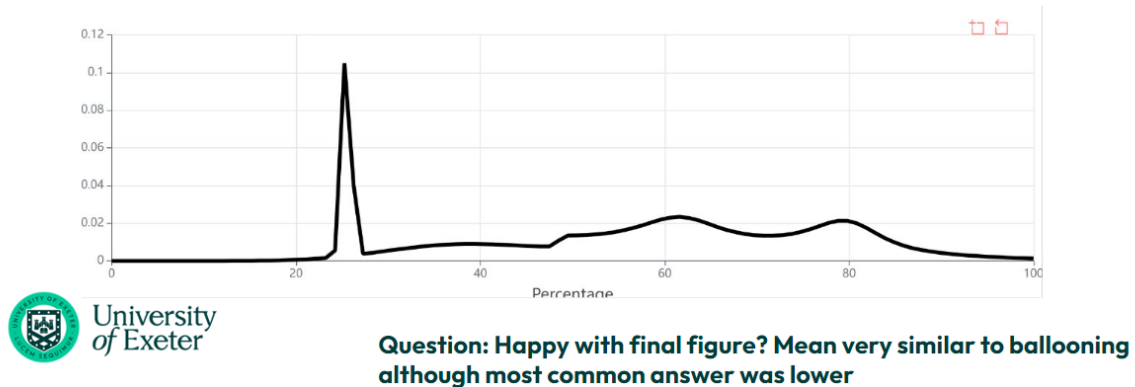


Rationales given

- Expert 1 "It is likely the filter for the brand does not work and they will need a different brand bags"
- Expert 2 "Possibility may use accessory more than change bag type"
- Expert 3 "It would depend how attached the person was to the existing pouch, they may strongly want to keep using it for reasons of appearance/discretion and so try and persist with additional products rather than changing the pouch."
- Expert 4 "50/50 of switching"
- Expert 5 "ballooning is a filter issue so i think a bag change is more likely"
- Expert 6 "Ballooning is not something that patients present with, so I am aware of my experiential bias but it does not appear in my practice"
- Expert 7 "very likely for patients to change the bag due to regular ballooning"

Bag switching pancaking

- For an average person with a colostomy one year following their surgery, the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Regular (daily) pancaking 56.5%

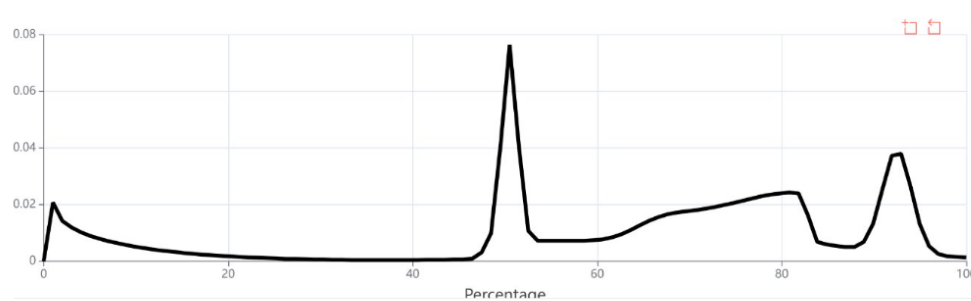


Rationales given

- Expert 1 "It is likely the filter for the brand does not work and they will need a different brand bags."
- Expert 2 "Possibility may use accessory more than change bag type"
- Expert 3 "my first treatment option would not be change the appliance but it is more likely than an add on"
- Expert 4 "Pancaking is an issue that affects many and a change of pouch is often the sought solution. I am just mindful that all these answers are dependant on whether the ostomate also seeks stoma nurse advice as the outcomes might differ eg looking for solutions oneself vis SoMed or forums or companies versus having expert advice form SCN"
- Expert 5 "Attitudes to and impact of this problem vary"
- Expert 6 "very likely for patients to change the bag due to regular pancaking"

Bag switching: bad odour

- For an average person with a colostomy one year following their surgery, the probability (Percentage) they would switch to a different bag (rather than using an add-on product) if they were experiencing the following complication and decided they needed to make a change:
Regular (daily) issues with bad odour 61.2%



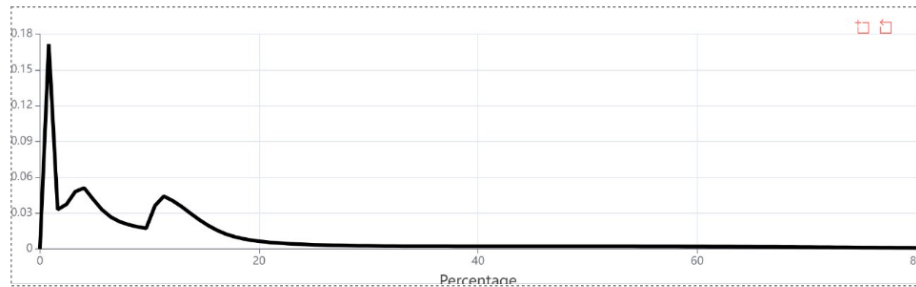
Question: Happy with final figure? Similar again to pancaking and ballooning

Rational given

- Expert 1 "It is likely the filter for the brand does not work and they will need a different brand bags"
- Expert 2 "Bad odour is likely to mean patients will change to a different bag"
- Expert 3 "Odour is a problem for some patients and not a problem for others"
- Expert 4 "odour might be filter related i think it is more likely to be a bag change than add on"
- Expert 5 "As previously stated not such an issue unless associated with pancaking"
- Expert 6 "very likely, as odour will seriously affect patient qol "

Skin complications hospitalised

- For an average person with a colostomy one year following their surgery, the probability (Percentage) they would: Be **hospitalised** if they were to experience peristomal skin complications **13.4%**



Question: Happy with final figure? Makes sense relative to data for first year post surgery (14%)

Rationales given

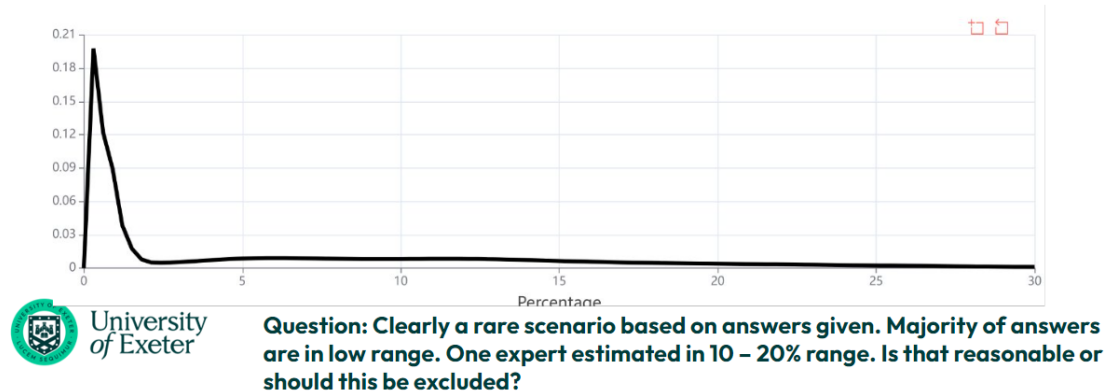
- Expert 1 "If patient has access to stoma nurses, and waiting time is no longer than 24 hours it is unlikely to need admission as the stoma nurse would have reviewed them. However, lack of specialist nurses, long waiting times, and inadequate staffing may increase the risk of admission significantly"
- Expert 2 "Usually managed in primary care"
- Expert 3 "I have only rarely seen people hospitalised with skin issues, and this is much more likely to be in the early weeks and months of having a stoma if it were to happen"
- Expert 4 "Equal probability dependent upon the severity."
- Expert 5 "this is an uncommon reason to be admitted to hospital, it is a very common reason to be seen in hospital by a stoma nurse"



- Expert 6 “It would be unlikely to be hospitalised with poor peristomal skin unless immunocompromised or admitted for surgical resolution such as debridement or refashioning or resiting of stoma. “
- Expert 7 “depends on type of complication, and unlikely to attend hospital if enough support by local stoma nurse given “

Skin complications resited

- for an average person with a colostomy one year following their surgery, the probability (Percentage) they would: Have their stoma resited if they were to experience peristomal skin complications **6.26%**

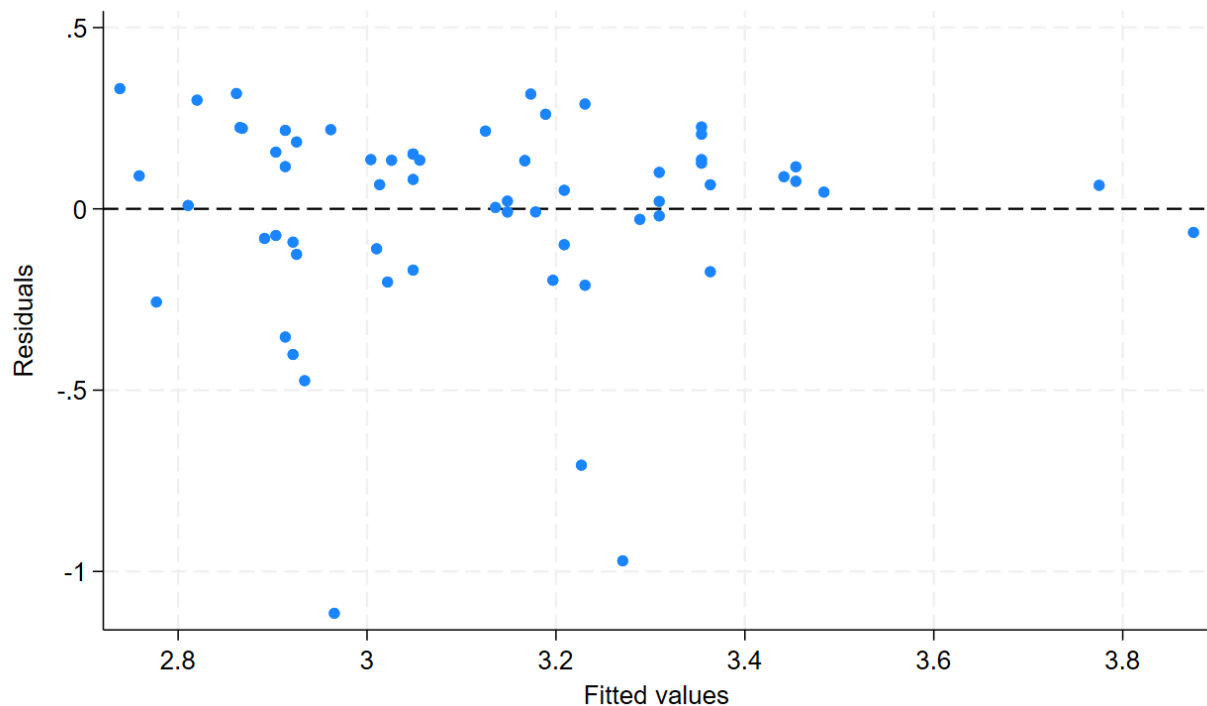


Rationales given

- Expert 1 “It is very unlikely for a stoma to be resited, as every surgery carries risk of further complications and won't necessarily resolve the stoma related problem, or may just solve it temporarily.”
- Expert 2 “Likely to be managed with pouches and products”
- Expert 3 “I don't think I have ever witnessed this scenario.”
- Expert 4 “Dependent upon the severity and surgeon willing to resite the stoma”
- Expert 5 “i dont ever remember having a stoma resited with the main reason being skin issues”
- Expert 6 “This is a more likely outcome but is still uncommon”
- Expert 7 “if patient has good support from their stoma nurse, very unlikely to need surgical intervention”

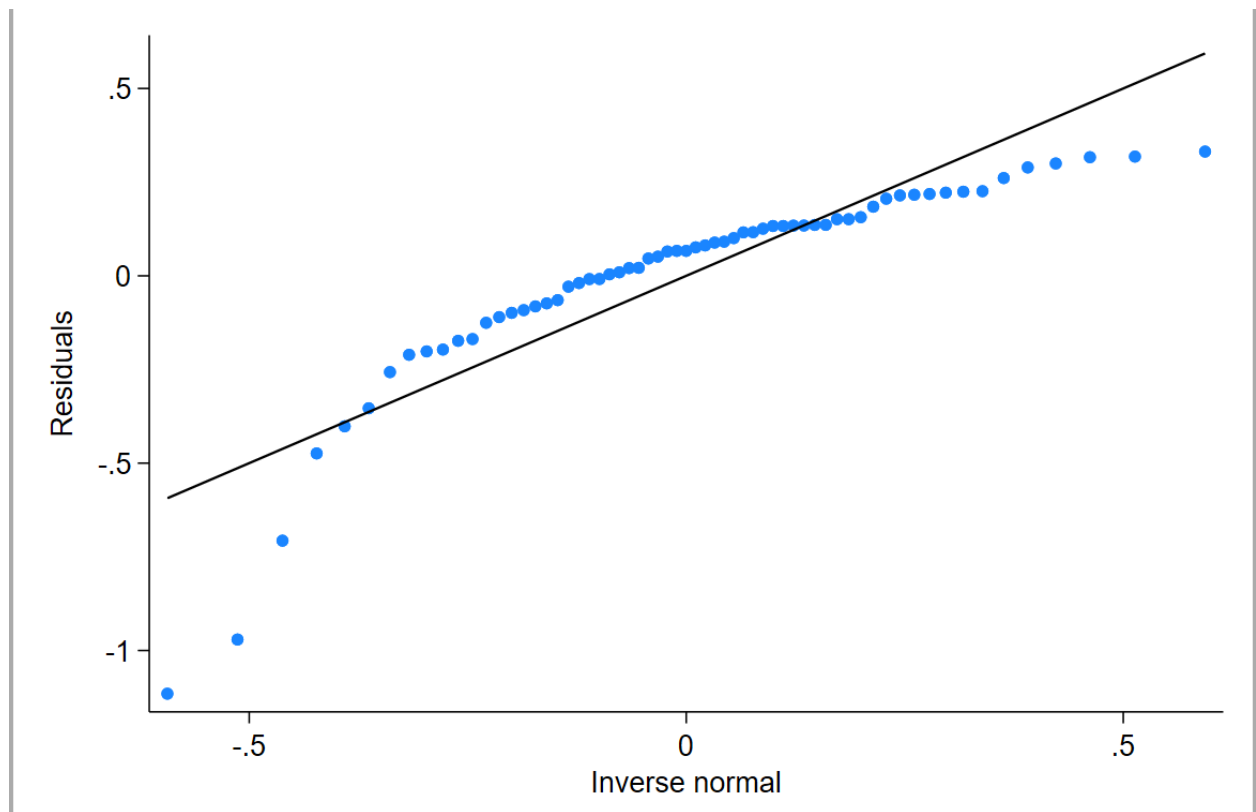
Appendix L – Regression Diagnostics

Linearity and homoscedasticity



Residuals vs. Fitted Values Plot shows residuals appear to be randomly scattered around the horizontal axis (zero line) with no clear pattern, suggesting that the **linearity** assumption of the regression model is reasonably satisfied. There is no funnel shape or other obvious signs of heteroscedasticity (non-constant variance) suggesting that the assumption of **homoscedasticity** is likely met. Furthermore, the use of robust standard errors adjusts for any change in the variance of the error terms (residuals) in case the assumption of homoscedasticity is violated, leading to a more reliable result.

Normality



The Q-Q plot indicates that the assumption of normally distributed residuals is violated in the tails of the distribution. While the middle of the distribution appears reasonably normal. As a corrective measure **robust standard errors** were used to make the model less sensitive to violation of the normality of residuals assumption.

Collinearity**. vif**

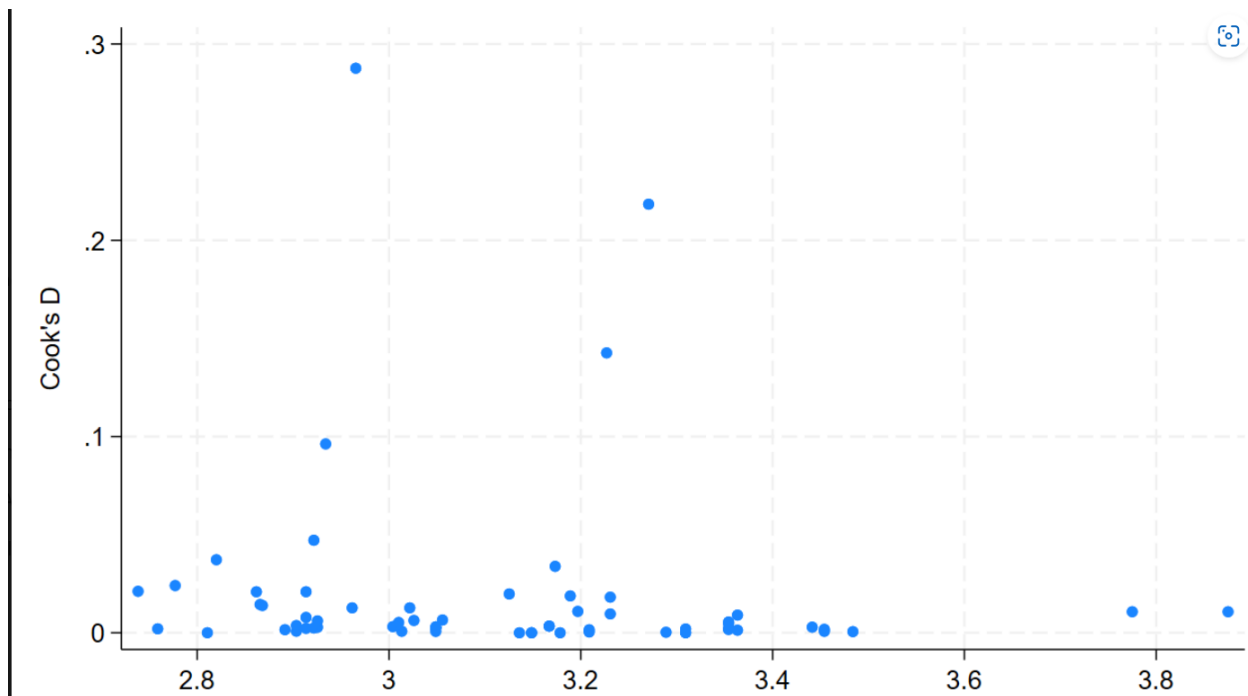
Variable	VIF	1/VIF
modified_m~l	3.12	0.320697
modified_f~r	2.48	0.403685
modi~e_shape	2.06	0.484741
modi~g_shape	1.54	0.649356
modified_~ve	1.43	0.697113
inspection~w	1.43	0.698114
flushable_~l	1.34	0.743917
baseplate_~e	1.22	0.819232
convexity	1.10	0.910942
Mean VIF	1.75	

The Variance Inflation Factor (VIF) analysis indicates that multicollinearity is not a concern in the model, as all the VIF values are below the threshold of 10. The independent variables are not highly correlated which makes the estimates more reliable.

Omitted variables

The Ramsey RESET (Regression Equation Specification Error Test) was used to verify the linearity assumption and determine whether a non-linear combination of variables could offer a better explanation for variation in the dependent variable (price). The p-value is 0.7827. Since the p-value is large, we fail to reject the null hypothesis. A non-linear combination of variables is unlikely to offer an improvement in model fit.

Influence



The Cook's Distance plot was used to identify influential observations in data—those that have a substantial impact on the regression coefficients if they are removed.

Most of the data points have low Cook's D values, which indicates that they are not exerting high influence on the results. Although there is no specific cut off for the test, one observation around 0.3 Cook's D value (Opus Naturfit) seems to be influential. To explore this further the EAG ran a scenario where this observation is removed.

Removing this observation resulted in R-squared value has increasing from 0.4189 (before removing the observation) to 0.4974. suggesting that the model now explains approximately 49.7% of the variance in the price, up from 41.9% leading to a better fitting model.

The removal of the influential observation also led to slight changes in some coefficients. The presence of a baseplate additive and an inspection window became statistically significant with an impact on price of 14p and 16p, respectively.

Linear regression

Number of obs = 62
 F(9, 52) = 17.96
 Prob > F = 0.0000
 R-squared = 0.4974
 Root MSE = .2499

price	Coefficient	Robust std. err.	t	P> t	[95% conf. interval]	
baseplate_additive	.1373957	.0609817	2.25	0.028	.0150269	.2597644
modified_baseplate_shape	.0172079	.0764739	0.23	0.823	-.1362482	.1706641
modified_baseplate_adhesive	.0257447	.0878303	0.29	0.771	-.1504996	.2019891
modified_bag_shape	.1441889	.062697	2.30	0.026	.0183782	.2699995
modified_filter	-.0910152	.1637816	-0.56	0.581	-.419667	.2376366
modified_material	.0489801	.1416689	0.35	0.731	-.2352993	.3332595
flushable_disposal	1.004213	.1064008	9.44	0.000	.7907041	1.217722
inspection_window	.1627342	.0616269	2.64	0.011	.0390707	.2863976
convexity	.2588632	.0654741	3.95	0.000	.1274798	.3902466
_cons	2.768379	.079619	34.77	0.000	2.608612	2.928147

Interactions

Given that the EAG was not provided with a clear theoretical basis to justify why certain features would interact with each other to change the effect on the dependent variable (price), and considering the small number of observations, it would be impractical to check all interaction terms. Doing so would likely lead to overfitting, as the model would become too complex without a guiding theoretical framework. Overfitting can then lead to the model performing well on the current data but poorly on new, unseen data, limiting its generalisability and practical utility.

One-piece closed bags for adults with a colostomy [GID-HTE10045]

Late-stage assessment

Assessment report overview

NICE National Institute for
Health and Care Excellence



Introduction

Population, condition and diseases

- Colostomy surgery is an operation to divert 1 or both ends of the colon through an opening in the abdomen ([NHS, 2020](#)). This opening is called a stoma.
- A bag (also known as a pouch or appliance) can be placed over the stoma to collect bodily waste (poo).
- A colostomy may be needed during the treatment of conditions including, but not limited to, anal cancer, colorectal cancer, vaginal or cervical cancer, ovarian cancer, diverticular disease, Crohn's disease, endometriosis, Hirschsprung's disease, birth defects, faecal incontinence or trauma.
- Colostomy surgery may be temporary and can be reversed, or it can be permanent. People with a permanent stoma are entitled to receive prescriptions of stoma supplies for free.
- It is estimated that there are over 200,000 people with a stoma in the UK ([Colostomy UK, 2024](#)).

Current management (1) – surgery and bag choice

- A clinical nurse specialist (CNS) in stoma care will perform colostomy siting assessments before surgery to ensure the stoma is in the most appropriate location for each person. This may not always happen for emergency surgeries.
- After surgery, initial bag choice can be based on multiple factors including the person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output and a person's manual dexterity ([Bowles et al, 2022](#)).
- CNS in stoma care identify a local dispensing appliance contractor (DAC) or community pharmacy as options for the ongoing collection or delivery of bags, as well as additional services such as bag cutting. The majority get their bags from a DAC.
- The level of involvement for people with a colostomy in the decision-making process related to bag choice may vary across services ([Bowles, 2022](#)). [NICE's guideline on shared decision-making](#) states that people have the right to make informed decisions about their care and should understand the choices available to them.

Current management (2) - complications

- Some people with a colostomy will experience complications ([Burch, 2021](#)).
 - Common issues are bag leakage and peristomal skin complications (PSC) which can be painful and difficult to manage.
- Colostomy surgery and related complications can also significantly impact a person's psychological and emotional health. But, each person's journey to their colostomy may vary.
 - For example, a person may feel more positively about their colostomy if it can relieve negative symptoms that they were experiencing beforehand. Whereas people experiencing fewer symptoms before their surgery, or people that have an emergency procedure, may have more difficulty adjusting.
- As a person's colostomy wound heals after surgery, or if they experience issues with their colostomy, they may need to try alternative products to find a more suitable bag.

Current management (3) - follow up

- The CNS in stoma care (in the community or hospital) will continue to provide ongoing physical and psychological support. Sometimes people will seek support for a complication from a DAC directly rather than talking to a CNS in stoma care.
- Periodically, or in response to stoma complications, an appliance user review may be done by a community pharmacy contractor or a CNS in stoma care working with a DAC.
- [The Association for Stoma Care Nurses stoma care nursing standards and audit tool for the newborn to elderly \(2021\)](#) says that appliance use reviews should be offered on an annual basis to support appropriate use and good prescribing practice.
- Appliance use reviews can help ensure that people are using the most suitable bag, monitor prescription requests and reduce product waste, but they are not conducted consistently in all areas of England.

Current NHS market for the technologies

- In community and primary care, 1-piece closed bags are supplied using an NHS prescription for technologies listed in [Part IXC of the Drug Tariff](#).
- Approximately 80% of hospitals in England have a formal sponsorship agreement in place with stoma appliance suppliers or manufacturers.
 - Companies may provide funding for stoma care services including CNS in stoma care roles.
 - Hospitals may also have non-formal agreements in place.
 - Most DACs are linked to specific stoma appliance companies.
- Currently, there are over 15 companies and over 1500 bag variations listed under the 'colostomy bags' subheading in Part IXC of the Drug Tariff.
- The price for 1-piece closed bags with a flat baseplate ranges from £1.85 to £3.84 per bag. The price for 1-piece closed bags with a convex baseplate ranges from £2.05 to £3.61 per bag.

The technology

- People with a colostomy typically use closed bags (rather than drainable bags) as they are more suitable for people with firm, well-formed poo (faeces) and a less frequent output.
- Bags are made up of a baseplate that attaches to the skin around the stoma, and a bag that collects poo. In 1-piece closed bags, these components are stuck together. But, for 2-piece closed bags, the bag can be removed while the baseplate remains around the stoma between bag changes.
 - Feedback from CNS in stoma care highlighted that most people with a colostomy in England use 1-piece closed bags.
- Baseplates are generally made from hydrocolloids, are adhesive and come in flat, convex, concave or mouldable variations.
- Bags can also come in different sizes, colours and have additional features that may be considered innovative.

Technology features (1)

- For this assessment, NICE considered 1-piece closed bags that are currently available for NHS prescription under the 'colostomy bag' subgroup on Part IXC of the Drug Tariff. Details of the decision problem are described in the [final scope](#).
- During the assessment, the EAG characterised the presence of potentially innovative features identified during scoping, from information provided by companies, and from the evidence review for 1-piece closed bags available on the Drug Tariff.
- The EAG added inspection window and sustainable material to the list of features to be considered in the assessment.
 - Inspection window was not included in the list of 'basic' features in the NICE scope as it was thought that it was unlikely that this would impact price or outcomes. Feedback from clinical experts said that this was a useful feature that allows users to monitor their poo.
 - Specialist committee members (SCMs) highlighted that sustainability should be a feature of importance, although it is unclear if any bags currently available offer this as a feature.

Technology features (2)

- The availability of baseplates as flat, convex, concave or mouldable was considered to be essential, and so this was not considered as a feature for this assessment.
- Potentially innovative features in the assessment included:
 - Baseplate additives, baseplate shape, baseplate adhesive, bag shape, filters, bag material, flushable disposal, inspection window and sustainability.
- Further details related to the features of 1-piece closed bags are in section 2, table 2 and table 3 of the external assessment report (EAR).

User preference assessment

Aims and user selection

- The aim of the user preference (UP) assessment was to transparently collect and present information on the criteria that users consider important when deciding which bag to choose.
- Users are defined people who will use, or have knowledge of using, one-piece closed bags and people that are directly involved in the decision to choose one bag over another.
- For this assessment, 2 user groups were identified:

People with lived experience, or knowledge of using one-piece closed bags

Clinical nurse specialist (CNS) in stoma care (or people previously in this role with ongoing knowledge in the area)

Methods

- The user preference assessment has been designed with Multicriteria Decision Analysis (MCDA) principles ([ISPOR task force report, 2016](#)). Further detail is in [NICE's Late-stage assessment interim process and methods statement](#).
- The UP assessment was done through 2 online workshops and 2 emails tasks, split into the following 4 stages:
 - Stage 1: identifying and defining criteria (workshop 1)
 - Stage 2: ranking criteria in order of importance (email task 1)
 - Stage 3: weighting of the top 10 criteria (email task 2)
 - Stage 4: developing performance rules for the 10 top criteria (workshop 2)

User engagement

- In total, 8 people with lived experience, or knowledge of using 1-piece closed bags and 10 CNS in stoma care took part in the UP assessment.
- User engagement for all stages is in the following table.

Stage	People with lived experience [n=8]	CNS in stoma care [n=10]
1	7	8
2	8	10
3	8	9
4	7	7

- For further detail about each stage of the assessment, see section 2 of the user preference report.

Identifying and ranking criteria (1)

- A total of 16 criteria were identified and defined by users. Users were then asked to rank the criteria in order of importance.

Order of importance	Criteria	Definition
1	Prevents leakage and seepage	A bag that prevents leakage (poo coming outside of the baseplate) or seepage (poo coming onto the skin under the baseplate), helping to prevent skin damage and odour. A bag that can be used with minimal use of supporting products.
2	Durability of the baseplate	A baseplate that securely adheres to the skin around the stoma without lifting during activity, when wet, in different temperatures and humidities, allowing the bag to be changed as required by an individual's poo rather than baseplate failure.
3	Baseplate that maintains and promotes skin health	A baseplate that doesn't tear the skin when being removed, doesn't cause irritation or skin sensitivities and can be used with a variety of skin conditions.
4	Fit of baseplate	A baseplate that has appropriate flexibility, follows the natural movements of skin and doesn't pull on the skin when moving.
5	Durability of the bag (external fabric and plastic inner lining)	A bag that keeps its form and holds poo under different conditions (such as when it is wet, in different temperatures and humidities, when it is full) when undertaking different activities until a person is able to change it.
6	Filter that remains functional during use	A bag with a filter that allows air to be released, doesn't cause ballooning, controls odour, prevents pancaking and remains functional during use when it is wet (externally with water and internally with poo).
7	Easy to attach the baseplate to the skin	A bag that can be attached with minimal effort and adheres well to the skin.

Identifying and ranking criteria (2)

Order of importance	Criteria	Definition
8	Comfort of bag against skin	A bag that has material (both the fabric and edging) that is comfortable against the skin such as it doesn't rub and doesn't itch when it's empty or full and is quick to dry.
9	Easy to remove	A bag that remains intact when it is removed and has a low risk of leaving residue (such as adhesive) on the skin.
10	Easy to remove the film or covering from the baseplate	A baseplate with an indicator (for example a coloured tab) to show where to remove the plastic film from the baseplate quickly. A film that comes off intact and allows the baseplate to retain its shape, integrity and adhesiveness.
11	Reduces noise	A bag made of material that makes minimal noise when moving.
12	Availability of different baseplate shapes and sizes	Baseplates available in pre-cut or cut to fit options that come in a variety of shapes (such as round, oval, square, flower, diamond) and sizes.
13	Availability of different bag sizes	A bag that is available in a variety of sizes (such as mini, midi or maxi) or has adaptable sizing (for example, can be folded to appear smaller).
14	Appearance of the bag	A variety of colours and shapes available. A bag that is minimally obtrusive and visible, such as a bag with a low profile that reduces dragging when filling, less bulky material and material that doesn't become see through when wet.
15	Easy to cut	A baseplate that is easy to cut without damaging the bag and has a film or covering that can be used as a template for cutting without disintegrating or distorting the baseplate shape.
16	Reduced environmental impact	A bag that strives to be more environmentally friendly (for example, uses less plastic and cardboard in the manufacturing of the bag and packaging). A reduced carbon footprint in manufacturing process.

Identifying and ranking criteria (3)

- The top 3 criteria to consider when choosing a 1-piece closed bag relate to maintaining and promoting healthy peristomal skin.
- When comparing the ranking between CNS in stoma care and people with lived experience, the top 3 criteria were the same but ranked in a different order of importance; with preventing leakage and seepage the most important for CNS in stoma care and durability of the baseplate the most important for people with lived experience.
- Both user groups ranked having a reduced environmental impact as the least important factor in the list of 16 criteria. But, people with lived experience did find the quantity of packaging they received with their products to be unnecessary (particularly cardboard).
- For further detail about identifying and ranking criteria, see section 3.1 and appendix A of the user preference report.

Criteria weighting and creating performance rules

- 16 out of 17 users weighted at least 1 criteria as equally important as another, with 7 users weighting over half of the criteria as equally important as another.
- 22.5% of the total weighting score was given to preventing leakage and seepage. 2 users explicitly stated preventing leakage and seepage was by far the most important criterion.
- Users were able to create multiple performance rules for all criteria. Some rules can be answered as a simple yes or no answer whereas others may have a number of answers.
- For those with a number of answers, users were asked to state acceptable or unacceptable levels of performance. This was achievable for some rules but for others, a consensus could not be reached.
- For further detail about criteria weight and the performance rules for each criteria, see section 3.2 and appendix B of the user preference report.

Performance matrix (1)

Order of importance	Weight (%)	Criteria	Performance rule
1	22.4%	Prevents leakage and seepage	- Does leakage occur? - Does seepage occur? - Is the skin assessed to be intact? - Supporting products used to help prevent leakage or seepage over time Unable to reach consensus on acceptable levels of leakage, seepage or use of supporting products
2	17.6%	Durability of the baseplate	- Does the baseplate lift? - Does the baseplate maintain integrity during storage until it's expiry date? - Does the baseplate maintain integrity during use?
3	14.9%	Baseplate that maintains and promotes skin health	- Does the baseplate cause skin tears or damage when removed? - Does the baseplate cause or worsen peristomal skin complications (such as irritation, sensitivities, skin tears or damage) - Does the baseplate maintain or improve skin integrity? No level of worsening to the peristomal skin was considered acceptable and all baseplates should maintain or improve skin integrity.
4	11.4%	Fit of baseplate	- Does the baseplate lift? - Does the baseplate fit around the stoma taking into account body shape? - Is the baseplate flexible across all dimensions when still, moving or changing position?

Performance matrix (2)

Order of importance	Weight (%)	Criteria	Performance rule
5	9.5%	Durability of the bag (external fabric and plastic inner lining)	- Does the bag keep its form and hold poo until a person is able to change it? - Does the bag stay fully attached to the baseplate and intact (such as seams staying together around the edge of the bag and the edge of the filter) during use? - Does the bag begin to disintegrate or puncture when in contact with poo (for example, due to acidity or undigested food)? No level of a bag losing the ability to hold poo, coming away from the baseplate, disintegrating or puncturing was considered acceptable.
6	7.6%	Filter that remains functional during use	- Does the filter release air helping to reduce ballooning? - Does the filter allow air to be released without causing a vacuum? - Does the filter allow air to be released whilst controlling odour? - Does the filter remain functional when wet? No level of odour was deemed acceptable. Unable to reach a consensus on the rates of ballooning, creating a vacuum or filter malfunction when wet that are considered acceptable.
7	6.7%	Easy to attach the baseplate to the skin	- Is additional adhesive needed to apply the baseplate? - Does the baseplate maintain its shape during application? - Time to secure adherence of the baseplate on application (less than 3 minutes considered acceptable)

Performance matrix (3)

Order of importance	Weight (%)	Criteria	Performance rule
8	4.6%	Comfort of bag against skin	- Time to drying (less than 5 minutes for air drying considered acceptable) - Does the bag material cause skin discomfort or irritation? - Does the bag material prevent or reduce skin irritation? - Does the edging of the bag cause skin irritation? - Does the bag material change in feel or texture (such as developing bobbles) during use?
9	3.5%	Easy to remove	- Does the bag remain intact when removed? - Does the bag leave residue on the skin when removed? It was considered unacceptable for a bag to not remain intact during removal. Unable to reach a consensus on amount of residue that may be considered acceptable.
10	3.0%	Easy to remove the film or covering from the baseplate	- Does the baseplate have an indicator to show where to remove the film? - Does the film come off the baseplate intact? - Does the baseplate retain its shape, integrity or adhesiveness when the film is removed? - Time to remove the film from the baseplate (less than 1 minute considered acceptable)

Additional considerations

- Bag choice can be influenced by a person's body shape, stoma anatomy, formation and consistency of a person's poo, how many bag changes are needed per day and a person's skin type and integrity, which are individual to each person and can change over time.
- Some people use supporting products to provide additional security, help to secure or remove the baseplate from the skin or to help maintain skin condition.
 - People with lived experience stated that the need for supporting products varies from person to person and an acceptable amount of use cannot be specified.
 - CNS in stoma care highlighted that there is variation in practice in who is given supporting products, particularly adhesive removing products. CNS in stoma care stated that some people may not need them but other people, for example people changing their bags more regularly or those with skin complications, may be more likely to need products such as adhesive removers. They also said that they would preferentially look for alternative bags before offering supporting products if leakage or seepage is the main concern.

User preference assessment limitations

- Users highlighted the difficulty of ranking and weighting criteria, when they are all considered important. Users chose to create performance rules for all 10 criteria (rather than just those weighted above 5%) to emphasise this importance.
- For some criteria, users could not reach a consensus on levels of acceptable or unacceptable performance for a number of rules due to the variation in what is considered normal from person to person.
 - The wide range of variability between people with a colostomy is reflected by the large number of products available for prescription and highlights the importance of individual product use reviews and maintaining a wide range of product choice.
- Volunteer bias may be a limitation of this assessment, but the active engagement of users in the colostomy community means they also have increased awareness of problems faced by the wider community and their views may represent this wider population more accurately.

User preference assessment summary

- Users reiterated that choosing a 1-piece closed bag is driven by multiple factors that will vary from person to person (for example, preference, clinical need and certain features) and that all identified criteria were important when choosing which 1-piece closed bag to use.
- The top 3 criteria had a combined weight of over 50% and were all linked to maintaining and promoting healthy peristomal skin, with preventing leakage and seepage being the most important criteria.
- Throughout the assessment, users also highlighted the need for bags to be tested in various groups of people with different skin conditions, lifestyle, mobility levels and people with underlying health conditions to ensure a person can be confident in the security and durability of their bag.

This assessment highlights the importance to users of bag security, preventing leakage and seepage and maintaining healthy skin around the peristomal area in allowing people with a colostomy maintain their quality of life.

Clinical evidence

Summary of searches and study selection

- The clinical evidence search is described in the [final protocol](#). No amendments to the planned searches were made.
- The EAG reviewed the evidence in line with the protocol. Due to the limited evidence base, the following minor amendments were made:
 - A study assessing outcomes related to [REDACTED]
[REDACTED] The EAG excluded mixed comparator studies from their initial review. But, included them in the expanded evidence base.
 - A number of studies included used unvalidated scales to measure outcomes with a lack of information about how to interpret the evidence. The protocol states that only outcomes reported using scales that had been psychometrically validated would be included in the evidence review.
- The EAG excluded a number of studies evaluating 1-piece closed bags in people without a stoma and evaluations of bags or their features that were conducted in a lab.
- The EAG reviewed an expanded evidence base to consider 2-piece bags and mixed comparators (discussed in more detail in later slides)
- Further detail is in section 5.1 of the EAR.

Summary of included studies

- The EAG included 5 studies directly related to the decision problem on 1-piece closed bags for adults with a colostomy in the initial evidence review (3 full text articles, 1 confidential internal company report and 1 record from clinicaltrials.gov that reported results). A full list of studies excluded during full-text screening is in appendix C of the EAR.
- Four of the studies were randomised crossover trials. One trial was in Germany (Teniere, 2007 [online link unavailable]), 2 were in Denmark ([Voergaard, 2007](#) and [Virgin-Elliston, 2023](#)) and 1 was in Denmark and France ([NCT01243294, 2011](#)). All 4 studies had less than 100 participants.
- The 4 published crossover trials were sponsored by Coloplast and evaluated the SenSura or SenSura Mio bags, with comparisons including each other and with Nova 1 or Moderma Flex (bags from Hollister and Dansac).
- The fifth study is commercial in confidence. [REDACTED]
[REDACTED]
[REDACTED]
- For further detail, see sections 5.2.1, 5.2.2 and table 5 in the EAR.

Summary of the clinical outcomes (1)

Voergaard (2007): SenSura (Coloplast) compared with Nova 1 (Hollister and Dansac)

- Crossover RCT including 68 people in Denmark with a colostomy using 1-piece closed bags that did not have a PSC at baseline.
- The study reported no difference between the bags for wear time, rate of PSC, filter leakage, pancaking, odour or perceived adhesion of the adhesive.
- People using SenSura had a lower rate of ballooning (████) and ██████████ compared with people using Nova 1 (53% for ballooning and ██████████). No differences in other outcomes relating to an improvement of filter were identified (pancaking, leakage, odour control).
- Participants rated the SenSura bag more positively overall, with higher ratings for comfort, ease of removal, flexibility and bag security. The EAG did not consider these outcomes reliable due to the use of unvalidated scales of measurement.
- Further detail about this study is in section 5.4.2 and table 8 of the EAR.

The EAG stated a key finding was reduction in ballooning and ██████████ with SenSura compared to Nova 1. Most participants (72%) used a Coloplast bag at baseline, and the EAG considered it plausible that the findings may have been influenced by participants' familiarity with Coloplast bags.

Summary of the clinical outcomes (2)

Teniere (2007): SenSura (Coloplast) compared with Moderma Flex (Hollister and Dansac)

- Crossover RCT including 69 people in Germany with a colostomy using flat 1-piece closed bags that did not have broken skin or bleeding around their stoma at baseline.
- The study reported no difference between the bags for filter leakage, odour, and the presence of skin conditions.
- SenSura had a lower reported rate of ballooning (6.0%) compared with Moderma Flex (23.0%; $p < 0.0001$) and less reported filter dysfunction (mostly due to ballooning) for any reason (10.0% for SenSura compared with 29.5% with Moderma Flex).
- SenSura was also perceived as having better security, greater tack and adhesion, a better shape, and as being easier to remove compared with Moderma Flex. The EAG did not consider these outcomes reliable due to the use of unvalidated measurement scales.
- Further detail about this study is in section 5.4.3 and table 9 of the EAR.

The EAG considered the differences between bags in filter dysfunction and ballooning to be meaningful. Most participants used a Coloplast bag at baseline, and participants may have a stronger preference and greater familiarity with Coloplast bags.

Summary of the clinical outcomes (4)

NCT01243294: SenSura compared with 'a new ostomy bag' [REDACTED]

- Crossover RCT in Denmark of 56 people with a colostomy using flat 1-piece closed bags. None of the participants had a PSC at baseline.
- A higher proportion of people rated the new bag as having very good security and being comfortable compared with SenSura. But, the EAG did not consider these outcomes reliable due to the use of unvalidated scales of measurement.
- The study reported no clear difference between the bags for wear time, leakage when changing baseplates, handling of the bag (self-reported), and intervention-related adverse events. No further outcomes were reported.
- Further detail about this study is in section 5.4.5 and table 11 of the EAR.

The EAG considered the bags comparable, but highlighted the limited evidence that people may have a preference for the [REDACTED].

Summary of the clinical outcomes (5)

Virgin-Elliston (2023) SenSura compared with SenSura Mio

- Crossover RCT in Denmark of 20 people with a colostomy using flat 1-piece closed bags. The study objective was to evaluate filter function. Included participants experienced at least 1 ballooning event per week at baseline.
- The rate of ballooning was lower with SenSura Mio (11.2%) compared with SenSura (22.8%; $p < 0.0007$).
- There were no differences reported in pancaking, odour issues, perception of bag discretion, or length of time between switching bags.
- Six adverse events (AEs) were observed in 4 participants (20%). One was a PSC and considered to be related to the use of SenSura Mio, which led to discontinuation from the study. Further detail about this study is in section 5.4.5 and table 11 of the EAR.

The results indicated that SenSura Mio was associated with a lower risk of ballooning compared with SenSura. Given the small sample of AEs, the EAG did not consider there to be enough evidence of a difference in the risk of PSC.

Summary of the clinical outcomes (3)

- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]

[REDACTED]

Summary of the reported clinical outcomes

	Voergaard 2007	Teniere 2007	██████ ██████	NCT01243294	Virgin- Elliston 2023
Psychological and social impact	N	N	█	N	N
PSC	Y	N	█	N	N
Leakage	Y	Y	█	Y	N
Pancaking	Y	N	█	N	Y
Ballooning	Y	Y	█	N	Y
Odour	Y	Y	█	N	Y
Ease of use and acceptability	Y	Y	█	Y	Y
Intervention- related AEs	Y	Y	█	Y	Y
Length of time before changing bags	Y	N	█	Y	Y
Length of follow-up	1 week	Not reported	█	1 week	2 weeks

NICE

Quality appraisal of included studies

- The clinical trial registry record (NCT01243294) was excluded from the formal quality assessment assessment due to insufficient methodological detail.
- The EAG considered the remaining 3 published crossover RCTs to have either high or unclear risk of bias, with major potential for performance and detection bias.
- [REDACTED]
- The EAG also had the following concerns in relation to the evidence base:
 - Use of unvalidated measures to collect outcomes and lack of consistency in how clinical outcomes are measured across the studies.
 - Short follow up which may not allow accurate measurement of certain outcomes, such as presence of PSC.
 - Limited detail related to included populations and how inclusion in the studies were done. There is a risk that different criteria were used across the studies, limiting the comparability of results in the evidence base.
 - All published studies were sponsored by Coloplast and had authors with a direct financial conflict.
- For further detail of the EAG's quality appraisal, see section 5.3 and appendix F of the EAR.

Expanded evidence base - 2-piece bags (1)

- Due to the limited clinical evidence identified directly related to the decision problem, the EAG explored additional evidence sources, including evidence of the effectiveness of 2-piece closed bags.
- In relation to 2-piece closed bags, feedback from SCMs and clinical experts suggested that:
 - Differences in the populations using 1-piece or 2-piece closed bags were likely to be related to lifestyle choice or personal preference, rather than clinical differences.
 - People using 2-piece bags may be at a higher risk of leakage due to the baseplate staying on the skin for longer, or incorrect or faulty attachment of the coupling mechanism.
 - The reduced frequency of changing the baseplate for 2-piece bags may mean features related to this (such as baseplate additives, shapes and adhesives) may vary in effectiveness between the groups.
- It was unclear whether the features of 2-piece bags were directly comparable to 1-piece closed bags as there was limited information in the evidence and some of the bags did not share the same brand name as the 1-piece closed bags.

The EAG concluded that the impact of different bag shapes, filters, bag material or flushable disposable is likely comparable between people using 1-piece and 2-piece closed bags. But, outcomes related to the baseplate may be less comparable. For more detail, see appendix J in the EAR.

Expanded evidence base – 2-piece bags (2)

Author, year, intervention comparator	Design, location and participants	Key results
Welser 2009 SenSura (Coloplast) Combihesive Natura (ConvaTec)	Crossover RCT in Germany of 73 people (60 people completed the study) with a colostomy using 2-piece closed bags. Excluded people with PSCs.	SenSura had less seepage ($p < 0.05$), improved PSC between 0 to 2cm ($p < 0.05$), less ballooning and fewer participants bothered by odour compared with Combihesive Natura.
Arnaud 2008 SenSura Flex (Coloplast) Esteem Synergy (ConvaTec)	Crossover RCT in France of 46 people with a colostomy using 2-piece bags. The study was reported as a conference abstract. Excluded people with PSCs.	- SenSura Flex was associated with improved odour control when compared with Esteem Synergy. 3 participants reported device-related PSC for Esteem Synergy and none were reported for SenSura Flex. 74% participants reported preferring SenSura Flex to Esteem Synergy.
Schröder 2007 Easiflex (Coloplast) Esteem Synergy (ConvaTec)	Crossover RCT in Germany of 66 people with a colostomy using 2-piece closed bags. The study was reported as an abstract with a corresponding poster. Excluded people with PSCs.	- Leakage in the adhesive coupling was experienced - more often with Esteem Synergy (21% participants) than with the Easiflex appliance (9%), $p < 0.05$.

For further detail, see appendix J in the EAR.

EAR: external assessment report; PSC: peristomal skin complications; RCT: randomised controlled trial

Expanded evidence base – blended comparators (1)

- The EAG also explored studies comparing 1-piece closed bags with blended comparators (multiple bags were included in the same arm without distinction).
 - These were originally excluded from the initial evidence review as the EAG said that, where there are multiple comparators, they cannot generate a relative effect estimate that can be associated with a specific feature or set of features.
- The EAG highlighted the following ways in which data from studies with mixed comparators could be interpreted:
 - Outcomes reported specifically for each bag could be compared with the outcomes for bags in the initial evidence review. Differences in study designs and population would be expected to influence the comparability of outcomes.
 - Outcomes that compare the effectiveness of bags with a mixed comparator may mean it is not possible to determine the amount or direction of effect of bag or feature, as it may vary between the bags in the comparator arm.
- For further detail, see appendix J in the EAR.

Expanded evidence base – blended comparators (published)

Author, year, intervention comparator	Design, location and participants	Key results
Belfield-Cockings (2022) Genii 1-piece closed bag (Trio Healthcare) compared with mixed comparator	Before and after study of 61 people with a colostomy using 1-piece closed bags. Excluded people with broken or bleeding skin.	36% of participants experienced an improvement in peristomal skin condition compared with baseline, 57% reported that their skin remained the same, and 6% reported a worsening of their skin. - At the end of the study, 69% of people reported having normal skin, compared with 49% at baseline.
Sundberg (2012) and Rasmussen & Martins (2012) SenSura Mio (Coloplast) compared with mixed comparator	Randomised crossover study in Germany, Netherlands, France and Norway of 144 people with a colostomy using 1-piece closed bags. Results were reported across 2 posters.	44% of participants went from having a PSC to normal skin with SenSura Mio compared with 22% for standard care. - Mean DET score improved with SenSura Mio (mean DET = 1.4) and worsened with standard care (mean DET = 1.6).
Dialogue Study (2011) SenSura (Coloplast) compared with mixed comparator	Real world non-comparative study with a subgroup of 2021 people with a colostomy.	- Mean stoma-QoL score improved from approximately 45.5 at baseline to approximately 49 at follow-up. - PSCs improved between baseline and follow-up. - The proportion of participants with a colostomy reporting that they had leakage 'always', 'often' or 'sometimes' fell from approximately 55% at baseline to approximately 35%. - Lack of information bag type at baseline meant that little could be interpreted about the relative clinical effectiveness of the SenSura bag

Expanded evidence base – mixed comparators (unpublished)

Author, year, intervention comparator	Design, location and participants	Key results
[Redacted]	[Redacted]	• [Redacted]
		[Redacted]
		[Redacted]
		[Redacted]
[Redacted]	[Redacted]	• [Redacted]
		• [Redacted]
		• [Redacted]

For further detail, see appendix J in the EAR.

Excluded evidence – people with an ileostomy

- Due to the limited evidence directly relevant to the decision problem, the EAG also considered if studies with a mixed population of people with a colostomy or ileostomy would be appropriate for inclusion.
- The EAG wanted to determine whether baseline characteristics for key outcomes are different between the populations, and whether the impact of using 1-piece closed bags would be comparable in both populations.
- Feedback from SCMs and clinical experts highlighted that differences between people with a colostomy or an ileostomy may limit the generalisability of outcomes between the groups.
 - SCMs or experts did not unanimously agree that baseline characteristics for key outcomes in the decision problem, or the impact of bag features would be comparable between the populations.
- So, the EAG did not expand the clinical evidence base to include studies where less than 80% of participants had a colostomy. For further detail, see appendix E in the EAR.

Conclusions from the clinical evidence (1)

- The EAG identified 5 studies directly relevant to the decision problem including 5 bag types. 3 published studies reported the impact on leakage, 1 published study (Voergaard, 2007) reported the impact on PSC and none of the published studies reported the impact on psychological or social outcomes.
 - This suggests that the majority of 1-piece closed bags available to adults with a colostomy in the NHS are not supported with robust clinical effectiveness evidence and outcomes related to maintaining and promoting healthy peristomal skin, as highlighted by users as the most important, are not consistently reported.
- The results from the directly relevant evidence suggested that the presence of potential innovative features, and variation in the types of features, could impact outcomes for adults with a colostomy. But, these findings were from low quality studies and not conclusive due to inconsistency in reporting across outcomes.
- In many cases, there was no difference in outcomes between the bags evaluated in the directly relevant evidence, especially on outcomes most important to adults with a colostomy (including PSC and leakage).

Conclusions from the clinical evidence (2)

- The EAG explored wider sources of evidence, including evidence for 2-piece closed bags and evidence that used mixed comparators, and concluded that there were uncertainties around the generalisability of this evidence to the decision problem.
- 8 of the published studies (direct evidence and that is in the expanded evidence base) excluded people with peristomal skin complications at baseline. Some of the studies also report other exclusion criteria including those receiving chemotherapy or radiation therapy during or before the study and those who cannot apply the bags themselves.
- The EAG concluded that there was insufficient evidence to demonstrate a difference in clinical effectiveness of 1-piece closed bags for adults with a colostomy, and whether bags with potentially innovative features offered greater benefits to adults with a colostomy than bags without.

Economic evidence

Summary of searches and study selection

- The economic evidence search is described in the [final protocol](#). No amendments to the planned searches were made.
- The EAG included studies in adults with a colostomy or ileostomy with a stoma where an economic evaluation or assessment of health-related quality of life (HRQoL) was done. Studies reporting outcomes for 1-piece closed bags were prioritised.
- The EAG included 13 economic evaluations in its economics evidence review.
 - None of the studies fully addressed the decision problem. For the 2 studies most closely addressing the decision problem, 1 reported on 2-piece bags and 1 reported outcomes from a mixed population (colostomy and ileostomy) on a mix of 1 and 2-piece closed and drainable bags.
- The EAG also identified 5 reports of utilities for relevant complications, 19 studies reporting other information for quality of life and 26 studies reporting resource use.
- For further detail, see section 6.1 and 6.2 of the EAR.

Approach to the economic analysis

- Due to the limited clinical evidence base (both related to the benefits of bag features and individual bags), the EAG stated that directly estimating the cost-effectiveness for 1-piece closed bags with specific features and benefits was not possible for the assessment.
- So, the EAG divided the economic analysis into 3 parts:
 1. A regression analysis to identify associations between bag prices (as listed on the Drug Tariff) and potentially innovative bag features.
 2. Calculation of the maximum cost-effective price (economically justifiable price) for a bag possessing features that can fully or partially prevent different bag-related complications.
 3. Exploratory analysis around the price of 1-piece closed bags included in the clinical evidence base that reported a difference in outcomes to explore whether the difference in bag price is explained by a difference in the outcomes.

Regression analysis methods

- The EAG wanted to investigate whether the pricing of 1-piece closed bags was driven by the presence of potentially innovative features and to see if bags with these features claimed to provide benefits by companies were priced accordingly.
- 1-piece closed bags can have a flat or convex baseplate, where convex (concave and mouldable also included) bags are known to be priced higher due to increased manufacturing costs (also shown by the 'all bag' regression analysis). So, the EAG ran a regression analysis for both flat and convex bags separately.
- Bag usage data was taken from England community prescribing data (2023).
- The regression model used the number of 1-piece closed bags at each price level to calculate a weighted average price per bag type, based on the current price in the Drug Tariff (April 2024). This approach accounted for variation in the price per bag based on the bag size, baseplate size and the number of bags in a pack.
- The features for each bag were taken from the company request for information documents, additional question responses or, where these weren't available, the EAG's interpretation of publicly available information.

Regression analysis results

Flat bags

40.3% of the variability in price was accounted for by the presence of different features.

Convex bags*

22.5% of variability in price was accounted for by the presence of different features

- The most impactful feature on price was flushable disposal in flat bags.
- No other feature had a significant impact on the primary regression analysis.
- The results of the regression analysis suggest that the presence of potentially innovative features only partially explain the price for 1-piece closed bags.
- It also suggests that pricing of 1-piece closed bags may not currently driven by the presence of potentially innovative features.
- One of the bags included in the regression was found to be a potential outlier (Opus Naturfit); when this bag was removed from the analysis two additional features were found to be significant predictors of price (the presence of baseplate additives and the presence of an inspection window with an impact on price of 14p and 16p, respectively). However, it remained the case that <50% of the variability in price was accounted for by the presence of different features.
- For further detail, see section 7.3.1, table 25, table 26 and table 27 of the EAR.

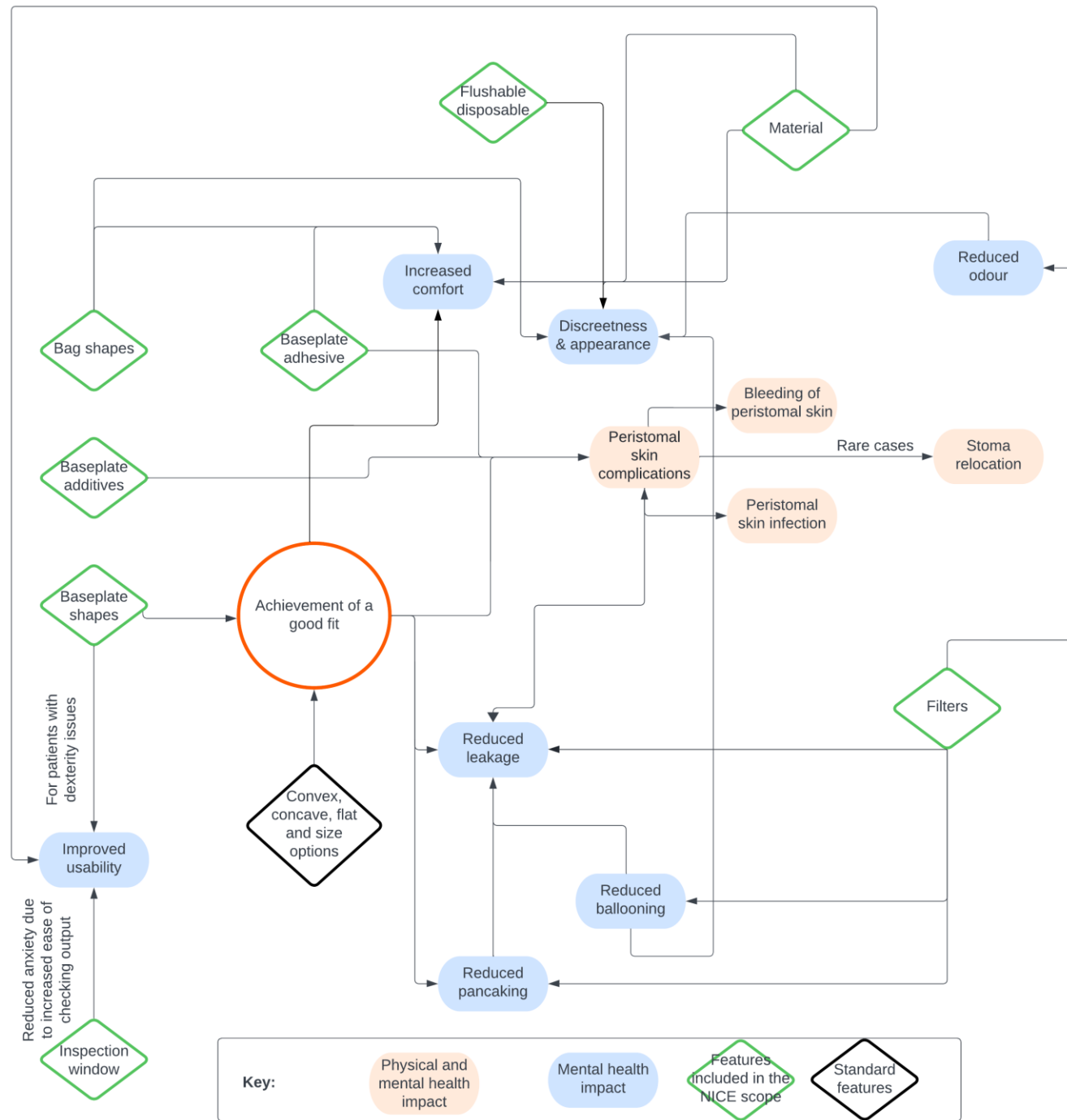
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Model overview

- Due to the limited evidence base, the EAG constructed multiple state transition models to account for the cost and quality of life impact for 6 separate health states: PSCs, leakage, pancaking, ballooning, odour and discreteness, appearance and comfort.
- Health states were defined as either the presence or absence of the complication. But, PSCs and leaks were both split into 3 severity subgroups (mild, moderate and severe), as these are considered the most impactful complications and more data was available.
- The EAG used a 1-year time horizon representing an average year for a person experiencing a complication. This was considered appropriate due to the acute nature of complications.
- The modelled population was defined as a person who had adjusted to their colostomy (1 year or more after surgery) and the model started when a new bag is prescribed to alleviate a complication.
- Due to the limited evidence, the EAG conducted a structured expert elicitation on disutility due to complications, utility gains due to discreet bag design, probability of switching due to complications, and probability of more serious complications such as hospitalisation

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Model structure



Structured expert elicitation

- Due to the limited published evidence available for a number of model parameters, the EAG conducted a structured expert elicitation (SEE) to fill data gaps on:
 - HRQoL parameters (disutility due to complications and utility gains due to discreet bag design)
 - the probability of switching to a different bag type (from the same or an alternate brand) if a person experienced complications rather than using supporting products. Complications included:
 - Leakage
 - Odour
 - Ballooning
 - PSC
 - the probability of more serious complications such as hospitalisation or stoma re-siting happening due to PSCs.
- For further detail, see section 7.2.5 and appendix D of the EAR.

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Structured expert elicitation - Results

Parameter	Mean value
Disutility: Regular (daily) Ballooning	0.058
Disutility: Regular (daily) Pancaking	0.066
Disutility: Regular (daily) Bad odour	0.082
Utility gain: Discreet bag design with preferred appearance	0.077
Probability switching: 4 leaks/month	61.69%
Probability switching: 1 leak/ month	43.89%
Probability switching: 1 leak per 6 months	25.12%
Probability switching: PSC 2/10	29.97%
Probability switching: PSC moderate level of pain, itching and burning (5/10); no bleeding or ulcers	58.22%
Probability switching: PSC weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers	63.92%
Probability switching: PSC-bleeding or ulcers and a moderate level of pain, itching and burning (5/10)	63.25%
Probability switching severe PSC 8/10	73.50%
Probability switching: Regular (daily) Ballooning	44.10%
Probability switching: Regular (daily) Pancaking	52.26%
Probability switching: Regular (daily) Bad odour	61.17%
Probability: Hospitalisation due to skin complications	13.39%
Probability: stoma re-sited due to skin complications	1.95%

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Cost and resource use parameters – PSC (1)

Cost or resource use item	EAG base case input	Source
Number of 1-piece closed bags per day	No PSC: 1.5, mild: 3, moderate: 4.5, severe: 5.5	Clinical expert opinion (2 CNS in stoma care; revised by consultation with 6 CNS in stoma care)
Cost per bag	£3.02	Bennett Institute average bag cost 2023
Cost of wastage when bag type is switched	Half of an average prescription of 75 bags (60 or 90 bags are usually supplied)	Clinical expert opinion (2 CNS in stoma care)
Supporting products cost		Nørtoft (2019) subgroup analysis Assumed not to vary by PSC type as data on this not available
Duration of symptoms	Mild: 1.67 weeks, moderate: 2.63 weeks, severe: 3.61 weeks	Rolls (2023) HCP survey Confirmed appropriate by 2 CNS in stoma care
Number of CNS in stoma care consultations	Mild: 2 phone/online contacts, one face to face contact. Moderate and severe: 50% and 86% increase in contact overall based on Rolls (2023)	Clinical expert opinion (2 CNS in stoma care) Rolls (2023) HCP survey
Cost per CNS in stoma care consultation	Face to face: £76.80 Telephone/online: £45.17	Band 6 nurse cost from PSSRU 2023 x 1.2 to include indirect time N24AN Specialist Nursing, Stoma Care Services, Adult, non-face-to-face from NHS cost ref 2021/2022 inflated to 2023 cost using PSSRU
Proportion of patients referred	Dermatologist: 0% mild, 4%, moderate 8% severe. Gastroenterologist: 0.5% mild, 1% moderate, 2.5% severe GP: 0% Surgeon: 1% mild, 2% moderate, 7% severe	Rolls (2023) HCP survey Clinical expert opinion (2 CNS in stoma care) NHS cost ref 2021/2022 inflated to 2023 cost using PSSRU

Cost and resource use parameters – PSC (2)

Cost or resource use item	EAG base case input	Source
Cost of referrals	Dermatologist: £163.39 Gastroenterologist: £215.57 Surgeon: £216.38 Then inflated by 7.03% to 2022/2023 prices	Consultant-led outpatient appointments service codes: 330; WF01B, 301; WF01B, 100; WF01B, NHS reference costs 2021/2022
Proportion of patients prescribed medication	Steroids: 3% mild, 17% moderate, 20% severe Silver nitrate: mild 1%, moderate 2%, severe 9% Tacrolimus: 0%	Rolls (2023) HCP survey Clinical expert opinion (2 CNS in stoma care)
Cost of medications	Topical corticosteroids: £10.21 Silver nitrate: £4.28	CNS in stoma care stated they used beclomethasone inhalers or fludroxycortide tape. Costs taken from eMIT and BNF. Cost of silver nitrate from BNF
Hospitalisation	13.4%	Expert elicitation mean. Aligns with hospital readmissions within the 120 days following surgery (47% vs. 33% without PSCs) from Taneja (2017)
Cost of hospitalisation	£489 Then inflated by 7.03% to 2022/2023 prices	Weighted average cost codes JD07E – JD07K as day case from NHS reference costs 2021/2022
Stoma resiting	1% at all severities	Rolls (2023) HCP survey (aligns with SEE value of 1.95%)
Cost per stoma resite	£4,463 Then inflated by 7.03% to 2022/2023 prices	Weighted average cost of elective surgery for codes WH07A-G from NHS reference costs 2021/2022 Cost code taken from Mohiuddin 2021
Number of PSCs per year	2.4 [$41/(74 \times 12) \times (365.25/7)$]	ADVOCATE RCT standard of care arm – assumes constant rate over a year
Severity split	44% mild, 48% moderate, 8% severe	ADVOCATE RCT

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Cost and resource use parameters – leakage

- For leakage, the base case included:
 - Costs for additional supporting product use and changing bag type from the Nørtoft (2019) subgroup analysis [REDACTED]
 - Data from De Fries Jensen (2023) to calculate the cost of consultation with CNS in stoma care to resolve issues with leakages.
 - An assumption that leakages 4 times per month would need 3 weeks to be resolved and that leaks twice a year are not resolved, as people would be unlikely to contact their stoma service for support.
 - Costs of CNS in stoma care equal to costs used for PSC and the cost of a home care visit assumed to be the same as a face-to-face visit in surgery plus a 5% additional cost for travel time.
- For further detail, see section 7.2.8.2 of the EAR.

Cost and resource use parameters – pancaking and ballooning

- For pancaking and ballooning, the base case included:
 - Costs for additional bags and supporting products from the Nørtoft (2019) subgroup analysis (██████).
 - An assumption that 2 telephone consultations and 1 in person visit with a CNS in stoma care as sufficient to resolve the issue of pancaking, and 2 phone calls are sufficient to resolve ballooning.
 - An assumption that 50% of people with regular ballooning required an additional bag change at night and that 50% of people with regular pancaking doubled their bag use.
 - An assumption that the average time to resolution of issues for both complications was 3 weeks.
- For further detail, see section 7.2.8.3 of the EAR.

Cost and resource use parameters – odour and discreteness, appearance and comfort

- There were no directly relevant publications related to odour or discreteness, appearance and comfort. So, cost and resource use parameters were estimated through discussions with CNS in stoma care. The base case included:
 - Odour - assumptions that 1 phone call or online appointment and 1 in-person visit would be required to reduce issues with odour to the point where impact on HRQoL is minimal, and the average time to resolution of odour issues was three weeks.
 - Odour - The average cost of 1 bottle of drops (£7.96) and 1 bottle of spray (£10.40) and an assumption that 1 of each bottle would be required per week for people using them (estimated to be 10% of people).
 - Discreteness - assumptions that finding a bag with the right appearance, discreteness and level of comfort would require on average 2 phone calls and 1 in person visit, bags given to people to trial come at no cost and the average time to resolution of issues to a satisfactory level was 3 weeks.
- For further detail, see section 7.2.8.4 of the EAR.

Health state utilities – PSC

- The EAG identified 4 studies with information on the impact of PSCs on HRQoL in the form of utilities. None of the studies reported data using the EQ-5D.
- The EAG concluded that all studies had limitations and would be likely to incorporate bias. After considering the limitations, the EAG used data from Nichols (2019) in the base case as it done in the UK.
- A rare consequence of PSCs is the need a stoma to be re-sited. The EAG identified 1 paper where a one-off QALY decrement of 0.25 was applied.
- The EAG identified 1 paper on the impact of hospitalisation on HRQoL. A decrement of 0.083 was applied during the hospital stay. The EAG assumed an average duration of 4.2 days based on duration of stay data for readmission with PSC. For further detail, see section 7.2.9.1 in the EAR.

PSC severity	Utilities	Disutilities
Normal	0.7340	-
Mild	0.6860	0.048
Moderate	0.6400	0.094
Severe	0.6100	0.124

Health state utilities – leakage

- The EAG identified 2 studies reporting data for the impact of leakage onto clothes according to the frequency of leaks.
- It used data from Rolls (2022) for the base case as it was conducted in the UK and had a larger sample size (n=758). But, the population was people with an ileostomy and was a vignette study. The EAG stated that this study is likely to overestimate the impact of leaks as it did not account for participants’ other underlying conditions. For more detail, see section 7.2.9.2 of the EAR.

Leakage utilities	Rolls (2022)
No PSC (Leakage group)	0.8100
Health state with 4 leakage events per month	0.6910
1 leakage event per month	0.7510
2 leakage events per year	0.7820
Health state with no leakage events due to a digital notification solution	0.8070
Leakage disutilities	Rolls (2022)
4 events/month (p < 0.0001)	0.1140
1 event/month (p < 0.0001)	0.0570
2 events/year (p < 0.0001)	0.0220

Health state utilities – pancaking, ballooning, odour, discreetness appearance and comfort

- Due to the limited evidence base, the EAG used the following utility increments and decrements from SEE for the remaining health states.

Complication	Utility
Regular (daily) pancaking	0.0664 (SD: 0.020; Decrement)
Regular (daily) ballooning	0.0580 (SD: 0.020; Decrement)
Regular (daily) odour issues	0.0820 (SD: 0.074; Decrement)
Discreet bag design with preferred appearance	0.0775 (SD: 0.123; Increment)

- For further detail, see sections 7.2.9.3 to section 7.2.9.5 of the EAR.

Economically justifiable price

- The EAG calculated the maximum cost-effective price (total economically justifiable price) for a bag possessing features that can fully or partially prevent different bag-related complications.
- The eJP can be calculated by reversing the equation used to calculate an incremental cost-effectiveness ratio in a cost-effectiveness analysis.

$$\text{eJP} = (\text{threshold of } \text{£}20,000 \times \text{incremental QALY}) - \text{incremental cost}$$

- The EAG calculated the expected costs and QALYs over a year for a person experiencing a bag-related complication (comparator), and the costs and QALYs for a hypothetical bag that eliminates the complication (intervention).
- For the base case, the EAG calculated the incremental eJP per year, and the incremental eJP per bag.
- The EAG added the incremental eJP per bag to the cost of the cheapest bag available on the Drug Tariff (flat bag £1.85, convex bag £2.30; Opus NaturFit range) to get a total eJP for a bag resolving a complication.

Results – base case summary

- The base case shows that the most impactful bag-related complication was PSC, followed by leaks, pancaking, ballooning, discreteness, appearance and comfort and finally, odour.
- The average price of all bags available on the Drug Tariff in 2023 was £3.02. At the time of the assessment, the price for bags with a flat baseplate ranged from £1.85 to £3.84 per bag, and £2.05 to £3.61 for convex bags.
- For bags that improve individual complications by 100%, the total eJP per bag ranged from £2.22 (odour) to £4.24 (PSC) for flat bags, and £2.66 (odour) to £4.69 (PSC) for convex bags.
- For bags that improve individual complications by 50%, the total eJP per bag ranged from £2.01 (odour) to £3.00 (PSC) for flat bags and £2.45 (odour) to £3.44 (PSC) for convex bags.
- The EAG did not identify any robust data on how bag features may reduce the chance or impact of each complication.
- For further detail, see section 7.3.2 and tables 28 and 29 in the EAR.

Results – base case (100% improvement in complication)

Complication	Inc costs	Inc QALYS	Inc eJP per year	Inc eJP per bag	Total eJP per bag (flat)*	Total eJP per bag (convex)*
PSC	-£1,093	0.011	£1,312	£2.39	£4.24	£4.69
Leakage 2 x yearly	-£430	0.022	£868	£1.58	£3.43	£3.88
Leakage monthly	-£462	0.003	£526	£0.96	£2.81	£3.26
Leakage 4 x monthly	-£540	0.007	£670	£1.22	£3.07	£3.52
Pancaking	-£381	0.004	£457	£0.83	£2.68	£3.13
Ballooning	-£285	0.003	£352	£0.64	£2.49	£2.94
Discreetness, appearance and comfort	-£167	0.004	£256	£0.47	£2.32	£2.76
Odour	-£106	0.005	£201	£0.37	£2.22	£2.66

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*Total eJP is calculated by adding the incremental eJP to price of the cheapest bag

Results – base case (50% improvement in complications)

Complication	Inc costs	Inc QALYS	Inc eJP per year	Inc eJP per bag	Total eJP per bag (flat)*	Total eJP per bag (convex)*
PSC	-£519.32	0.0055	£628.66	£1.15	£3.00	£3.44
Leakage 2 x yearly	-£189.30	0.0110	£409.30	£0.75	£2.60	£3.04
Leakage monthly	-£211.76	0.0016	£243.76	£0.44	£2.29	£2.74
Leakage 4 x monthly	-£256.78	0.0033	£322.78	£0.59	£2.44	£2.88
Pancaking	-£174.01	0.0019	£212.17	£0.39	£2.24	£2.68
Ballooning	-£123.18	0.0017	£156.54	£0.29	£2.14	£2.58
Discreetness, appearance and comfort	-£39.71	0.0024	£86.87	£0.16	£2.08	£2.53
Odour	-£83.57	0.0022	£128.11	£0.23	£2.01	£2.45

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*Total eJP is calculated by adding the incremental eJP to price of the cheapest bag

Results – eJP for reduction in all complications

- The EAG explored scenarios where the total eJP per bag was additive for all complications (with no overlap between complications), and where the total eJP per bag was for the complication with the maximum effect only.

% reduction in complications	Total eJP per bag assuming complications are additive		Total eJP per bag assuming only the benefit from the maximum impact complication applies	
	Flat	Convex	Flat	Convex
100%	£7.52	£7.96	£4.24	£4.69
75%	£6.01	£6.46	£3.62	£4.07
50%	£4.51	£4.95	£3.00	£3.44
25%	£3.00	£3.45	£2.37	£2.82
10%	£2.10	£2.55	£2.00	£2.44

For further detail, see table 30 in the EAR.

Scenario analysis results

- The EAG did multiple scenario analyses for flat and convex bags in relation to a number of different model inputs. Further detail is in section 7.3.3 and tables 33 and 34 of the EAR.
- The EAG found that the scenarios with the biggest impact on eJP per bag included:
 - alternative (lower impact) sources of resource use for PSC – decreased the eJP
 - alternative (higher) estimates of the number of bags per day for patients with no complications – decreased the eJP
 - alternative time to resolution for PSC – higher time increased the eJP, lower time decreased the eJP
 - alternative (higher impact) sources of utilities for PSC – increased the eJP
- Results for complications other than PSC were generally robust to the scenarios tested.

Exploratory analysis for bags with clinical evidence (1)

- Voegaard (2007) reported lower ballooning rates for SenSura compared with Nova 1. SenSura had a higher price, but the EAG stated that the price difference was not explained by the difference in ballooning rates in the study, as it was higher than the incremental eJP per bag.
- In Virgin-Elliston (2023), SenSura and SenSura Mio were priced the same and the newer bag (SenSura Mio) had lower reported rates of ballooning.
- [REDACTED]
- The EAG did not consider the difference in outcomes to be robust. But, it stated that the analysis provides further evidence that there may be limited association between current pricing and demonstrated or expected clinical benefits of 1-piece closed bags for adults with a colostomy.
- For further detail, see section 7.3.4 of the EAR.

Sponsorship

- Over 80% of hospitals in England have a formal sponsorship agreement (awarded by an NHS tender process) in place with stoma appliance suppliers or manufacturers ([Kettle, 2019](#)).
- There is limited evidence discussing the impact of sponsorship in England. A survey of 108 CNS in stoma care in England reported the following points in terms of industry involvement:
 - Areas where industry involvement was seen as a benefit included provision of home delivery services, free stock for hospitals, educational events for staff and patients, and increases in number of staff available
 - 35% of respondents highlighted a need for improvement on the reliance of financial and resource support from industry, and 27% of respondents raised issues relating to the ethics and potential tension around conflicts of interest.
- The EAG were unable to identify evidence to be able to quantify the impact of sponsorship in the economic model but provided anecdotal evidence on the benefits (such as additional service provision) and disadvantages (such as promotion of more expensive products) in its report. Sponsorship may influence the eJP as there are both costs and benefits associated with it.
- For further detail, see section 7.4 of the EAR

Limitations of the economic model (1)

- There was a lack of data to quantify the clinical and economic benefits of specific features or types of bags
- The total eJP per bag is highly uncertain due to the lack of evidence directly related to the decision problem and uncertainty around the accuracy model parameters, such as those obtained through expert elicitation.
- The incremental eJP of reducing or eliminating multiple complications is unknown but is likely to be between the incremental eJP of the single most impactful complication and the sum of the incremental eJP of all of the complications. This is because the impact of complications, such as PSC and leaks, can overlap
- The EAG used the cheapest bag available on the Drug Tariff as the bag price comparator (which has <1% of the market share). But, this assumes that this bag is priced appropriately, which may not be the case.
- The model does not account for the impact of sponsorship due to the lack of available evidence on how it impacts the NHS and service users.

Limitations of the economic model (2)

- Data on the impact of bag-related complications on HRQoL and resource use generally came from a mixed population, with a higher proportion of ileostomy cases compared to colostomy cases
- Some optimistic assumptions were used, such as assuming all users experienced complications with the cheapest bag, and use of more optimistic estimates for the resource use impact of PSC and leaks. The model also starts after the initial adjustment period following surgery.

Conclusions from the economic evidence

- The EAG's regression analysis found that the feature with the most impact on price was flushable disposal in flat bags and that current prices may not currently be driven by the presence of potentially innovative features.
- The EAG found that the most impactful bag-related complications was PSC and leaks, aligning with the findings of the user preference assessment that users prioritise maintaining and promoting healthy peristomal skin.
- The EAG found that the total eJP for a bag improving individual complications by 100% is £4.24 for a flat bag and £4.69 for a convex bag. But, this does not account for the fact that complications likely overlap.
 - It may be that the true total eJP that impacts multiple complications is between the maximum price for a single complication and the maximum price for all relevant complications added together.
- Key model drivers were the unit cost and frequency of healthcare professional (HCP) interactions, cost of supporting products and expected QALY gains.
- Exploratory analysis done on published evidence provided further evidence that there may be limited association between current pricing and demonstrated or expected clinical benefits of 1-piece closed bags for adults with a colostomy.

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Due to the limited evidence, the EAG were unable to determine if difference in current bag prices can be explained by improvements in outcomes. For further detail, see section 7.5 of the EAR.

Evidence gap analysis (1)

	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Sustainability
Leakage	N = 0 studies RED	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 0 studies RED	N = 4 studies AMBER	N = 0 studies RED
Length of time before switching bags	N = 0 studies RED	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 0 studies RED	N = 3 studies AMBER	N = 0 studies RED
Number of appointments with CNS in stoma care	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Medicine use	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Number of or time to ballooning events	N = 0 studies RED	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 0 studies RED	N = 4 studies AMBER	N = 0 studies RED
Odour control	N = 0 studies RED	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 4 studies AMBER	N = 0 studies RED	N = 4 studies AMBER	N = 0 studies RED
Supporting product use for attachment and removal	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED

Evidence gap analysis (2)

	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flushable disposal	Inspection window	Sustainability
Pancaking events	N = 0 studies RED	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 0 studies RED	N = 3 studies AMBER	N = 0 studies RED
Peristomal skin complications	N = 0 studies RED	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 0 studies RED	N = 1 study AMBER	N = 0 studies RED
Mucocutaneous separation	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Other intervention related adverse events	N = 0 studies RED	N = 5 studies AMBER	N = 5 studies AMBER	N = 5 studies AMBER	N = 5 studies AMBER	N = 5 studies AMBER	N = 0 studies RED	N = 5 studies AMBER	N = 0 studies RED
Ease of use and acceptability	N = 0 studies RED	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 3 studies AMBER	N = 0 studies RED	N = 3 studies AMBER	N = 0 studies RED
Health-related quality of life (for individual complications and jointly)	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED	N = 0 studies RED
Psychological and social impact	N = 0 studies RED	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 1 study AMBER	N = 0 studies RED	N = 1 study AMBER	N = 0 studies RED

Ongoing studies

Sponsor, registry number and study type	Date and country	Population	Research objective	Outcomes
Sponsor: Coloplast NCT05641168 Randomised, open, parallel assignment trial	Registration: 15 Nov 2022 Last update: 7 Dec 2022 Country: Denmark	Participants will have a colostomy, ileostomy or urostomy for more than one year and have suitable peristomal skin area (assessed by investigator)	A pilot evaluation exploring new adhesive materials and their ability to adhere to abdominal and peristomal skin.	Adherent area (assessed by photos of adhesive materials)
Sponsor: B. Braun NCT05373888 Non-interventional, prospective, international, multi-centre, post market follow-up investigation	Registration: 15 Nov 2022 Last update: 7 Dec 2022 Country: Spain	Participants will be Softima users (new and experienced users) with either a colostomy, ileostomy or jejunostomy	To evaluate the number of patients with at least one adverse bag effect	Allergic contact dermatitis Mechanical dermatitis – trauma Irritant-chemical dermatitis Infectious conditions Any other bag related complication (as judged by a clinician)
Sponsor: Zhende medical supplies* ChiCTR2300072043 Randomised, open, parallel, positive-controlled, multicentre, non-inferior clinical trial	Registration: 01 Jun 2023 Last update: 28 Jul 2023 Country: China	Participants will have a DET score of 0 for peristomy dermatitis and a stoma that meets the requirements for using a convex baseplate.	To evaluate the safety and effectiveness of Zhende medical ostomy products, and the related performance of the products is not inferior to that of Coloplast stoma care products.	Leakage Length of time before switching bags Incidence of dermatitis Comfort Patient satisfaction

*Zhende medical supplies do not currently list any one-piece closed bags on the Drug Tariff

DET: discolouration, erosion, tissue overgrowth

Future research (1)

The EAG highlighted the following major challenges for developing evidence for 1-piece closed bags:

1. The need for clearer comparators, more precise and generalisable populations, and a broader range of bags and features (for example, baseplate additives and flushable disposal) evaluated in robust comparative designs
2. Clearer regard for outcomes that matter to patients, such as peristomal complications, and greater development and use of validated measures
3. Greater inclusion of subgroups of people with colostomies that have complex needs, and greater detail of how these groups are considered in research
4. Real world data to understand how 1-piece closed bags are used in clinical practice

For further detail, see section 8.4 of the EAR.

Future research (2)

- The EAG stated that the following evidence generation is needed to develop the evidence base for this topic:
 - Generation of robust estimates of clinical effectiveness of 1-piece closed bags OR of features of 1-piece closed bags for adults with a colostomy.
 - Development of a core outcome set and validated patient-reported outcomes is needed to ensure that each bag is assessed using all the outcomes that are important for adults with a colostomy in choosing a bag.
 - Identification and definition of key groups or 'indications' for adults with a colostomy that could be used to guide evaluations as some bags may be inappropriate comparisons.
 - Identification of data for 'lost ostomates' and people with poor outcomes from their bags.
- For further detail, see section 8.4 of the EAR

Comments from patient organisations

Comments from patient organisations – Colostomy UK (1)

- Interim results from a recent survey of 3742 people with a stoma (69% of responders having a colostomy) done by Colostomy UK highlighted the impact of a stoma on a person's physical and mental health. It reported that 33% of people believe their physical health has gotten worse since stoma surgery, and that 34% believe their mental health has gotten worse. When asked if they feel in control of their lives, 49% of people said no.
- The survey highlighted that a number of things having the greatest impact on quality of life are directly linked to stoma management.
 - For example, 53% of responders reported that they were impacted by leakage, 48% by pancaking, 44% by skin irritation, 39% by ballooning, and 28% by odour.
- Colostomy UK highlighted that failure to manage these issues can lead to people stopping doing things like going to work, socialising and more, which leads to feelings of loneliness and isolation.

Comments from patient organisations – Colostomy UK (2)

Advice from Colostomy UK was summarised in the following 3 points:

- Leakage, skin conditions, ballooning, odour, and parastomal hernias are all major stoma management challenges for people with a stoma. Having the correct bag hugely influences the impact these can have on a person's quality of life.
- People living with stomas need to have access to the right products at the right time from the supplier of their choice, and free from commercial influence.
- Regular contact with a health care professional (CNS in stoma care) is vital in ensuring that patients are using the right bag for them, regardless of its perceived quality. Changing circumstances, such as changes in body shape, hugely impact product reliability and need to be taken in to account when choosing the right product.

Comments from patient organisations – Ovacome

Advice from Ovacome was summarised in the following 4 points:

- It is important that people have access to and a choice of a range of stoma bags with different features to ensure that they are able to benefit from products that meet their own individual needs.
- The use of the correct stoma bag is vital for ensuring best management of the physical effects of a stoma, as well as the psychological effects (such as confidence in use and in reliability of the bag), to enable someone to have a good quality of life.
- When people have a stoma as a result of treatment for ovarian cancer, the stoma products they need may change over time (for example, due to side effects from cancer related treatments).
- It is important that everyone has equal access to the variety of stoma bags available and are made aware of the products that are available to ensure that they are able to live well with a stoma and have a good quality of life. For this to happen, information needs to be provided in an appropriate and accessible way, taking into account individual needs.

Equality considerations (1)

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

- People having colorectal surgery may have an underlying condition such as cancer or inflammatory bowel disease. People with a colostomy undergoing treatment for cancer, such as chemotherapy, may experience changes in skin condition or output as a result of this treatment. This may impact the type of bag that is needed.
- People who have been diagnosed with cancer or chronic diseases may be considered disabled under the Equality Act (2010).
- Older people or people with underlying skin conditions may be more likely to have fragile skin that is prone to tearing. They may experience a higher rate of peristomal skin complications due to the continued removal and application of the colostomy bag baseplate. It is also reported that women experience a higher rate of peristomal skin complications compared with men ([D'Ambrosio, 2023](#)).

Equality considerations (2)

- Some people may need additional support or may struggle to use certain bags because of a visual or cognitive impairment, reduced manual dexterity or a learning disability. Autistic people may also find certain bags unsuitable or may need additional support.
- People in a wheelchair, people who are sat for long periods of time or people with excessive sweating, may struggle with the durability and security of certain bags.
- Colostomy bags are mostly offered in beige, grey or clear. A small number of bags are offered in black. People may prefer choosing a bag that most closely matches their skin tone if this is available.
- Age, disability, gender and race are all protected characteristics under the Equality Act (2010).

Issues for consideration (1)

Limited clinical evidence

- Only 5 studies directly relevant to the decision problem, and 8 studies in the expanded evidence base were identified by the EAG.
- Suggests that there is limited evidence to support improvements in outcomes for 1-piece closed bags available on prescription to adults with a colostomy in the NHS.
- EAG concluded that there is insufficient evidence to demonstrate the difference in clinical effectiveness, and whether bags with potentially innovative features offered greater benefits to adults with a colostomy than bags without.

Difficulties in clinical study design

- Currently, there a lack of information to support the development of robust studies to evaluate 1-piece closed bags (epidemiological data in people with a colostomy, validated HRQoL measures and other outcome measures, lack of real-world evidence sources that can estimate bag use data).
- There are many subgroups of people with a colostomy that are not defined but need to be considered separately in future research as all bags will not be suitable for everyone. There is a need for a clear breakdown of which groups of people can be compared with other groups to ensure future evidence generation is appropriate.

Issues for consideration (2)

Lack of evidence for model parameters

- The EAG were unable to assess the cost-effectiveness of features of 1-piece closed bags due to the lack of evidence.
- Instead, the EAG modelled the total economically justifiable price of a bag that has features that can improve specific complications.
- A number of model parameters were obtained through discussion with CNS in stoma care and SEE due to the lack of clinical evidence.
- Data on the impact of bag-related complications on HRQoL and resource use were generally from a mixed population and either used methods that did not align with the NICE reference case (vignettes or the SF-6D for utilities) or were poorly reported.

Likely overlap of impact on complications

- The model structure considers each complication in isolation and does not account for a feature or bag impacting multiple complications at once.
- The incremental eJP of reducing or eliminating multiple complications is unknown but is likely to be between the incremental eJP of the single most impactful complication and the sum of the incremental eJP of all of the complications.

Impact of sponsorship is not included in the model

- Due to lack of information about the impact of sponsorship, the EAG were unable to quantify this in the model, although this information has been considered separately.

Issues for consideration (3)

Bag choice is based on a number of different factors which can change

- Bag choice can be influenced by preference and clinical need.
- Bag choice might depend on a person's body shape or stoma anatomy, as well as the formation and consistency of a person's poo, how many bag changes are needed per day and a person's skin type and integrity. These are individual to each person and can change over time.
- All bags will not be suitable for all people.

Users value bags or features that can maintain and promote healthy peristomal skin

- The user preference assessment reported that the top 3 criteria related to maintaining and promoting healthy peristomal skin. This was considered to be considerably more important than other preferences.
- This aligns with previous studies reporting that creating and maintaining a leak free seal is key to maintaining quality of life for people with a stoma.
- The EAG report also found that PSC and leakage had the largest impact on both HRQoL and costs to the NHS.
- Bags that are proven to maintain or promote healthy peristomal skin may be worth paying a higher price for. But no evidence was found to do this in the evidence.

HealthTech Programme

One-piece closed bags for adults with a colostomy: Late-stage assessment

External Assessment Report, User preference report and economic model

Collated comments

Section A: Comments on the External Assessment Report

Comment no	Organisation	Page no	Section No	Comment	Response from the EAG
Care pathway					
1	Coloplast	90	7.2.3.92	‘One responded that bag switching may be influenced by marketing strategies from companies that they had witnessed in practice, for example, insisting that people switch to their latest branded products.’ This sentence is potentially misleading when clinical context is properly considered: As we have previously commented in the NICE or EAG documents, the description of the circumstances where a different bag is chosen is misleading. In typical ostomy care, changes in product choice would be expected, due to the ‘multifactorial issues’ attributed to	Thank you for your comment. The statement as written in the EAG report is factually correct as it represented the experience of one CNS in stoma care we consulted. The report does state that the main reason for people changing to another type of bag is experiencing complications with their current bag but that marketing ‘may’ also have an influence. NICE recruited 5 clinical specialist committee members and 4 clinical experts to contribute to this process. During the assessment, views were sought multiple times from more than two CNS in stoma care. All CNS in stoma care had the opportunity to view and comment on the draft report.

				the Clinical Nurse Specialist on p90. In our experience, this is most likely due to changes in body profile and output which are common in people living with a stoma. In fact, in a consensus-based practice guidelines for the assessment and treatment of persons with an ostomy, it is stated that peristomal body profile and skin health should be checked by the person living with a stoma at every product change (Colwell et al. WOCN, 2019), as using improper fitting between the ostomy and the ostomy product(s) is one of the main reasons for leakage (James-Reid et al. BJN, 2019). Furthermore, the recent study of Vendelbo et al. showed that change to optimally fitting ostomy products reduced the number of leakages and increased individuals' quality of life (Vendelbo et al. BJN, 2023). This would therefore justify a CNS reassessment and potential need for a change in appliance. As per the User Preference Report NICE / EAG have highlighted variation in stoma care across the UK. Having only two opinions from stoma care nurses is limited and does not reflect UK-wide practice. In an evidence-based assessment an anecdote in this section from 1 or 2 CNS' is not appropriate.	

2	Coloplast	144	7.4	'These services do vary from trust to trust' Coloplast believes this should be addressed by incorporating a GIRFT evidence-based stoma care pathway across the UK.	Thank you for your comment. This is beyond the remit of a NICE Late-stage assessment.
3	Association of Stoma Nurses	15	Research recommendations	We are pleased the EAG recognise the need for further research recommendations as a priority. The unmet treatment needs, implications of pouch on physical and mental health for people is not accounted for as the whole piece is reductive and related to price of bag. Albeit you have acknowledged <i>Adults with a colostomy are a highly diverse group of people...</i> and we are pleased you have recognised within your report pg 28 the profound enormity of the <i>Negative outcomes that cause embarrassment for people with a colostomy, such as leakages or a lack of discreetness</i>. As clinicians, we strongly believe within this EAG there appears to be very limited insight and understanding of the holistic needs of patients as individuals – your segmented outcomes have been generalised to such a degree that it does not represent the significant collective variations that will impact the specialist assessment, choice or type of stoma bag required. This includes and is not limited to variation of diagnosis and treatment, which would impact on the number of times they open their bowels; the types of medication they take that may affect their	Thank you for your comment. The EAG appreciate that the treatment pathway, including the choice of device used by a person with a colostomy, will essentially vary according to the individual's needs. We have noted these considerations in the report (specifically section 3 on clinical context and section 8.3 and 8.4 which provide further details around the research recommendations) and don't consider there to be a factual inaccuracy in the section you have highlighted. The aim of late-stage assessment is to assess if the value added by incremental innovation justifies the price variation. This will involve capturing the product features most relevant to users and NHS healthcare providers, and evaluating how they impact outcomes and user preferences. These product features can include basic product specifications and features that add value. This will help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are

				bowels, other life preserving treatments that may affect them, their HRQoL & mental health status; as well as the over 200 different body profiles; body habitus, surgical intervention, physical ability to manage the stoma pouch, personal preferences; lifestyle etc etc. In addition to this, many of these factors change over time which impact on the need to change the type of bag worn by the individual. Fundamentally and essentially ALL of these factors individually impact on the choice of which one piece closed bag may be assessed, chosen and worn to achieve a secure and leak proof appliance. The ramifications of not having appropriate choice and ranges of quality bags available to meet individual patient needs, will have a greater economic impact on the NHS (compared to savings made to reduce costs in the prescribing budget). Based on experience and expertise of the representatives of the ASCNUK completing this review of the EAG; it is foreseen that increased stoma related complications and reduced ability to effectively meet the priority criteria you have identified in your User preference will lead to increased NHS costs. These would include increased specialist OPAs and home visits; GP and community nurse visits as well as a negative impact on mental health, inability to work all being incurred as a result of stoma related clinical problems.	available for use while maintaining choice in the system.

				As innovation in quality products over the years has occurred and specialist assessment by SCN 'has been undertaken. It has been by those who have been working in stoma care over the years that patient's are returning to work and contributing positively to society. It would surely be a backward step if innovative quality products that maybe at a higher price were threatened, or made so difficult to prescribe they were avoided	
4	Association of Stoma Nurses	17	Setting of care	GP's do write prescriptions for patients in primary care settings and non expert prescribers but this again NOT fully accounted for in the cost analysis In addition, it should be acknowledged the fact that within stoma care in primary care settings there has been a growth of centralised prescribing centres- this allows for better long terms outcomes and the management of the patient sits with those with expert knowledge	Thank you for your comment. The type of prescriber would not be expected to be impacted by bag type choice and therefore it was not necessary to account for this in the cost analysis. Text has been amended to: "In its assessment, the EAG considered that prescriptions for 1-piece closed bags may be issued in primary care, or outsourced to prescribing hubs, but that care for people with a colostomy was largely coordinated and delivered by a clinical nurse specialist (CNS) in stoma care in a secondary care setting or Dispensing Appliance Contractors (DACs)."
5	Association of Stoma Nurses	26	Choice of pouch	From a clinical perspective – if a holistic clinical assessment has been undertaken of the person who has complex needs there may be a limited number of bags with features suitable to their individual needs. It would be a consideration in response to the comment that the patient was not offered a choice – that the patient	Thank you for your comment. The EAG have noted in the report that there may be limited bags for people with complex needs. We don't consider there to be a factual inaccuracy in this section and no change has been made to the report.

				wants may not be what the patient needs – again in view of the lack of transparency from the colostomy UK survey – we are restricted from understanding the context	Colostomy UK have kindly provided NICE with interim results of their survey as part of their patient organisation submission to provide contextual information for this assessment. The clinical context section of the external assessment report also acknowledges that clinical nurse specialists are key in ensuring that people would be prescribed the appropriate bag for their needs
6	Association of Stoma Nurses	28	Supporting products	From a clinical view – we would wish to challenge the use of supporting products are indeed essential / necessary items identified to be used to ensure the person is leak free (based on clinical assessment)	Thank you for your comment. This topic is discussed in the EAG report and covers a range of views identified by both clinical specialist nurses and people with lived experience. No change has been made to the report.
7	Association of Stoma Nurses	77	7:2:1	Cost of pouches-this is set by drug tariff based on their process of assessment and request of information from the manufacturing companies- this consultation is not looking at this criteria- We would agree there is a need to review the drug tariff process and would value the inclusion of a board of SCN 's to assess products In addition not all products found in part 9 are used by those with a stoma as discussed within this document No acknowledgement of development of products as a result of research within the field	Thank you for your comment. A review of drug tariff process is also outside the remit of this assessment. As stated in the assessment protocol, only those technologies listed in Part IXC of the Drug Tariff at the start of the assessment (April 2024) would be eligible for consideration in the assessment as late-stage assessment is based on existing procurement/prescribing frameworks. The EAG acknowledged that some products listed on the tariff have low levels of prescribing and a lack of available information and so were excluded from the regression analysis. The EAG have acknowledged ongoing studies in section 8.2 of the assessment report.

8	Association of Stoma Nurses	82	7:2:3	You have identified within your report that <i>two experts proposed that the presence of a parastomal hernia should be included, however, later correspondence confirmed that the type of bag used does not contribute to the risk of hernia and therefore this remained excluded from the model.</i> we would wish to explore the rationale behind the exclusion of a parastomal hernia – as it would be advocated that this stoma complication would affect the choice of bag chosen	Thank you for your comment. The report includes acknowledgement that the presence of a hernia affects the choice of bag. The comment you have highlighted is concerning whether the choice of bag affects the risk of developing a hernia. The EAG do not consider this to be a factual inaccuracy and no change has been made to the report.
9	Association of Stoma Nurses	83	Conceptual model	We are surprised that parastomal hernias did not come up as a complication to be most impactful- from experience this is a major complication that impacts on people living with a stoma	Thank you for your comment. The consideration of this within the conceptual model was based on feedback that the choice of bag does not affect the risk of developing a hernia. The EAG do not consider this to be a factual inaccuracy and no change has been made to the report.
10	Association of Stoma Nurses	84	7.2.3.3	Skin damage due to repeated pouch removal and application- this is a symptom not a cause- the rational for this needs the skill of the SCN to assess	Thank you for your comment. The statement made comes from a published paper: Fellows J, Voegeli D, Håkan-Bloch J, Herschend NO, Størling Z. Multinational survey on living with an ostomy: prevalence and impact of peristomal skin complications. Br J Nurs. 2021;30(16):S22-s30. The paper states: “PSCs can arise from a multitude of factors including trauma and mechanical injury due to adhesive stripping from repeated barrier application and removal.”

					The EAG are aware of the key role of CNS in assessing the causes and best treatment for PSC. The vital role that CNS play has been emphasised throughout the report.
11	Association of Stoma Nurses	86	Leakage	'nurses' please be consistent in description of SCN – we are specialist practitioners within the field of stoma care The use of seals may be necessary even for those with a colostomy-based on clinical need	Thank you for your comments. The EAG have generally used the term CNS in stoma care throughout the report and we have changed this instance to be consistent. The use of seals is presented in a manner consistent with the input given to the EAG during consultation with experts and supporting product use is considered as part of the economic analyses.
12	Association of Stoma Nurses	107	Pancaking and ballooning	In relation to stoma bridges- It would be agreed they are helpful but we are sure if you reviewed the market use – these are now not widely used – as product innovation and filters are improving	Thank you for your comment. As stoma bridges are still used by some people with a colostomy, we have retained the comment in this section.
Clinical Evidence					
13	Convatec	34	5:1	Whilst it is understood that human real life studies regarding features will offer meaningful results, the paucity of such studies related to specific features is also apparent. As such, we would propose that the exclusion of scientific lab data, which has previously been deemed acceptable by BSA should be considered	Thank you for your comment. The review protocol for the LSA excluded laboratory-based studies, on the basis that these studies do not provide evidence that can inform estimates of cost effectiveness within NICE preferred methods. Moreover, feedback from SCMs during the assessment was that this evidence would not be meaningful to understand the potential benefits of 1-piece closed bags for people with a colostomy, and this is noted in the report. No change

					has been made to the report in response to this comment.
14	B Braun Medical	Throughout	Throughout	The EAG report uses almost none of the information submitted by manufacturers in RFI; the only studies considered were RCTs. The process of completing the RFI is incredibly resource-intensive for manufacturers, particularly given the short timeframes imposed. This dismissiveness of the evidence provided is disheartening and may lead to some manufacturers being unwilling to engage in the LSA process in the future if they believe their efforts will be disregarded. Moreover, it indicates a lack of understanding by the EAG that in ostomy (and many other disciplines), RCTs are rare and other study designs should be considered in addition. NICE could use the EAG report as a basis for their decision whilst additionally considering other forms of evidence from manufacturers.	Thank you for your comment. The aim of this assessment was to evaluate the clinical and cost effectiveness of 1-piece closed bags, and/or their features, for people with a colostomy. This requires the identification of robust evidence as opposed to evidence that is unreliable and potentially does not accurately represent the experiences of people with a colostomy. The inclusion criteria for the evidence review was not restricted to RCTs – prospective and retrospective observational studies, time series analyses, and single arm studies were all considered eligible for the assessment, where these were robust. As described in the EAG report, the evidence evaluating 1-piece closed bags is of poor quality and very little was considered by the EAG to be meaningful for understanding the potential value of these for people with a colostomy. The EAG concluded that further research is needed in order to inform any further assessment of these devices. All companies were provided with a user guide alongside the request for information which listed the evidence types considered by NICE. NICE will take on board this feedback as part of its lessons learnt process to ensure information is made clearer in future assessments.

15	B Braun Medical	N/A	N/A	The choice by the EAG not to use evidence submitted by manufacturers indicates that ostomy is an unsuitable topic for LSA in its current form. Future LSAs should either be more open to non-RCT evidence, or focus on topics which are more likely to have RCTs.	Thank you for your comment. As noted in response to your previous comment, the assessment was not restricted to RCT evidence - prospective and retrospective observational studies, time series analyses, and single arm studies were all considered eligible for the assessment, where these were robust. The overall evidence base for 1-piece closed bags was considered to be poor quality and very little was considered by the EAG to be meaningful for understanding the potential value of these for people with a colostomy. The EAG concluded that further research is needed in order to inform any further assessment of these devices.
16	CliniMed			How do you set up a non-biased RTC in stoma care? A few years ago, in partnership with a University Welland Medical tried to undertake a trial led by the university. The recruitment of patients was very difficult through local stoma care nurses.	Thank you for your comment. In its report, the EAG has provided some guidance for the design of studies, including RCTs, to evaluate 1-piece closed bags for people with a colostomy. Recruitment challenges are common for studies across various conditions, though RCTs and other robust study designs are accomplished, even in rare conditions.
17	Hollister Ltd	99	7.2.8.1	ADVOCATE Study: Much of this was excluded. Whilst acknowledging that the LSA was focused on one piece, the skin health benefits featured in the study are agnostic to barrier type or ostomy type so the company would have believed still very relevant.	Thank you for your comment. The evidence included in the assessment was guided by the NICE scope and the review protocol. This study was on a mixed population where outcomes were not reported separately as well as being on 2-piece bags. This meant it did not meet the inclusion criteria for

					the clinical evidence review. The exclusion list has been amended to reflect this reasoning.
18	Hollister Ltd	149	8.1	The report notes that evidence is particularly required where a feature impacts more than one complication. Our own experience of product development in conjunction with many end users, is that bag features typically resolve a number of interrelated complications.	Thank you for your comment. The EAG agree and have noted this as a limitation of our approach.
19	Hollister Ltd	241	Appendix J		
20	Coloplast	45	5.3	Quality appraisal of studies - The risk of bias tool used (NICE ROB tool) is a generic risk of bias tool that can be applied across disease areas. However, the nature of medical device research makes some parts of the ROB appraisal difficult. Blinding of study participants will almost without exception be impossible for physical products like stoma bags. We recognise that this is a drawback of all our clinical studies and appreciate that the	Thank you for your comment. It is important to note that risk of bias tools assess for the potential for bias inherent in the study design, regardless of whether the source of the risk was avoidable by the study authors or not. For instance, as acknowledged in the EAG report, it would not be possible for participants to be blinded to the bag that they were using in the study, though this does not mean that the lack of blinding would not still be a potential source of bias. The lack of blinding was therefore not disregarded in the EAG assessment of study quality. The same applies to the use of crossover designs, which as you say may have value given that

				EAG has also acknowledged this bias to be inherent to device studies. Still the EAG elaborates on the different ways participants' expectations may influence their attitudes towards products, and therefore we feel it is unclear whether the blinding aspects of the studies has indeed been disregarded in the evaluation. It should also be recognised, that there may be an inherent experience bias, where people are likely to prefer their current stoma bag, further complicating evidence generation. The LSA also criticises the use of cross-over trial design, as the EAG was unsure of a potential carryover effect. This is also an inherent issue with device trials, as after participating in one of the study arms, they still have to use a stoma product (i.e. their usual product) between study periods, or in one of the study arms, which in turns also could impact results. Therefore, a pragmatic approach has to be taken, where users should be enrolled in the study arm for a sufficient time to avoid a potential study effect. Moreover, we would still consider the cross-over design where participants act as their	each participant is their control but also pose potential risks of bias where the washout period between interventions is short. In its report, the EAG has commented on the potential for bias from the short washout periods used in the studies, with the caveat that the order of treatments were random.

				own control eliminating most variance to be preferred over a traditional RCT where an unpaired analysis will induce unknown amount of variance.	
21	Coloplast	48	5.4.2	The reference product mentioned is wrong. It is noted as Moderma Flex, however, in Voergaard 2007, the reference product was Nova1. This mistake is repeated throughout the document including table 8 on page 52, table 13 on page 65 and section 7.3.4 on "Exploratory analysis of specific bags",	Thank you for raising this issue, it is much appreciated. The EAG have re-labelled the device name throughout the report.
22	Coloplast	48	5.4.2	It is reported that a higher rate of [REDACTED] was found with SenSura vs. reference product [REDACTED] in the Voergaard study. This is a misinterpretation by the EAG, as in the evidence request made to Coloplast, it was reported that SenSura had a [REDACTED] of the reference product. This mistake is continued throughout the document. It is also reported in the conclusion where the evidence on [REDACTED] was seen as "mixed" due to this misinterpretation. Therefore, all evidence reported on the [REDACTED], and this should be reflected in the report.	Thank you for raising this issue, it is much appreciated. The EAG have corrected the error in the data and updated the description of the results, accordingly.
23	Coloplast	49	5.4.3	The reference product mentioned is wrong. It is noted as Nova1, however, in	Thank you for raising this issue, it is much appreciated. The EAG have re-

				Teniere 2007, the reference product was Moderma Flex. This mistake is repeated throughout the document including table 9 on page 54, table 13 on page 65 and section 7.3.4 on “Exploratory analysis of specific bags”,	labelled the device name throughout the report. The EAG have also updated the summary of the results from this study, following the correction
24	Coloplast	63	5.4.7.2	‘This evidence suggests that innovations in filters may be impactful on patient outcomes...’ This suggests that there is actually differentiation between. Please can the EAG clarify why is this not carried through in the conclusions?	Thank you for this comment. The text in this section has been changed following the correction of the error that you identified in the data extraction. The text in the conclusions of this section has also been updated.
25	Coloplast	Various	Appendix A, 5.1 and Protocol	<u>Selection of search filters</u> Search filters were used in both searches, although these have not been referenced in the EAG report. The filters used in the primary MEDLINE search strategy were referenced within the Protocol, but filters used for the other databases do not appear to be referenced. The filter to limit the MEDLINE search to observational studies was sourced from the Scottish Intercollegiate Guidelines Network (SIGN, https://www.sign.ac.uk/what-we-do/methodology/search-filters/). This search filter is not validated. It is not currently recommended good practice	Thank you for your comments. As you noted, and as stated in the LSA interim process and methods guide, the evidence reviews used to inform LSAs are pragmatic in nature. The pragmatic selection of search filters, along with their modification where it was appropriate, therefore fits with this approach. The EAG note that over 3,000 records were retrieved for the clinical review and nearly 6,000 records for the economic review. Given these figures, the EAG does not consider that the searches were too narrow. Moreover, all companies who were stakeholders to the assessment were invited to notify the EAG of potentially relevant evidence for their devices, which were screened separately, as outlined in the review protocol. Further to this, this stakeholder comment period provided

			to use an observational studies filter, and using this type of filter may have excluded relevant studies. Due to the imposed time constraints of the LSA process, it is not possible to check what, if any impact this has had. <u>Modification of search filters</u> It is not recommended practice to modify search filters, as performance of the filters has usually been tested and validated using an accepted methodology. However, the Protocol notes that three of the filters used in the searches (the observational studies filter, the economic evaluations filter and the utilities filter) were modified to remove and add terms. This may have impacted the search results. Due to the imposed time constraints of the LSA process, it is not possible to check what, if any impact this has had. Perhaps the most significant modification is the modification of the Embase filter for randomized controlled trials. This appears to be a modification of the Embase filter in the Cochrane Handbook of Systematic Reviews of Interventions. Line 31 appears to exclude any studies indexed with the terms "randomized controlled trial" or "controlled clinical trial". It is not clear	opportunities for stakeholders to notify the EAG of omitted evidence. The Embase (2019) RCT filter was not edited by the EAG. However, the EAGs notes that a 2023 update is now available. No change has been made to the report in response to this comment.

				why this modification has been made to the filter, but it would seem to potentially exclude some highly relevant studies. Due to the imposed time constraints of the LSA process, it is not possible to check what, if any impact this has had. <u>Limiting the search using a geographic filter</u> The search for economic evaluations has been limited to OECD countries using a geographic filter. This filter relies on accurate indexing of the country information in order for records to be retrieved. This may have compromised the search for economic evaluations. Term selection <u>Brand names</u> We note that no brand names appear in the search strategy. A number of brand names of stoma bag appear in Table 2, these terms may have enriched the search strategy and identified further studies. Due to the imposed time constraints of the LSA process, it is not possible to check what, if any impact this has had. Search translation	

				Translating a search to other databases should replicate the primary search strategy as far as is feasible. However, we note some significant differences between the MEDLINE search strategy and the search strategies provided for other databases. For example: The subject heading for Surgical Stoma is absent from the CINAHL search although it does exist in the database. There are no medical subject headings in either the NHS EED search or the HTA database search, but they are available for use. The searches for the clinical trial registries do not use all the term variations used in the primary search strategy (e.g. stomas, colostomies, aid/aids, appliances, products). Inconsistent search syntax The search syntax in the MEDLINE clinical search is inconsistent and slightly different fields are searched in the text word searches. Lines 3 and 6 search the title, abstract and keyword fields, but line 4 is less broad and only searches the "tw" field (i.e. only the title	

				and abstract). It is not clear why line 4 is more restrictive. <u>Conclusion</u> The search strategies have some highly pragmatic elements which may have compromised search sensitivity and missed relevant studies. However, this pragmatic approach may be acceptable in the context of the LSA project methodology and timeframes. The most potentially limiting factor is the application of search filters and limits. The clinical search is conceptually structured as: (stomas AND bags AND (RCTs OR observational studies)) The economic search is structured as (stomas AND (utilities OR (economic evaluations AND OECD countries))) The topic search (stomas AND bags) retrieves 2,679 studies on MEDLINE, it is unclear why this search was not performed and screened for clinical evidence, without restricting by study design, it may have been more appropriate to limit the search by date instead. It appears that a broader search (i.e. for all stoma care rather than only bags) was undertaken for the economic evidence which then had to	

				be restricted by applying limits and filters, because of the paucity of evidence from initial scoping searches as described in the Protocol. However, it could be argued that the OECD filter limit is too restrictive as it relies only on indexing terms and there may have been other ways to bring search numbers to within acceptable limits. A search narrative may have been beneficial to understand the rationale behind these decisions. It is not possible for Coloplast to meaningfully critique this approach without an explanation as to why it was taken and so are not able to fully engage with this process.	
26	Coloplast	Various	Appendix J, protocol	The protocol states that “single-arm studies (those reporting outcomes before and after a change in an intervention feature in a single group of people with a colostomy) will be considered for inclusion provided these are considered to be robust.”. Although the literature search identified multiple studies of this type, “these studies were excluded from the evidence review as by comparing multiple variations in bag features, the results were not informative for understanding the effectiveness of any one feature or bag.”. It was not possible to	Thank you for your comment. The EAG sought to include the best quality evidence that was able to address the decision problem for the assessment. The reasoning for considering an expanded evidence based is outlined in appendix J. Stakeholder comment periods allow for identifying if key studies have been excluded based on the parameters outlined. In line with NICE’s health technology evaluations manual, NICE encourage stakeholders to keep confidential evidence to an absolute minimum to aid transparency in NICE’s decision making process. In some circumstances, NICE will accept

				independently identify and assess the studies excluded from the review as full references were not supplied (only an author and year was listed). Due to the paucity of evidence identified by the review, “studies comparing mixed interventions (i.e. outcomes with a 1-piece closed bag compared to outcomes for a mix of different 1-piece bags)” were included in a broader assessment detailed in Appendix J. “As these evidence types were not selected during screening in the clinical effectiveness review, a decision was taken to identify this evidence from company RFIs.”. The possibility exists that some studies may have been missed at this stage. Without conducting our own scoping searches and screening it is not possible to further investigate the scale of this possibility. Of the eight studies included in the expanded evidence base (including 2-piece bags, and studies with mixed comparators), information for two is redacted. The whole of the “mixed comparators” summary section of the expanded evidence base is also redacted. It is unclear to a reader who is not familiar with specific products exactly what features each study was assessing; for example, Belfield-	evidence and information not in the public domain under agreement of confidentiality. This can include clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document. If a technical engagement happens, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement.

				Cockings 2022 investigates a Genii bag, but the novel feature of the bag (breathable silicone adhesive) is not specified in the EAG writeup. The EAG also noted that “companies provided information about their 2-piece bags in their RFIs but were not asked for further clarification about the features of their 2-piece bags by the EAG during the initial assessment. Due to this, the EAG did not have a record of the potentially innovative features of the evaluated 2-piece closed bags, the EAG was unable to draw conclusions about the associated [sic] between bag features and outcomes”. Due to the above limitations, it is not always clear to the reader what kind of bag or features each study (and outcome summary) relates to. In summary, it is not possible for Coloplast to critique the evidence in the time frame allowed, nor has enough information been provided for Coloplast to check the factual accuracy of the information reported.	
27	Association of Stoma Nurses	11	Clinical and technological evidence General comments	Overall we are grateful for this review being undertaken by NICE The paucity and lack of quality of evidence is overarching – as the ASCNUK we acknowledged this and by highlighting this within this LSA can only heighten the	Thank you for your comment. The EAG agree that there is a paucity of evidence to understand the effectiveness of 1-piece closed bags for people with a colostomy and that further research is needed in this area.

			desperate need for further research in relation to ostomy products. From a clinical perspective we agree the value of research evidence going forward is essential to understand the variations in costs However, the 5 studies chosen within the EAG does not represent the plethora of products available – some products have been around too long before evidence of their benefit was required at a commercial/economic level but may represent value for money. There is an assumption any research undertaken outside of the UK may not be suitable for application within the uk- it would be considered that the agreed criteria for ranking of priorities within the user report and your EAG for a bag would be congruent in many other countries As we read this report, we are unclear why redacted evidence is not available to review when this information is most obviously being used to influence the outcome of the report. In regard for transparency of information this exclusion potentially leads us to be disadvantaged in our review of the literature. It seems ‘unfair’ that decisions on such availability of products is being judged at this time in view of the lack of evidence and methodological robust research – when it has not been called upon in the past. Historically – we have seen studies in stoma care based on case studies, anecdotal evidence and expert opinion. It has been observed that a lack of nursing	The EAG acknowledge that, until now, 1-piece closed bags for people with a colostomy have not been evaluated within a NICE assessment and therefore there has not been a similarly pressing need for manufacturers to produce high quality evidence. The EAG report includes recommendations for research priorities, which we hope will be taken forwards. In line with NICE's health technology evaluations manual, NICE encourage stakeholders to keep confidential evidence to an absolute minimum to aid transparency in NICE's decision making process. In some circumstances, NICE will accept evidence and information not in the public domain under agreement of confidentiality. This can include clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document. If a technical engagement happens, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement. The EAG's assessment was based on the NICE scope, which excluded drainable bags. This was due to the additional variation in features available and additional population (people with an ileostomy) that drainable bags were relevant too. It was determined that it would not be

			clinical studies/research within stoma care can be attributed to a minimum demand for such evidence. Specialist nursing roles within stoma care are clinically based; this has led to limited research expertise within the speciality, lack of resource and confidence, to apply research methodology to such studies. Commercial companies/manufactures have more recently demonstrated their eagerness and attempts to support robust , methodological studies to demonstrate the benefits of their products – historically it has been disrespectful to compare products like for like As clinicians we applaud the need for further investment and resource into research to support the ongoing innovative development of products as well as the evidence to demonstrate their effectiveness. We are also disappointed at the exclusion of drainable bags there was no rationale to this. When considering the criteria for the priorities and ranking of what the users are looking for, these would be exactly the same for all types of bags 1pc / 2 pc; closed and drainable. Insight into the needs of individuals who may wear a 1pc closed bag should also be provided the option of a 2pc closed pouch or drainable bags depending on their needs. On reflection we hope the EAG would reflect and reconsider this fact and revisit your literature review.	feasible within one assessment due to the level of complexity. During the assessment, the EAG consulted with SCMs on the generalisability of evidence between different types of bags and received mixed feedback. Further exploration of this would be useful to inform future research and any further assessment. Thank you for your comment on the generalisability of the data from the Colostomy UK survey. Colostomy UK have kindly provided NICE with interim results of their survey as part of their patient organisation submission. Data from the survey was used to provide context and understanding to the assessment, but was not used to guide conclusions about the effectiveness of 1-piece closed bags for people with a colostomy. The report highlights the important role of CNS in stoma care in addressing issues with people's colostomy bags. It is however acknowledge that not all people with a stoma would seek support.

				We note your comment pg 12 - <i>the EAG sought advice from CNS in stoma care as to whether it would be appropriate to expand the scope for the assessment to include evidence that evaluated 1-piece closed bags in people with an ileostomy.</i> However, it would NOT be appropriate for an individual to use a closed bag for an ileostomy for all the reasons stated in Appendix E – Again we note pg 12 <i>There was mixed feedback from CNS in stoma care about the relevance of evidence from 2-piece bags, and the EAG considered that the evidence for mixed interventions was not informative for understanding the effectiveness of potentially innovative features of 1-piece closed bags.</i> We strongly believe if you had included a larger number of Specialist clinically practising SCN's in this feedback you may have received different feedback – The EAG decisions have been made on limited opinions – on pg 20 you state 2 'CNS in stoma care' were spoken to and this would be contested that this is not a true consensus of opinion and not representative. To date the drug tariff appears to have demanded minimal evidence before products are added, on part 1XC of the drug tariff. As clinicians we have relied upon the NHSBSA/ Prescription services process's to approve and enable inclusion of ostomy products onto the Drug tariff. This EAG review appears to now be penalising the SCN's and patients for this	

				lack of evidence. Our faith and trust in the NHS regulatory process's and approvals for products available on the Drug tariff part 1X believed would have been undertaken prior to any products being included. Comments within the Colostomy UK survey have been referred to within both the User preference and EAG – but this survey is not in the public domain and transparency of the results is compromised and disadvantages us within this review. For example: You reference 31% reported not actively involved in choosing their stoma bag - so we would wish to review the positioning of the question and data. From a clinical perspective, many patients new to a stoma will not know the differences in stoma bags, and in the initial post operative period would be too overwhelmed with the choices, but wholeheartedly agree as soon as the patient is receptive to information their choices should be offered. As per the highest ranked criteria within your user preference study – preventing leaks and seepage requires a bag being assessed based on body profile, habitus, physical ability to manage, output and of course choice. We note your reference from a statistic also within the Colostomy UK survey that only 69% of the respondents were colostomists . It would also be unknown of these respondent's whether they were	

				users of 1pc or 2pc closed bags or even drainable bags. Fundamentally this would impact on the outcome of the results for the purpose of this EAG. Therefore, there could be a significant reduction in the respondents of this survey that are applicable to the EAG thus devaluing the statements and assumptions made within this User and EAG report or indeed invalidate. You have also highlighted from the colostomy uk survey leakage, pancaking, skin irritation, ballooning and odour are impacting stoma management. If a patient is experiencing any of these issues; as clinicians and specialist SCN's we would categorically wish to understand why they were experiencing such issues and invite them for a specialist assessment . It is disappointing patients are experiencing such issues, (as you state on pg 91 <i>may instead continue without any support</i>) all SCN's would wish their patients to contact them under these circumstances. Despite the variations in provision of support and follow up (as stated in your user review, which could predominatly be attributed to local resource), we are sure when you have spoken to any SCN the essence of their SCN role is to undertake a specialist holistic assessment to understand, explore, identify, problem solve, advise and resolve such issues with the added option of identifying choices of bags to solve these issues. An integral factor to the choice of bag is the SCN interpreting	

				the unique features of each bag that may best meet these individual needs. As clinicians we all desperately wish to eliminate variations in provision of support and follow up. Many stoma related studies have recommended the benefits of annual reviews, and SCN's across the UK have implemented these where resources have enabled. We look forward to the opportunity to be able to evaluate the impact where regular stoma follow up has been provided to demonstrate the numbers of stoma related issues.	
28	Association of Stoma Nurses	33	Evidence search strategies	It has been stated Evidence from ASCN UK- conference abstracts were hand searched We would request from the EAG a greater understanding about how and what access to this information was gained. It would be questioned also iif they were only abstracts – based on your study selection this would not be relevant without pursuing the original studies and as the ASCN UK we would have anticipated we would have been approached to enquire further A study by Hoeflock was ruled out as she focused on two piece systems but not included when the EAG highlighted these would be considered	Thank you for your comment. The ASCN website had a page with links to previous conferences (https://www.ascnukconference.com/past-conferences/). For some of these conferences, there were subsequent links to their books of abstracts (for years 2023, 2019, 2018, and 2017). These were searched as PDFs by using a combination of key words to identify potentially relevant abstracts. These abstracts were then reviewed by the IS, and if they met inclusion criteria were included for appraisal by the clinical team. For any poster abstract that was subsequently included, we contacted authors directly, rather than the conference organiser. Regarding the study by Hoeflok et al. When including 2-piece bags, the EAG only included studies submitted by companies (i.e. included in the RFI) –

					as described in the introduction to Appendix J.																				
29	Association of Stoma Nurses	45	5.3 Quality appraisal of studies	NICE risk of bias tool – Was this the only tool used? Perhaps this limits evaluation	Thank you for your comment. The NICE risk of bias tool was used to assess potential risk of biases from RCTs identified in the evidence review. As with other similar checklists, this considers common sources of bias in RCTs but reviewers consider additional sources specific to the study being assessed, where relevant.																				
Comparator																									
30	CliniMed	21	Table 2	The Opus NaturFit is stated as being the lowest priced closed bag on the Drug Tariff. But it had a limited range compared to many of the other companies. The bags come in two sizes (Midi and Max), with no choice of colour or a filter. It is a basic hydrocolloid with no baseplate additive, even though in the description table it states that it has an additive: Table 2: Potentially innovative features of 1-piece closed bags for adults with a colostomy <table><tr><th>Flat bags</th><th>Baseplate additive</th><th>Baseplate shape</th><th>Baseplate adhesive</th><th>Bag shape</th><th>Filter</th><th>Material</th><th>Flexibility disposal</th><th>Inspection window</th><th>Source</th></tr><tr><td>Opus NaturFit</td><td>Y</td><td>Y</td><td>Y</td><td>N</td><td>N</td><td>Y</td><td>N</td><td>Y</td><td>Company</td></tr></table> Once the clinician has selected the pouch / pouch range that clinically suits the patient, the patient then has the choice within the range to fit their lifestyle, i.e. the need for bending at work, exercise etc. Currently Alliance Pharmaceuticals Ltd, who sell the Opus NaturFit have less than 1% of the market, these products were brought to the market in February 2021. Their market share hasn't increased over the past two years, is this related to quality / limited range of their closed pouches?	Flat bags	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flexibility disposal	Inspection window	Source	Opus NaturFit	Y	Y	Y	N	N	Y	N	Y	Company	Thank you for the comment. Selection of a comparator in this area is challenging. CNS were consulted to see if a “basic bag” could be defined to use as a comparator. Whilst a number of bags were suggested the pricing of these bags was variable with some bags classed by CNS as “basic” being above the average price. This reflects the lack of a link between price and features of a bag demonstrated in the regression analysis. Given this the EAG chose to use the cheapest bag as the reference for the economic analysis as this is objectively definable. The EAG also note that if the Committee or other stakeholders wish to use a different price to which to apply the incremental eJP they are able to do so with the information provided in the report. The EAG are aware of the limited market share of this bag. This is already noted in the report in Table 35.
Flat bags	Baseplate additive	Baseplate shape	Baseplate adhesive	Bag shape	Filter	Material	Flexibility disposal	Inspection window	Source																
Opus NaturFit	Y	Y	Y	N	N	Y	N	Y	Company																

				In Scotland where it is stated that they use lower priced products, the Opus NaturFit isn't growing as fast as other products – the total closed pouch market in Scotland is £30,616,237 and Alliance Pharmaceuticals have only £66,153 of this (0.22%). In the colostomy bag market this is £41,361 from a total market of £12,273,458 (0.34%)	
31	Hollister Ltd	167	9	The price range of products on Drug Tariff is referenced (£1.85-£3.84). Typically sales volumes of lower priced products is very low which may indicate in real world use they are less effective than higher priced products.	Thank you for your comment. Information on market shares for companies is already provided in Table 35 and demonstrates that Alliance who provide the cheapest bags have a market share of <1%.
32	Coloplast	71	7	The use of Opus NaturFit Flat and Convex as the comparator for the LSA isn't fit for purpose. In 2023, a total of 10,760 bags were prescribed of this brand (making up 0.032% of the Colostomy Bags category). This corresponds to a yearly use for 15-20 users. However, it is more likely that people have been prescribed Opus NaturFit and switched to a different product that is within current standard of care. The low volumes reflect the clinical reality - the product has a marginal use by patients and nurses who generally do not prescribe the product, so, in this context, we believe that Opus NaturFit should not be considered as a standard of care and used in the analysis. The	Thank you for the comment. Selection of a comparator in this area is challenging. CNS were consulted to see if a “basic bag” could be defined to use as a comparator. Whilst a number of bags were suggested the pricing of these bags was variable with some bags classed by CNS as “basic” being above the average price. This reflects the lack of a link between price and features of a bag demonstrated in the regression analysis. Given this the EAG chose to use the cheapest bag as the reference for the economic analysis as this is objectively definable. The EAG also note that if the Committee or other stakeholders wish to use a different price to which to apply the incremental eJP they are able to do so with the information provided in the report.

				use of the Opus NaturFit bag as a comparator is unethical towards the patients.	Information on market shares for companies is already provided in Table 35 and demonstrates that Alliance who provide the cheapest bags have a market share of <1%.
33	Coloplast	42	5.2.2	'SenSura, SenSura Mio, Moderma Flex, *****. Redacting the product investigated means we are unable to challenge attributed information. While redacting clinically and commercially sensitive information can be necessary, we believe that, in this case, NICE and the EAG should make summary information public to allow for equitable scrutiny.	In line with NICE's health technology evaluations manual, NICE encourage stakeholders to keep confidential evidence to an absolute minimum to aid transparency in NICE's decision making process. In some circumstances, NICE will accept evidence and information not in the public domain under agreement of confidentiality. This can include clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document. If a technical engagement happens, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement.
34	Association of Stoma Nurses		In summary	this has been impossible to provide the depth of critique and robustness to the EAG in respect of the time frame allowed. It would also be highlighted in view of the omission of the redacted information and colostomy UK survey that has not been published – there is lack of transparency of the evidence provided that have influenced the analysis of this EAG. We have also reiterated the sample size of the user groups are not representative of the populations, with bias's incurred and questionable validity of the consensus statements and views referenced within	Thank you for your comment. In line with NICE's health technology evaluations manual, NICE encourage stakeholders to keep confidential evidence to an absolute minimum to aid transparency in NICE's decision making process. In some circumstances, NICE will accept evidence and information not in the public domain under agreement of confidentiality. This can include clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document. If a technical engagement happens, all

				the EAG report and the User preference report In conclusion, we very much welcome a focus for further evidenced based studies and research to support the effectiveness of available products for patients – but essentially insist this needs to be initiated and undertaken <u>before review of the drug tariff products availability of products and costings</u>	information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement. Thank you for your comment about the sample sizes of user groups. The LSA involved multiple rounds of engagement with experts, including CNS in stoma care and people with a colostomy, and stakeholders to the assessment have been invited to comment throughout the assessment. Please see the response to comment 1 in the user preference section for a response on engagement during assessment process.
Dispensing appliance contractors					
35	Convatec	15 & 25	Exec Summary	The EAG concluded that there was likely to be/ suspicions from CNS, that a significant number of people suffering with bag related complications due to the fact that they are not engaging with their CNS. Absence of consideration appears to have been given to the expert support these people receive from their DAC supplier. With vast majority of people bypassing Nurse Specialists in favour of self-managing their complications, supported by their DAC. Furthermore, absence of consideration of the cost & time savings elicited to the NHS as a result of DAC support to Ostomates. Databases exist to demonstrate this fact.	Thank you for this comment. Page 25 has been amended to : “However, comments from a manufacturer pointed out that patients may bypass their CNS in stoma care and seek help from their DAC instead.”

36	Convatec	18	1	The conclusion that 'care' is coordinated and delivered by secondary CNS needs challenge. The Bowles report and experience of DACs indicates otherwise, with many people with a stoma receiving little to no follow up care post the adjustment period following surgery.	Thank you for your comment. The section refers to amendments to the protocol for the setting of the analysis rather than whether patients receive appropriate care or not. The latter point is considered elsewhere in the report (section 3, Engagement with Health Services and section 4, Equality issues). The EAG have therefore not edited the text.
37	Convatec	27	3	The choice of bags and the transparency of available information is provided by the valuable service offered by DACs, and due to case load restrictions, CNS lose sight of what happens post adjustment period therefore leading to the assumption and comment that people with a stoma may be uninformed about bag choice. Agree that best outcomes will be achieved through patient engagement & adjustment, but not solely with the CNS Stoma nurse. Statement neglects to call out interaction & support from the DACs & how this can impact a positive outcome. As stated within the EAG report, <i>'it may be beneficial to not overwhelm people with a new stoma with the wide choice of bags available, it may be important to ensure that people are informed and involved with the choice of bags they use throughout their lives'</i>. Unfortunately, this contrasts significantly with the how the sponsorship works, whereby 'choice' really means that the sponsoring supplier places an	Thank you for this comment. P27 has been amended to "Comments received from a manufacturer highlighted that some patients may receive the support they need from their DAC rather than or in addition to the CNS in stoma care." Thank you for this comment. The issue of conflicts of interest and the impact of sponsorship on patient choice is covered in section 7.4 (factors not included in the decision model)

				expectation on the CNS in the acute setting that the majority of, if not all, ostomates are offered only products from the sponsoring supplier and that a cadence of both regular monitoring and 'interventions' are applied by the sponsoring suppliers to ensure CNS compliance with this in the acute setting. Sponsoring suppliers request a report from the hospital to record number of new patients started on their brand and referred to their DAC service. Convatec would therefore conclude that sponsorship has a higher influence over bag features when it comes to initial patient 'choice'	
38	Convatec	107		Again, no recognition of the role of DACs in supporting patients: <i>The EAG was, however, informed that CNS in stoma care are not always contacted when issues are experienced and that there may be a sizeable population of "lost ostomates" who do not seek help for complications.</i> Please refer to point 7 above, as this may be the view of the 2 CNSs, but, in reality, many Ostomates seek help from their DAC or charities, such as Colostomy UK	Thank you for your comment. The EAG have added to paragraph, P109: "However, comments from a manufacturer pointed out that care may be delivered through the DAC rather than the CNS in stoma care"
39	Coloplast	15	Executive Summary – key points for decision makers	'The analysis did not consider the impact of sponsorship and additional services from manufacturers and DACs' We would suggest that additional services (sponsorship is merely one vehicle of this) are taken into account because you need the 'right bag on the right person'.	Thank you for your comment. The EAG have stated this as a limitation of the analysis and acknowledged as such in the report.

40	Coloplast	141	7.4	'as well as to require use of their own preferred Dispensing Appliance Contractors' This statement is factually incorrect. Currently DACs are not allowed by law to require use of a specific DAC as part of sponsorship. This must be deleted from the report. See DAC Code of Ethical Business Practice by The British Healthcare Trades Association - Issuu	Thank you for this correction. The EAG have amended to '...as well as to be affiliated with...', as per the language used on P12 of the StoMap report (Kettle J, reference 35).
41	Coloplast	142	7.4	'advantages were that the NHS now had freedom of choice of DACs' This is not factually correct as the NHS is not a customer of DACs. NHS may contract in hospitals with manufacturers, while DACs dispense to patients, where there is freedom of choice. See DAC Code of Ethical Business Practice by The British Healthcare Trades Association - Issuu	Thank you for this comment. Text edited to "The advantages were that people with a colostomy now had freedom of choice of DACs as well as products from any manufacturer;"
42	Association of Stoma Nurses	141	7.4	<i>'as well as to require use of their own preferred Dispensing Appliance Contractors'</i> This statement is not correct. Currently DACs are not allowed by law to require use of a specific DAC as part of sponsorship.	Thank you for this correction. Please see our response to comment 41, above.
Economic evaluation					
43	Coloplast	105	7.2.8.2	In the report, it is mentioned that the De Fries Jensen paper considered leakages in the last 3 months. While	Thank you for your comment. The EAG are aware that £32.47 is a per

				this was true for the recall of quantifying leakages onto clothes, the calculations were done on a per event basis, summarizing the costs in the 3 weeks (not months) following a leakage event. It is then concluded that the total cost of leakages is £32.47, which is not the case. A more accurate representation of the publication would be to take the reported mean leakages in the publication of 3.81 per 3 months times 4 (to get to a year), times the cost of £32.47, meaning a yearly cost of £494.84 (£556.71 adjusted for inflation) in the investigated population. This cost is then much more on level with the cost reported by the EAG.	leak cost and this is how it is applied in the model. This is correctly presented as a cost per event in Table 19. The EAG acknowledge the wording in Section 7.2.8.2 could be improved to reflect this and have made this amend: "Despite these, the cost per leak estimated in were similar: £32.47 vs [REDACTED] in 2019 prices."
44	Coloplast	144	7.5	The data identified for the impact of bag-related complications on HRQoL and resource use were generally from a mixed population (a high proportion of ileostomy relative to colostomy) Coloplast would like to clarify that we agree this is a justifiable approach to modelling within ostomy care. From a patient perspective the criteria based on the user preference we would consider would be the same – for example leakage onto clothes would impact people with Colostomy and Ileostomy equally. While incidence of PSCs might differ between stoma types, the impact on bleeding, pain, itching burning of a severe PSC would be the same.	Thank you for your comment. This does not align with input received from two CNS consulted on this point who considered that there would be a larger impact on patients with an ileostomy vs colostomy on quality of life from PSC even within health states, as their poo is looser and more acidic and more likely to irritate, and additionally people with ileostomy are generally younger and therefore the level of impact is likely to be higher relative to general quality of life.

45	Association of Stoma Nurses	15	Economic evidence	Whilst it is recognised that the ED-5Q questionnaire is a suitable measurement for most individuals, it does not explore specific issues pertinent to someone who has undergone surgery that impacts their bowels and alters body image – so should not be sole measure used.	Thank you for your comment. The EAG has not said the EQ-5D should be the sole measure used.
46	Association of Stoma Nurses	72-73	Review of previous economic analyses	Having reviewed The Berger comments several times especially the first two sentences there is confusion in regards to the evidence from Allied Pharma- We would wish to understand why they have been asked to comment and including the redacted information is unhelpful in appraising the document	Thank you for your comment. The evidence supplied by Alliance Pharma is not related to the Berger paper. This paragraph relates to a separate information supplied by Alliance Pharmaceuticals in confidence. In line with NICE's health technology evaluations manual, NICE encourage stakeholders to keep confidential evidence to an absolute minimum to aid transparency in NICE's decision making process. In some circumstances, NICE will accept evidence and information not in the public domain under agreement of confidentiality. This can include clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document and evidence that is commercially sensitive. If a technical engagement happens, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement.
47	Association of Stoma Nurses	75	Evidence by Dale 2019	This is in biased in view of peristeen where cross referencing of costings in relation to colostomy use are not validated	Thank you for your comment. This data is not used in the EAG's economic analysis.

48	Coloplast	89, 120, 202, 210	Various	<i>'Comfort' Utility Gain Inclusion</i> • The utility gain associated with the comfort of a stoma bag is assumed equivalent to its appearance and discreteness (applied concurrently) (page 89). • <i>After the elicitation exercise when CNS in stoma care were asked to review the outputs, they informed the EAG that the impact of comfort on utilities would be the same as for appearance and discreteness. These were therefore modelled as one complication.</i> • The inclusion of comfort as an additional factor in the economic model was based on the input of only one CNS under the rationale that patients would not use the bag if it were very uncomfortable (pages 89 and 120). • <i>Comfort was suggested as an additional factor to include in the economic model by one of the CNS in stoma care consulted after</i>	Thank you for your comment. The input in respect of comfort was not from one CNS. Multiple CNS attended the meeting to discuss the results of the structured expert elicitation; all CNS who participated in the survey were invited to the meeting and 6 attended. After the initial CNS flagged comfort as a missing factor from the economic model early on in consultation multiple comments along this theme were received. The EAG acknowledge that discreteness, appearance and comfort are individual aspects of bags each with their own impact, however, data is not available to model each of these individually and the EAG was not able to collect data for these aspects individually as this would have meant that the number of questions in the expert elicitation exercise exceeded what would be plausible to ask without compromising results.

				<i>the expert elicitation exercise had been distributed.</i> <i>In addition, the CNS in stoma care considered that the impact of comfort would be like discreteness – a person wouldn't wear the bag if it was very uncomfortable, so it would influence bag choice but any bag they're using wouldn't be so uncomfortable as to make a larger reduction in HRQoL.</i> - Comfort within the question text (page 202) or feature definition (page 210), and the impact of (dis)comfort on health-related quality of life was not assessed. - The company does not believe there are enough supportive data to conclude the impact of comfort on health-related quality of life, nor does the company accept the rationale that if a bag were very uncomfortable it would not be worn. This logic infers that not wearing the bag is an option.	

				Coloplast believes that the assumption that comfort is included in the utility associated with appearance and discreteness is incorrect. A bag that is comfortable to wear does not necessarily have to be discrete or have a good appearance.	
49	Coloplast	13	Executive summary – Economic evidence and analysis	The modelling approach (eJP) is flawed as while it solves the issue conceptually, it is not executable and is based on flawed assumptions as detailed throughout the LSA. The eJP should represent the price to pay to eradicate an issue although this would only be true if there were any evidence informing the calculations and the noted errors in the calculation are amended. Even if evidence were available to support calculations, knowing the eJP would require the local commissioner to know the clinical likelihood of an issue before they chose the bag which as noted throughout by the EAG and Company, is not known as this evidence does not exist. Commissioners will therefore not know this and often rely on business case models to estimate the impact (which should include an assessment of efficacy). It is not possible to include this because it does not exist. As such, it is irresponsible to impose	Thank you for these comments. As you state, the eJP is the estimate of the maximum willingness to pay to resolve an issue completely. This is derived from conventional NICE methods which looks at costs and effects together, taking into account that cost represents resources that must be taken away from one use and hence represents foregone healthcare to one group of patients. The eJP calculated in the analysis provides a necessary but not sufficient criterion to assess whether a particular bag represents value for money: i.e. it is necessary for the bag to be priced below this. The sufficient condition would require data on how effective a particular bag was at resolving the issue. If a bag is less than 100% effective, then the eJP would be correspondingly lower. The purpose of the analysis is to estimate whether the prices charged by the manufacturers represent reasonable value for money for the tax payer. Decisions to supply product are for the manufacturer.

				restrictions on the availability of products to people who use them. Doing so will harm patient outcomes. Commissioners are predominantly concerned with budget so arbitrarily declaring an upper limit for each feature could result in strict adherence and an unknown (but likely negative) impact on patient outcomes. The magnitude of this is completely unmeasured and not assessed in this process. It also infers that purchasers will behave in a rational way which they may not. In summary, we do not believe that attributing an eJP to features is responsible or appropriate.	No amendments were therefore made to the report.
50	Coloplast	101-103	7.2.8.1.	The EAG Report Table 20 reports the following information and sources were used, but the base-case model does not reflect this, so the EAG reported information is factually inaccurate, or the model is set-up incorrectly and the results in the EAG Report are incorrect. The following parameters could not be evaluated on their applicability: The 'Number of 1-piece closed bags per day' is stated to be sourced from 'Clinical expert opinion (2 CNS in stoma care)', however in the model this is	Thank you for these comments. Each of the bullets are addressed individually: - Thank you for spotting this. This has been amended in the updated model and report - There are two cost per bag parameters in the model. c_costperbag_comp_source is used in the results to present the eJP versus a reference bag – this is the one that correctly uses the Lowest cost 2023. The other parameter c_costperbag_source is the one described in the report in relation to how wastage is

				actually sourced from 'Berger (2018)' in the model, which has a lower number of bags used per week - please could the EAG clarify which parameter is utilised here for the base-case analysis? • The 'Cost per bag' parameter is described in the EAG Report as being sourced from 'Bennett Institute average bag cost 2023', however in the base-case model it is set to 'Lowest cost 2023', which is £1.85 (rather than £3.02). Which is used in the analysis and is the report correct here? • The 'Cost per CNS in stoma care consultation' is described as being sourced from a mix of the National Cost Collection and PSSRU, but in the model this input is set to 'Berger (2018)' instead of 'EAG'. Which cost is correct for this parameter as this is inconsistent between the model and EAG report? • The 'Stoma resiting' proportion in Table 20 is described as being sourced from 'Rolls (2023) HCP survey', but in the model 'Proportion of patients	costed and correctly uses Bennett Institute 2023 • Thank you for spotting this. This has been amended in the updated model and report • Thank you for spotting this. This has been amended in the updated model and report The EAG has done a full cross-check of the model switches versus the report as it has become clear that some were overwritten when running the scenario analysis macro. Changes made to the model are listed below: • The addition of the variables from item 15 downwards, in the "Scenarios" sheet (look for cell enabled the model to fully return to the base case In addition we noticed that an older version of the code to complete the scenario analysis tables had been included in the model and have rectified this to allow the tables to be produced automatically. The changes to the model resulted in an increase to the total eJP for bags reducing the chance of PSC (from £3.89 to £4.24 for a flat bag) and a change of 1 pence to the total eJP for a bag reducing the chance of leaks for people experiencing these 2 times yearly. There were no other changes to the total eJPs.

				undergoing resit - Severe Health only' it is set to 'Expert Elicitation' in the model. Which of these two parameters should be used? The 'number of PSC episodes' in Table 20 has no impact on the model, as the 'Source of resource use for PSC' option is set to 'EAG', which means that the 2.4 used in the table does not impact the costs in any way. Is this intended? By not allowing recurrence of complications in the model, costs of complications are severely underestimated. These and many other issues with the health economic model should be addressed before it can be considered is appropriate for decision making.	This is not correct as the number of PSC episodes impacts on the health state occupancy (see Columns G to I) in the engine sheets. For simplicity the EAG models recurrent episodes as occurring back-to-back as the time horizon of this model is only one year and there is no discounting included.
51	Coloplast	109	7.2.8.5	'We assumed that an average of two phone calls and one face-to-face appointment were required to find a bag with the right appearance, discreetness, and level of comfort and that the bags given for people to trial come at zero cost' Trialled bags provided always come at a cost somewhere in the system, to the NHS or to the manufacturers. The cost to	Thank you for your comment. The economic analysis takes an NHS and Personal Social Services perspective was taken in line the NICE reference case and therefore costs to manufacturers are not considered.

				manufacturers of this practise should be considered.	
52	Coloplast	112	7.2.9.1	“In particular, the inclusion of generic aspects of HRQoL from participants’ underlying disease (colorectal cancer for a reasonable proportion of patients with a stoma) was not accounted for.” We assume this comes from the following statement from the referenced report: ‘Vignettes should include all important and relevant aspects of HRQoL to ensure accuracy and minimise bias.’ In the immediate period after having a stoma formed, people with a colostomy might still receive treatment in the forms of e.g. radiation or chemotherapy. However, for the majority of people living with a stoma, they would have been cured of their underlying disease. Therefore, it would not be considered appropriate to consider them as having both a stoma and colorectal cancer. Furthermore, there is an extensive range of conditions requiring intestinal stoma as part of their management that complicates the exercise, including colorectal (and other) cancers, inflammatory bowel disease, diverticular disease with obstruction, penetrating bowel injuries, anal incontinence, protection of a distal anastomosis,	Thank you for your comment. The EAG acknowledge that there are a range of conditions for which people may require a stoma. The wording has been amended to reflect this, however, the central point that underlying HRQoL has not been considered in the vignettes is correct. New wording: “There is an extensive range of conditions requiring intestinal stoma as part of their management, including colorectal (and other) cancers, inflammatory bowel disease, diverticular disease with obstruction, penetrating bowel injuries, anal incontinence, protection of a distal anastomosis, gangrenous /ischaemic bowel, sigmoid volvulus, Fournier gangrene, and anastomotic leak. This makes it difficult for a vignette to take background conditions into account and limits the appropriateness of this methodology in this patient population.” We have not updated our choice of preferred utility source as the NICE reference case specifies that were possible descriptions of health status should be provided by patients which is not the case in the Rolls (2023) study.

				gangrenous /ischaemic bowel, sigmoid volvulus, Fournier gangrene, and anastomotic leak. This list is not exhaustive. Therefore, the HRQoL associated with having an underlying condition would not be appropriate. As a result, the Rolls 2023 study should be considered of higher quality than noted and should also be used for estimating the impact of PSCs.	
53	Coloplast	125	7.3.2	There are key assumptions made in the base-case of the health economic model, which are highly questionable. For the comparator engine it is assumed that any complication is fixed by switching to a similarly priced bag. This would not be feasible, as there is no other bag listed at the same price as the one chosen for the comparator bag price. The model does not include recurrence of any complications in the comparator engine. This is not reflective of the etiology of stoma related complications. Instead, in the comparator engine, complications are resolved by switching to another type of bag at no additional cost, except potential wastage. If this assumption was reflective of reality, the prevalence stoma related complications would be very low, however, literature	Thank you for your comment. The EAG state that this is incorrect as the model does not assume that complications are fixed by switching to a similarly priced bag. We calculate the economically justifiable price of a bag that fixes the relevant complications. The EAG state that the comment on recurrence of any complications is incorrect as the model includes recurrence of PSC, includes recurrence of leaks (by defining health states based upon the number of leaks per year), the same is true of pancaking, ballooning and odour. In addition, the cost of switching bags includes staff time required to choose a new bag as well as wastage. The EAG are unable to state why the prevalence of complications is as high as it is, however, this is likely to be due to a combination of factors including differences in access and uptake of care from CNS in stoma care and DAC

				has consistently reported the opposite. These are some of the many issues with the model, which lead to heavily underestimating the impact of stoma related complications. This is evident by the example of having leakages twice per year being more impactful than having leakages 4 times per month which hardly reflect the reality lived by people with a stoma. The assumptions made in the model makes it unfit for decision making.	services to inform more appropriate bag choice, and there being no bag available that fully eliminated the risk of complications for some patients. The reason that leaks twice per year have more impact than 4 times a month is that the EAG was advised patients experiencing leaks only twice per year would be unlikely to seek support to resolve the complication whereas those experiencing more frequent leaks would seek support.
54	Association of Stoma Nurses	108	odour	the estimated use of products used for odour we would wish to understand further The use of deodorants has significantly reduced over the last few years and again reviewing the market data would demonstrate this The estimate of solving all problems within 3 weeks we also felt was ambitious based on assessing the underlying cause	Thank you for your comment. As stated in the report the EAG assume that only 10% of people use drops or sprays. This was based upon input from consultation with CNS's. The EAG are not aware of market data in the relevant format (% of people who have odour issues that use drops or sprays) for model input. The 3 week time was based on CNS input. We acknowledge the uncertainty around this parameter due to lack of data. The EAG tested a longer time to resolution (5 weeks) in scenario analysis in Table 32. The eJP for a flat bag with 100%

					improvement in this scenario is £2.33 vs £2.22.
55	Coloplast	112	7.2.9.1	The EAG made the following assessment on the impact of worry about leakage in the vignettes: 'Additionally, the descriptions related to leakage included the following wording around worry for all health states "you worry about when the leakage will happen", which may not be reasonable for the least frequent health state'. According to Jeppesen et al. 2022, people having leakage onto clothes just once per year experience significant emotional impact (measured on the Ostomy Leakage Impact Tool) compared to those never experiencing it, with more frequent leakages having a larger impact. The article also found a positive correlation between worry about leakage and frequency of leakage underneath the baseplate and/or onto clothes. Additional data on file showed that of those people having leakage onto clothes 'at least once every six months having leakage onto clothes, 17% reported worrying to a very high degree, 19% worried to a high degree 36% worried to some degree, 24% worried to a low degree and only 4% did not worry. We therefore suggest this speculation be removed from the LSA.	Thank you for your comment. The wording has been amended to clarify that as you state levels of worry would be expected to be linked to the frequency of leaks and to include the information from the paper on worry still being experienced with less frequent leaks. New wording: "Additionally, the descriptions related to leakage included the following wording around worry for all health states "you worry about when the leakage will happen." According to Jeppesen et al. (2022), there is a positive correlation between worry about leakage and frequency of leakage underneath the baseplate and/or onto clothes with people having leakage onto clothes only once a year still experiencing significant emotional impact on the Ostomy Leakage Tool."

56	BHTA	12-15	Exec summary	We are concerned that in the eJP analysis only assumptions have been used in how effective products are in managing complications, we feel there needs to more work done to have actual results rather than assumptions and that any suggested pricing should not be recommended in any final report outcome.	Thank you for your comment. The eJP analysis represents the upper bound price based upon an assumption of 100% effectiveness (or 50% in the scenario assuming 50%). The EAG searched for evidence to robustly inform effectiveness for the features specified in the scope. The overall evidence base was of poor quality which has been highlighted in the report.
57	Coloplast	94	7.2.5	<i>Probability of Switching: PSC</i> •The probability of switching to a different stoma bag one-year post-surgery due to PSC of varying severities was elicited during the SEE workshop. •The elicited probabilities align with the health states reported by Rolls et al. in a time trade-off vignette study eliciting utilities associated with PSC and leakages. The health state definitions for PSC were based on items from the Ostomy Skin Tool 2.0 (a validated instrument for assessing PSC severity). •The elicited probabilities for PSC PIB (5/10) + weeping (0.6392) and PSC PIB (5/10) + bleeding (0.6325) are approximately	Thank you for your comment. The utilities reported for PIB (5/10) + weeping and PSC PIB (5/10) + bleeding are not significantly different (see Figure 4 of Rolls 2022; confidence intervals considerably overlap) and therefore the observations of a similar probability of switching are reasonable. The same applies for PSC PIB (5/10) without weeping or bleeding which also has a similar probability of switching (58.22%). Experts were presented with the utility data from Rolls et al. (2022) as part of the exercise and will therefore have taken this into account. In addition, the probabilities were validated during a meeting to which all CNS participants in the exercise were invited. In addition, they are not a key driver of model results. The pooled distributions and rationales for all switch parameters have now

				equivalent (Table 18). •However, the Rolls et al. (2022) article indicates that the disutility associated with having bleeding skin compared to having no weeping or bleeding (-0.053) was significant ($p < 0.001$), while the disutility associated with weeping skin (-0.003) was not ($p = 0.298$). •The face validity of the cited probabilities is uncertain. Assuming the significant utility decrement associated with the presence of bleeding due to a PSC corresponds to a higher likelihood of switching stoma bags, the cited probabilities may represent an over/underestimation. •The pooled distributions and rationale statements associated with the elicited stoma bag switching probabilities are not reported by the EAG. Thus, it is impossible for the company to assess the validity and interpretation of these results.	been added to the report in Appendix K.
58	Coloplast	142	7.4	As noted at the bottom of page 142 of the EAG report “<i>Areas where industry</i>	Thank you for your comment. This statement is in a section labelled Factors not included in the decision

				<i>involvement was seen as a benefit included provision of home delivery services, free stock for hospitals, educational events for staff and patients, and increases in number of staff available, with a belief that the services were ethical and in the best interests of patients.”</i> Were the appraisal conducted via the STA or HST routes, Coloplast is of the opinion that such benefits would be viewed as additional benefits not captured during the economic modelling. Anecdotally, this would result in the threshold used in decision making to be increased beyond the stated £20,000 per QALY gained value (with the final choice being made by the relevant committee). Thus, we believe that any EJP calculation should be undertaken at a higher cost-effectiveness threshold than the £20,000 per QALY gained currently used.	model which addresses additional benefits not captured during the economic modelling. The HealthTech programme and STA/HST all utilise economics methods as outlined in the NICE health technology evaluations manual and so considered in the same way. The methods and process statement for late-stage assessment only includes the £20,000 per QALY threshold and therefore testing higher thresholds is not appropriate. The EAG would also note more generally that there are factors which reduce as well as increase the threshold. Uncertainty is a key factor which decreases the nominal threshold. In this assessment there is considerable uncertainty around all model parameters and therefore the EAG do not consider presenting EJPs at higher thresholds appropriate.
Expert advice					
59	Salts Healthcare		Conflict of Interest	We still retain concerns regarding the participation of members of the expert panel. All clinical representation is currently sponsored with their posts funded by manufacturers being reviewed. We believe in the importance of Clinical Nurse Specialism within stoma care but the make of the group in our opinion is both short of a representation of stoma	Thanks for your comment NICE have followed its policy on declaring and managing interests for NICE advisory committees for recruitment of specialist committee members and reviewing conflicts of interest. Clinical nurse specialists in stoma care were not recruited to the specialist committee member role if

				care within the UK and lacks independence.	they are directly funded by a manufacturer included in the evaluation. If there was any substantive reimbursement for meeting attendance by a company, then the clinical nurse specialist were only allowed to be an expert and not involved in committee decision making. As the majority of hospitals in England have some sponsorship arrangement (reported as 84% by the StoMAP report), it is hard to identify experts who are not impacted by sponsorship. Recruitment for the specialist committee members was done publicly, by advertisement on NHS jobs, and through asking manufacturers and professional organisations for nominations. Not all specialist committee members included work at sponsored hospitals. NICE tried to seek as much independency as possible whilst also ensuring it had valuable clinical insight.
60	Hollister Ltd	85	7.2.3.3	The view of one CNS is stated in relation to seals/convexity. The validity of the statement is not questioned per se, but in general terms quoting just one opinion would not be viewed as conclusive/comprehensive.	Thank you for your comment. The report is clear that this is the view of one expert is not used to directly inform the economic model and was therefore not considered necessary to go for comprehensive consultation.
61	Association of Stoma Nurses	41	5.2.1. Study pop	<i>As - the EAG noted feedback from CNSs in stoma care may be useful to determine whether the study populations appear representative of the populations that would use the evaluated bags in the NHS</i>	Thank you for your comment. The ASCN has been contacted if there are questions and also invite to nominate experts and invited as stakeholders to provide comment.

				<i>or whether the studies excluded some populations</i> we would welcome the opportunity as ASCNUK to be contacted and feedback	
62	Association of Stoma Nurses	85	7/2/3/3 PSC	As only one SCN was approached in relation to this – we would question the need to gain a consensus on this view from more than 1 SCN there is no mention of holistic assessment – and the cause of the peristomal skin condition would have a significant impact on the treatment options	Thank you for your comment. the EAG assume this comment relates to this statement: “One clinical expert noted that as PSCs are most often due to the type of bag used, they would prefer to try a convex product rather than a seal, on the basis that they considered seals to be cost-ineffective due to the number of times bags needing to be changed.” No model parameters are informed and it is clearly referenced to a statement by one expert and therefore a consensus is not considered to be required. The different causes of PSC are already discussed at the beginning of the section: “PSCs can arise from a multitude of factors including leakage under the baseplate resulting in an irritant contact dermatitis and trauma, skin damage due to repeated stoma bag application and removal, and a retracted or poorly located stoma, which makes the achievement of a good fit more difficult.”
63	Association of Stoma Nurses	88	7.2.3.7	We would wish to see a consensus of opinion in relation to bag appearance and reasons for choosing one that matches skin tone or matching underwear – there is no clarification where these comments came from	Thank you for your comment. The EAG have now clarified that these comments came from CNS consultations and that similar comments were made at the user preference workshop. The additional point in relation to clear pouches and visual issues has been added.

				Clear pouches can be advantageous if people have visual issues to ensure that the pouch is positioned correctly	
64	Association of Stoma Nurses	90	Probability of switching bags	Again this information is limited to 2 SCN's It is essential to emphasise bag changes will be undertaken within the first 3 months of a new stoma – this is NOT switching – the need to change the type of pouch will be based on SCN assessment of changes in stoma, output, body profile It would be highlighted that today we are seeing a significant impact of social media influencing peoples awareness and desire to 'switch' bags	Thank you for this comment. The information from the 2 CNS in stoma care is only interpretation of data supplied by companies. The EAG took the probabilities used in the model from the expert elicitation exercise. The EAG are aware that bag changes are to be expected with a new stoma and is not what we would classify as switching in the economic analysis. The EAG asked for data from companies split by whether the patient had a new stoma or not. This data was not available. The data provided, however, are generally for the full patient population. The expert elicitation exercise was also clear that switching was to be considered for patients one year or more after surgery. As per Appendix D: "A one-year mark was chosen so patients have largely healed from surgery, have a well-defined stoma shape, and have gained some experience with the use of stoma bags." Thank you for your comment on the role of social media in influencing the frequency of bag changes. In our report, the EAG highlighted the need for good quality data about the way people with a colostomy use and

					change their bags, and any such research may benefit from considering the factors that influence this in practice, such as social media.
65	Association of Stoma Nurses	91	Probability of switching bags 7.2.4 Expert input	In addition to the comments made, there is an also the acknowledgement that People don't always need to change bags - they may only need a change of template- In addition companies may not have the information about people changing pouches as this would be prescriber information It is commendable the EAG visited acute settings and went onto hospital wards- However, there were no apparent visits to community teams or observation of home visits which may have been able to provide a different perspective of living with a colostomy	Thank you for your comment. The EAG explored the possibility to get access to CPRD prescriber data this evaluation. However, due to variability in how care is delivered such as through CNSs in stoma care working predominantly in a secondary care setting, varying involvement of GPs in prescribing, the outsourcing of care to prescribing hubs, and the relevance of the outcomes available within primary care data, it was deemed that CPRD data would not contain the information required to inform the economic model. The EAG were unfortunately unable to visit community teams or attend home visits. The group of CNS in stoma care consulted by the EAG did include people involved in the delivery of care in a community setting.
66	Association of Stoma Nurses	92	7.2.4	It is stated in this report that <i>Questions sent to all stoma care nurses</i>- This is misleading as implies that this was sent to all stoma care nurses within the UK We note the questions were sent to 7 experts? were these all practising SCN's? - even though you have stated they were experienced specialists in stoma care from different geographies - we would still advocate 7 SCN's as a % of the SCN's in the UK is not representative.	Thank you for your comment. We have added the wording "involved in this assessment" to clarify. Questions were sent to 10 experts (Table 38). The information on their profession can be found in this table. Of these 7 provided answers to the formal expert elicitation exercise. NICE followed their standard processes for recruiting specialist committee members (declaring and

				As you have also highlighted the high banding of the experts does not reflect the average banded SCN It is unclear and not referenced in your EAG with an appendix what the questions were – we would collectively be keen to view these	managing interests for NICE advisory committees) and clinical experts. NICE publicly advertises its specialist committee member roles and encouraged companies, professional organisations and patient organisations to nominate or share this opportunity. Although a subgroup of experts are consulted during the assessment, the draft guidance and associated documentation has a public consultation period in which clinical experts can submit comments. The questions asked are provided in Appendix D and are as follows: For an average person with a colostomy one year following their surgery, what's the disutility associated with experiencing the following complications for a period of one year: • Regular (daily) ballooning • Regular (daily) pancaking • Regular (daily) issues with bad odour • What's the utility gain from a discreet bag design with preferred for an average person with a colostomy one year after surgery? For an average person with a colostomy one year following their surgery, what's the probability they would switch to a different bag (rather

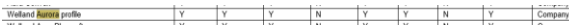
					than using an add-on product) if they were experiencing the following complication and decided they needed to make a change: • Leakage onto clothes 4 times per month • Leakage onto clothes once a month • Leakage onto clothes once every 6 months • Peristomal skin complications - mild level of pain, itching and burning (2/10); no bleeding or ulcers • Peristomal skin complications - moderate level of pain, itching and burning (5/10); no bleeding or ulcers • Peristomal skin complications - weeping skin and a moderate level of pain, itching and burning (5/10); no bleeding or ulcers • Peristomal skin complications - bleeding or ulcers and a moderate level of pain, itching and burning (5/10) • Peristomal skin complications - bleeding or ulcers and a severe level of pain, itching and burning (8/10) • Regular (daily) ballooning • Regular (daily) pancaking • Regular (daily) issues with bad odour For an average person with a colostomy one year following their

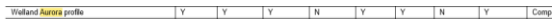
					surgery, what's the probability they would • Be hospitalised if they were to experience peristomal skin complications • Have their stoma resited if they were to experience peristomal skin complications
67	BHTA	19-20	2	BHTA are concerned that only 2 or 3 clinical nurses views have been stated in the report, there are c. 550 stoma specialists in England. We would suggest a much larger sample should have been recruited to give input to the EAG.	Thank you for your comment. NICE followed their standard processes for recruiting specialist committee members (declaring and managing interests for NICE advisory committees) and clinical experts. NICE publicly advertises its specialist committee member roles and encouraged companies, professional organisations and patient organisations to nominate or share this opportunity. Although a subgroup of experts are consulted during the assessment, the draft guidance and associated documentation has a public consultation period in which clinical experts can submit comments. 10 clinical experts were included in the overall consultation for the assessment report and all 10 were given the opportunity to provide feedback on the draft report. In some areas the EAG sought additional detailed input whilst developing the draft report from a selection of the included experts. This is a common practice across NICE's Centre for Health Technology Evaluation.

68	Convatec	20	1	The views of only 2 clinical nurse specialists who will have unconscious preferences, and bias cannot be deemed as statistically significant. Instead, it is worth noting that the Research and development process of Industry will demonstrate user need and preference at the point of design for iterative innovative features.	Thank you for your comment. Please see the response to comment 67. The EAG have not claimed the views of the 2 experts quoted to be statistically significant. 10 clinical experts were included in the overall consultation for this report and all 10 were given the opportunity to provide feedback on the draft report including this section. In addition to the consultation conducted with the EAG, NICE separately conducted a user preference workshop with robust methods to determine user preferences.
69	Convatec	23	1	It will have been noted through this review that there is no data to support many of the listed benefits & even less so the groups of people who may use them. These statements are therefore entirely subjective (n=2) so they should not bear any relevance to this review.	Thank you for your comment. Please see the response to comment 67. The report is clear that the benefits in Table 3 are subjective. In the report we state: "The views of these experts are shown in Error! Reference source not found. and represent the opinion of the two experts, which was based on a mix of personal experience and information provided by companies about their bag features. Clinical experts stated that, in some cases, they were uncertain whether the features delivered the benefits that were intended."
70	B Braun Medical	Throughout	Throughout	Only two clinical nurse specialists were consulted by the EAG. A larger sample of nurses, with varied experience (e.g. community vs. hospital-based, experience in a Trust which has sponsored nurses vs. a Trust with no sponsored nurses, from different geographical regions, depth and breadth of experience) would be more	Thank you for your comment. Please see the response to comment 67. 10 clinical experts were included in the overall consultation for this report and all 10 were given the opportunity to provide feedback on the draft report. In some areas the EAG sought additional detailed input from a selection of the

				appropriate. This would also enable opinions to be gathered more robustly via consensus and Delphi panels. This should be taken into consideration for all other ongoing and future LSAs. NICE may also choose to consult with other CNSs themselves prior to finalisation of this LSA, to supplement the opinions of the 2 consulted by the EAG.	included experts. This is a common practice across NICE's Centre for Health Technology Evaluation. Robust methods were used to inform the most important model parameters where data was not available (structured expert elicitation as recommended in the NICE manual) and user preferences which are reported in the separate user preference workshop report.
71	CliniMed	20 90 92 101	2 7.2.3.9 7.2.4. 7.2.8.1.	Where a clinical experts view has been required, in many situations the decision has been taken by only 2 CNS's, this is not representative of the 500-600 UK CNS in Stoma Care. How can a sample of 2 be considered representative, valid or robust? (examples below): <i>"The EAG discussed with its clinical experts (two CNS in stoma care) the way in which the features included in the NICE scope were intended to benefit people with a colostomy and the groups of people with a colostomy who might choose a bag with each feature. The views of these experts are shown in Table 3 and represent the opinion of the two experts, which was based on a mix of personal experience and information provided by companies about their bag features. Clinical experts stated that, in some cases, they were uncertain whether the features delivered the benefits that were intended."</i>	Thank you for your comment. Please see the response to comment 70.

				<i>“Two CNS in stoma care were asked to comment on the differences in the probability of switching across companies. One responded that bag switching may be influenced by marketing strategies from companies that they had witnessed in practice, for example, insisting that people switch to their latest branded products. CNS in stoma care also noted that people often switch within the first year due to multifactorial issues, and that where there is a larger range available (e.g. for Coloplast with convexity and Salts with different colours) there might be more incentive to switch to find a more ideal bag.”</i> <i>“Interviews were conducted with two CNS SCMs/experts in stoma care to inform model parameterisation for specific questions related to resource use.”</i> <i>“Other resource based on Rolls (2023), with changes to adapt to a colostomy population as suggested by two CNS in stoma care with some additional consultation for the number of 1- piece closed bags per day to validate inputs following commentary from one SCM that the values initially input appeared too high.”</i>	
72	Hollister Ltd	90	7.2.3.9	Two CNS were asked to comment on switching. Similarly to above, this would seem to be a very small number of opinions.	Thank you for your comment. Please see the response to comment 70.
73	Hollister Ltd	99	7.2.8.1	Two CNS were consulted on cost of treatment, Similarly to comments 12 and 13, these may well be very valid points but	Thank you for your comment. Please see the response to comment 70.

				the sample size seems small. It may be relevant for future work to consider gaining a broader range of opinions.	
Potentially innovative features table					
74	B Braun Medical	21-22	2: Table 2	Errors/amends required: Softima Active: Change N to Y for baseplate additive, baseplate adhesive, bag shape, filter, material – all detailed in RFI except bag shape, however, water repellence wasn't specified previously in bag shape (which all Softima products are) and terms "modified" and "innovative" were misleading. Softima Closed: Change Y to N for baseplate additive. Softima Closed: Change N to Y for baseplate adhesive, bag shape. Softima Closed Maxi bag has a split cover so should this be listed separately and marked Y for split cover (all other features are identical to Softima Closed). Softima Convex Closed: Change N to Y for bag shape – as above regarding water repellence and clarity of terms.	The words modified and innovative were provided in the RFI and final scope applied to the EAG. NICE removed this wording following stakeholder feedback that the terminology was not understandable. The table still lists all items as 'potentially innovative features'. The features in Table 2 have been amended as requested. The features included in the regression analysis were checked versus the company RFI. In all cases except the request to change N to Y for the Softima Active for baseplate additives the regression analysis reflects these amendments and was in line with the original company RFI. As baseplate additives were not listed in the original company RFI for the Softima Active the regression analysis has not been updated as the EAG considered it important that the features included in the regression came from a question asked in the same manner to all manufacturers.
75	CliniMed	22	Table 2	Welland Aura Profile has been incorrectly spelt in the table: 	Thank you for your comment. This has been amended

76	CliniMed	80	16	Welland Aura Profile has been incorrectly spelt in the table: 	Thank you for your comment. This has been amended
77	Coloplast	79	Table 15	Confidence supersoft is in the table of flat products but is a convex product. Furthermore, it is costed at £2.55, but checking the PCA 2023 shows a price of £3.11	Thank you for your comment. This has been amended
78	B Braun Medical	21-22	2: Table 2	No mention in table or anywhere in report about belt loops. These are a very important feature of convex bags and can help to prevent the biggest concerns of leakage/seepage and PSC, therefore it seems odd not to include this feature and any beneficial designs such as 3 belt loops on Softima – which increases the cost price of the products but can improve patient outcomes by providing more security.	Thank you for your comment. These were not a feature included in the final NICE scope. This is because they were considered as a feature found on all convex bags and so not an innovative feature.
79	BHTA	21	2	The table which highlights the features of a product is factually incorrect. This is due to the term 'modified' being removed after companies gave their feedback to the additional request from the EAG.	NICE removed the term 'modified' following stakeholder feedback that the terminology was not understandable. The table still lists all items as 'potentially innovative features'.
80	Convatec	17 & 21	1	As the table indicating whether a brand included potentially innovative features was compiled when the descriptor of 'modified' was still being considered, the data collected is now misleading and subjective based upon how the company interpreted 'modified'. Convatec would therefore propose that this table is revalidated with the true descriptor of what was intended. For example, our original submission assumed that 'filter'	NICE removed the term 'modified' following stakeholder feedback that the terminology was not understandable. The table still lists all items as 'potentially innovative features'. A filter that has not been subject to incremental innovation would still not be classed as potentially innovative.

				was a basic feature and that 'modified' meant it had been subject to incremental innovation, therefore we selected 'No'. Our products do contain a filter and many of the other features noted, and as such the table is incorrect. Amended version based upon removal of the word modified attached as an appendix [REDACTED]	
81	B Braun Medical	N/A	N/A	The original RFI used the term "innovative feature", which was later changed to "modified feature." This change was unclear and may have been misinterpreted by some manufacturers.	NICE removed the term 'modified' following stakeholder feedback that the terminology was not understandable. The table still lists all items as 'potentially innovative features'
82	CliniMed	17	1	<i>"Removal of the word 'modified' from the decision problem: In the NICE scope, several features of interest were defined as modifications from a more 'standard' 1-piece closed bag (e.g. modified baseplate, modified adhesive). Prior to submission of the EAG report, NICE requested that the word "modified" be removed from the features as presented in the decision problem. This was on the basis that there was variation in what might be considered to be 'basic' or 'standard' features and so it would be difficult to define which features were modifications. The EAG noted that the decision problem and the EAG's review did not consider all baseplates, adhesives, bag shapes etc, only those that were considered to be potentially innovative and/or potentially associated with increased cost."</i> Within the scope / protocol there has been a removal of the word "modified". We feel	NICE removed the term 'modified' following stakeholder feedback that the terminology was not understandable. The table still lists all items as 'potentially innovative features' This term considers additives to the baseplate adhesive.

				this word should be re-introduced. If a company has the usual hydrocolloid formulation and then it is also available with an enhancement to the skin, e.g. alginate, ceramide, manuka honey, vitamin E).	
83	CliniMed	20 77	List of tables 2 7.2.1	<i>Table 16: Convex/concave shaped bags included in the analysis.</i> <i>“With respect to the decision problem, the EAG noted that some of the available 1-piece closed bags are available as flat, convex or concave, but as this feature is considered to be essential for ensuring a suitable fit of a bag to a person, it was not considered to be an innovative feature for the purposes of the assessment and so was not included as a feature in the table.”</i> <i>“In addition to these features, convex and concave shaping was identified as an important feature in a sub-category of bags that improves body fit and is associated with increased cost. Consequently, the analysis was conducted separately for flat and concave/convex bags”</i> There needs to be clarity on the use of the description “Concave” – this is a Coloplast branding for their product that has a baseplate designed specifically for curves, bulges and hernias, e.g. SenSura Mio Concave. This is the same as Welland Medical’s Profile product which has a flexible and adaptable flange, which moulds and shapes around the contours	Thank you for this comment. The term ‘concave’ was used in the NICE scope for this assessment and was carried through to the EAG report. CNS confirmed it was a terminology they would use as it described what the baseplate looked like. The Welland Medical’s Profile was acknowledged in the report and Welland’s profile product was included in the regression analysis for convex / concave bags. The EAG have added clarification to the terminology in Section 2 of the report.

				of a parastomal hernia, giving it a concave appearance.	
84	Hollister Ltd	157	8.3	Flushable disposal bags are referenced in the same paragraph as environmental concerns There may potentially be issues with flushable products in relation to PFAS being released into the water – this could potentially benefit from future research.	Thank you for this comment. The EAG have modified the sentence slightly to clarify that flushable bags were not necessarily considered to be environmentally friendly. The EAG agree that flushable bags that are environmentally friendly would be ideal.
General comments					
85	CliniMed	15	Research recommendations	<i>“Overall, the EAG considered that there was an unmet treatment need amongst people with a colostomy, in that a significant number of people may be experiencing bag-related complications that have a major impact on their physical and mental health, and their ability to engage fully with their lives. Research to improve outcomes for people with a colostomy would therefore be of significant value.”</i> What is this based upon? Research to improve outcomes is therefore required.	Thank you for your comment. This is based upon the evidence identified that there are a substantial number of people may be experiencing bag-related complications that have a major impact on their physical and mental health as stated.
86	Coloplast	N/A	General	Please note ‘stoma’ and ‘ostomy’ are used interchangeably throughout this document	Thank you for your comment. the EAG have changed a few instances of ‘ostomy’ to ‘stoma’ to be consistent. Several instances of ‘ostomy’ remain in the report, however, such as when these are part of the name of a psychometric tool, the name of a company, or when included in the protocol for the structured expert elicitation (as this document needs to

					reflect the version that was shared with participants).
87	Association of Stoma Nurses	17	Language used	The word poo is used throughout the document which we are surprised at – As a professional document aimed at healthcare professionals we would have expected colostomy output to be used	Thank you for your comment. NICE chose to amend the wording from output or faeces to poo to reflect preference of terminology used by clinical nurse specialists and people with lived experience. The term ‘poo’ is also used by NHS guidance on colostomy.
88	Association of Stoma Nurses	98	Resource use and costings studies	There is no Definition of amber/ red within this table 19	Thank you for this comment. The EAG have added a footnote explanation to Table 19 and Table 22.
89	Association of Stoma Nurses	112	PSC	NICE health technologies manual is not commonly used within stoma care We would wish to highlight the insights, skill and expertise of other specialists who have greater knowledge of stoma care - professionally they should acknowledge that other methods may be used	Thank you for your comment. The reference to the manual relates only to NICE’s preferred measure to capture data for quality of life. Data from other measures has been included in the report and considerable consultation has been conducted with specialists in its development.
Previous evidence requirements/ evidence standards					
90	Convatec	66	5:5	It should be noted that as a class 1 medical device, clinical evidence has not been a prerequisite to DT listing, hence this was previously highlighted by industry to DHSC and NICE. Therefore, we would challenge that the statement and conclusion drawn by EAG that “there is no difference between bags evaluated”, could potentially be misleading.	Thank you for this comment. The EAG believe that the full quote you’re referring to is “In many instances, there was no difference in outcomes between the bags evaluated”. This section of the report is to draw conclusions about the evidence identified in the clinical evidence review. The statement is factually correct. Throughout the report, we have highlighted the poor quality and paucity of evidence available for 1-piece closed bags for people with a colostomy, and the associated

					uncertainty in drawing conclusions about bag effectiveness.
91	BHTA	11	Exec summary	The report mentioned the lack of evidence on the effectiveness of the products: N.B. Manufacturers have never been requested to provide detailed evidence in order to be listed either on DT or through NHSSC.	Thank you for your comment. The EAG conducted an evidence review for the available evidence evaluating 1-piece closed nags for people with a colostomy and the report text describes the evidence identified and the conclusions that can be drawn from it.
92	CliniMed	11		While four included studies were crossover randomised controlled trials (cRCTs), the overall evidence base was nevertheless of poor quality, with significant risks of bias that undermined the reliability and validity of the findings. The evidence provided for all products reviewed in this document has been deemed sufficient to achieve appropriate UKCA/CE marking for Class 1 devices. This process also requires oversight from the Notified Body and Competent Authority. Any concerns about data quality are related solely to the system which is overseen by the MHRA. It is not reasonable to expect RCT and that data quality is of a pharmaceutical standard. This is also in the context of EU MDR significantly raising the Regulatory Standards for Medical devices.	Thank you for your comment. The EAG conducted an evidence review for the available evidence evaluating 1-piece closed nags for people with a colostomy and the report text describes the evidence identified and the conclusions that can be drawn from it. The evidence considered sufficient for regulatory decision-making (self-declared for Class I devices) and routine commissioning are different, and therefore it should not be expected that a product that has received a licence for use in the UK will be recommended for reimbursement.
93	Coloplast	161	8.4	'The EAG believed that, to date, the manufacturers of 1-piece closed bags for adults with a colostomy have developed evidence to support the licensing of their	Thank you for your comment. The EAG do not believe that this text is factually inaccurate and so does not require amending. The statement is EAG belief at the time of the

				products and to inform marketing strategies and have not been developing an evidence base to inform a NICE assessment. In Coloplast we continuously try to elevate the quality of evidence within all our business areas. We have always delivered on the level of evidence required by our payers throughout the world. When generating evidence we also have to ensure it meets the HTA assessment in other countries, e.g. TLV in Sweden, HAS in France, HELFO in Norway. We would like the section to be amended to also mention that evidence has been generated for the inclusion in Drug Tariff which require evidence showing that: The products are safe and of good quality They are appropriate for HP and, if relevant, prescribing by appropriate practitioners They are cost effective	assessment and was intended to provide an explanation for the paucity of robust evidence for products that are widely available within the NHS. The scope of the assessment acknowledges the Drug Tariff criteria for listing based on their guidance. This assessment is an independent evaluation of evidence conducted for NICE and is separate to opinions decided by other NHS bodies.
94	Hollister Ltd	12	Executive Summary	Again in relation to the highly speculative findings, perhaps the process was more geared to being suitable for the Pharma sector rather than Medical Devices?	Thank you for your comment. The assessment was done in line with NICE's interim statement on late-stage assessment .
95	Hollister Ltd	12	Executive Summary	A General Comment but related to paucity of evidence/speculative findings, it is quite possible that the concurrent Intermittent Catheter LSA may come across similar challenges.	Thank you for your comment.

96	Hollister Ltd	12	Executive Summary	The EAG has undoubtedly undertaken a thorough piece of work, but given the findings were highly speculative is the LSA process the right process to assess these products?	Thank you for your comment. The assessment was done in line with NICE's interim statement on late-stage assessment , including topic selection.
Report findings					
97	Coloplast	N/A	General	We thank the EAG for their thorough work and the opportunity to comment on the report. In the spirit of constructive engagement, we have reviewed and added detailed responses. The aim of Late-Stage Assessment (LSA) was to “<i>provide a value assessment (based on evidence, clinical and patient input)</i>”. The process, scope, available evidence and execution in this instance will not allow for a safe judgement to be made that will not result in harm to patient outcomes. As such, any inference throughout the documents related to this LSA that it can meet its aim is considered by Coloplast to be a factual inaccuracy. Coloplast has consistently argued – in commenting on other draft process documents and through direct representation to the NICE executive team – that this LSA will not produce recommendations, which are a safe and reliable basis for guidance to the NHS and not in the interests of patients. This	Thank you for your review and detailed comments, the EAG state that they are appreciated. The assessment was done in line with NICE's interim statement on late-stage assessment, including topic selection. Colostomy bags (one-piece closed bags) were selected as this aligns with how products are listed on the Drug Tariff. The name of the topic was clarified to align with practice (one piece closed bags) and the main user of these products (adults with a colostomy). Please note that the final scope has been subject to a scoping workshop with input from multiple companies involved in the evaluation, along with clinical experts and people with lived experiences. Their input defined the final Population, Indication, Comparator and Outcomes used in this evaluation. With regards to the EAG statements, the EAG disagree that any change to the language is required. The report clearly states throughout that there is

			is borne out by the evidence assessment which, despite best efforts by the EAG, does not provide a basis for decision-making. We have previously explained the reasons for this which include: an underlying assumption that product features are fully responsible for driving value rather than the clinical context in which stoma care is delivered through added-value services; and the use of emerging methods which have not been rigorously researched and tested before being applied in a live evaluation. The same considerations apply in two of our other business areas selected for LSA – antimicrobial dressings and intermittent catheters – which we are gravely concerned will be following a similar path. In many places, the EAG states that there is no evidence to conclude that the variation in product price is related to features, or words to this effect. Without clarification, this infers that the EAG were able to and have examined evidence and been able to safely conclude no justification for price variation where this is not true. They in fact mean that there is no evidence with which to make any safe conclusions about the relationship between price and features.	an absence of evidence and discussed the implications of this. Thank you for your comments on evidence generation within stoma care. The EAG has highlighted complexities in generating evidence in this topic area in its report (see Section 8.4). The EAG has made some recommendations for future research in consideration of these complexities. The accepted evidence standards of other authorities is outside of the remit of this evaluation. The EAG acknowledge the challenge in selecting a comparator bag and noted this in its report. As part of the EAG's research recommendations, the EAG suggested that research to identify key groups or indications for adults with a colostomy that would be candidates for the same product may be helpful to inform selection of an appropriate comparator. In respect of the economic analysis CNS were consulted to see if a "basic bag" could be defined to use as a comparator. Whilst a number of bags were suggested the pricing of these bags was variable with some bags classed by CNS as "basic" being above the average price. This reflects the lack of a link between price and features of a bag demonstrated in the regression analysis. Given this the EAG chose to use the cheapest bag as the reference for the economic analysis as this is

				This is in part due to the chosen scope of the LSA being 'Colostomy Bags', which does not fit the current practise in the field. Coloplast has mentioned throughout the process that in practice a 'Colostomy Bag' does not exist. Manufacturers make bags for people living with a stoma who have diverse needs. This should be made clear on every mention so as not to prejudice decision makers; any mention without clarification is considered to be a factual inaccuracy by Coloplast. Fundamentally, it should be concluded that there is not sufficient evidence to meet the stated aim of this LSA because without evidence to support clinical, economic, resource use or HRQoL outcomes it is not feasible to ascertain value. Therefore, the only appropriate and factually accurate outcome should be that evidence is lacking and that the conclusions cannot be made, rather than infer that the conclusion is strong or that the eJP is known. This LSA process is, in practice, the reverse situation to a standard HTA. It is common that the submitting company is attempting to change the current system or care pathway, NICE evaluates the analysis and determines the quality of	objectively definable. In terms of evidence collection, NICE also encourage the collection of evidence through real-world sources. Please note that at this stage NICE cannot speculate on the outcome of this evaluation. The process needs to proceed to the next step of the committee deliberation before being able to comment on the outcome. Please refer to our interim statement mentioned above for more details on the types of evidence accepted for evaluation. They cover a broad range of study types, including published and unpublished RWE.

				the evidence or analysis. In this LSA, NICE is evaluating the current situation, and the companies are evaluating the evidence and analysis undertaken. However, if this analysis and evidence base was presented in any other appraisal workstream submission, the conclusion would be a rejection or denial of altering the current system/status quo due to insufficient evidence that support decision making. Therefore, we implore the committee to evaluate with this context considered. The major difference between an LSA and standard HTA, is that in a standard HTA, the benefits are the availability of new treatments, and the risk is that new treatments will not enter the system. In this situation, however, the assumed benefit is that NHS will be able to generate savings by not paying for certain features of bags, while in reality, there is a huge risk that patients lose access to bags and features they need. This also imposes a risk of clinical practice regressing to a state of reactive (instead of preventative) stoma care, where people with a stoma will be forced to use the cheapest product available, only to subsequently experience complications which impose costs	

				to the NHS in terms of treatment and staffing requirements. Coloplast understands that time constraints and scope were an issue but given time we believe the analysis would have substantial benefit from conducting a discrete choice experiment to determine the willingness-to-pay for each feature. This LSA benefits from there being a large population currently receiving each stoma bag, so given the time and scope, a robust decision could be made if it could be determined how each colostomy bag recipient values the features themselves. Evidence generation within stoma care In our earliest conversations with NICE and the EAG we explained that generation of stoma care evidence cannot be compared with that generated with other health technologies or with medicines due to complexity of the population, the number of products in the market, the reliance on individualised solutions based on the individual's usage of the products, and ostomy care management in the context of the delivery of added-value services. This context has previously been	

				accepted by other competent authorities both in UK (Drug Tariff) and across other European countries (HAS in France, TLV in Sweden, HELFO in Norway etc.). The evidence requirements set out by NICE for the LSA is simply not feasible for manufacturers to follow, especially due to the number of products variations and combinations of interventions needed to serve the individual need. In one of our product portfolios alone, SenSura Mio, there are 300+ SKUs. If we were to collect homogenous evidence at the level NICE require for decision making, we would need to consider 1pc vs. 2pc, 2pc mechanical vs flex coupling, baseplate type (flat, convex, concave), stoma type (colostomy, ileostomy, urostomy), stoma output type (formed or liquid faecal output), body profile, scarring or irregularities in the peristomal area, underlying disease type (colorectal cancer, diverticulitis, IBD etc.), what types of supporting products were used by participants, was the person enrolled in an stoma support programme and more. It is also mentioned in the report that there are large differences in the care delivered from country to country (and then in the UK differences across	

				regions and postcodes) and having account for these differences by conducting separate studies for each setting would further complicate evidence generation, and stifle innovation within ostomy care. As an example, there are more than three peristomal body profiles of inward, outward and regular, there are 216 individual body profiles, and when adding output types, we then have 648 different variations. When this is added to number of products, stoma types etc. the number of studies needed to be conducted to live up to the requirements set out by NICE for decision making, it is unobtainable. What should also be considered is that the choice of comparator is difficult, due to the number of products launched within stoma care and no one product has been established as the standard of care, which is why we often use a mix of comparators in the studies, to ensure comparability of the outcomes across local regions and countries. It is therefore important that the choice of study comparator be of relevance to decision makers across the care continuum, stoma care nurses, local payers (e.g. ICBs), and HTA authorities. As an example, if the reference product	

				for the LSA (Opus NaturFit) was selected in a study, it would be of no value to decision makers or clinicians, as the product is only used sparsely by people living with a stoma (0.032% of the total volume of products in the Colostomy Bag category, PCA 2023). In conclusion, to produce evidence suitable for use in the methodology chosen for this, Coloplast and other manufacturers would need to conduct 100s of trials, for products with an overall low budget impact to the NHS. This would impose significant costs on the whole sector, raising the cost of developing products and stoma care in general. Additionally, it would drastically slow down the process of bringing innovation to the patients who, ultimately, would be the ones most negatively impacted by the final decision. Therefore, as a suggestion for the next steps for NICE and the committee, we would suggest a pragmatic approach where product brands are evaluated based on best available evidence, and with the bespoke needs of people living with a stoma in mind. Feature based approach of the LSA and its impact on decision making	

				The EAG noted a paucity of clinical information relating to features, and in particular the link between features and clinical outcomes. As noted in detail later in this document, they also conduct what we believe to be a flawed regression analysis looking to link price to features. As has been communicated to NICE throughout the appraisal by Coloplast, we do not agree to the premise of evaluating the list of features included in the scope of work, or the process by which these features were chosen and defined. The performance of a bag should instead be evaluated as a whole, not by feature, as this is closer to real world use. As such, despite this being a key element of the scope of LSA2, we feel it would lead to illogical decision making should recommendations be made based around single features. The point that was made by the EAG on p.15 of their report is not that there was no link between features and price, but that there is no evidence to support such a link. They also note that individuals may well benefit from such features. Thus, to issue guidance worded in a similar way to the late stage LSA1 which analysed evidence by named proprietary product would be	

				misleading. It is noted clearly by a technical analyst and advisor from NICE in the User Preference Report (UPR), p.21 that the prescribing pattern of products <i>“highlights the importance of individual reviews and maintaining a wide range of product choice”</i>. To arbitrarily limit access based on no evidence would harm patient outcomes and reduce the tools SCNs have available to support them. If the committee feels such a situation is unavoidable, Coloplast propose that NICE accept that the evidence included in the LSA is not suitable to support a feature-based approach. The presence or absence of features is not suitable for logical, evidence-based decision making and as such no reference should be made to features in any recommendations. We would suggest that while imperfect, guidance based around EJP would be the least bad approach, given that the identified issues with the health economic model are fixed (we provide more details further in this document). The decision on which products should be available to patients should be based on their assumed or articulated need as judged by them, or a suitable health care professional. Such a decision would	

				allow clinicians to select the most appropriate product based on an individual's personal needs and circumstance while at the same time offering NHS England some security that they were not overpaying for the choice of product. The EAG highlighted throughout the report that “the paucity and limitations in the clinical effectiveness evidence for 1-piece closed bags for people with a colostomy meant that it was not possible to draw firm conclusions about the effectiveness of potentially innovative features of the bags, or about the relative or absolute effectiveness of any bag.” [p.64; see also p.66 and Section 8] For future assessment, a better approach might be to identify areas of interest well in advance and request that companies collect and supply the relevant data required to make these decisions. Coloplast and the stoma community has come a long way in ostomy product innovation. It is recognised that not just the physical needs for people living with a stoma should be addressed (which has impact on mental and e.g. ability to work) but the psychological aspects too. For	

				example, innovations in discretion, such as noise reduction (requires bag to be made of special fabric) or odour reduction (use of special materials to keep the smell inside) matter. These do not come as standard in all bags. Society can be cruel in terms of the way it treats people with stomas, and as a result they can become isolated. We ask the Committee / NICE to remember this when making their decisions in this area of healthcare.	
98	Hollister Ltd	161	8.4	The report identifies that much of the evidence (whatever the standard) is generated from manufacturers and not aligned with NICE requirements. To ensure independence, should the very valid research recommendations be undertaken by an independent body, possibly commissioned by the MedTech Directorate or similar appropriate body?	Thank you for your comment. The assessment and subsequent guidance can recommend what evidence is required which could support others when making funding applications.
99	Salts Healthcare		Conclusion	We are concerned that any LSA recommendations regarding the suitability and availability of product could have a damaging effect on people living with a Colostomy's quality of life. Therefore, it is crucial that this process be as robust as possible and if the evidence is not available, we recommend the process be paused to allow further thought and a wider group of unbiased clinicians to provide input.	Thank you for your comment. The assessment was done in line with NICE's interim statement on late-stage assessment , including topic selection.

100	B Braun Medical	N/A	N/A	It is unclear how NICE's recommendation will be interpreted by DHSC and the impact this may have on the Drug Tariff. NICE should clarify the impact of guidance when evidence on reductions in complications is currently lacking, and/or whether manufacturers will be expected to undertake further research on the clinical benefit of their current and future products. It should be noted that impacts on current pricing have the potential to result in some manufacturers withdrawing some products from the UK market, which would in turn impact patients' choice and outcomes.	Thank you for your comment. Comments on the potential recommendations and interpretation of them are outside of the remit of this stakeholder comment period.
101	Salts Healthcare		Lack of Evidence	We agree with the findings of a general lack of evidence and we feel as though this has meant that the only conclusion that can be drawn is that more evidence is required. We also believe that current standard test for features such as flow rates have not been identified and therefore not deployed when they are available and should consult industry experts regarding such tests before moving forward with future testing. We have concerns over the creation of an ejp using a model with an R-Sq of around 40% and the outcomes as factors in the model which were not statistically significant and do not believe that the report adequately highlights the insignificance of the results and that this model should not be used in any way moving forward.	Thank you for your comment. In relation to the ejp this was a separate analysis to the regression. We agree that the regression shows little link between the features tested and product price. We have highlighted this in the report. For example in the executive summary: "Exploratory analysis of bag price vs. benefit showed little association between current pricing and demonstrated benefits, with only the flushable disposable feature for flat bags significantly impacting price in regression analysis"
102	Coloplast	12	Executive Summary – Clinical and	The executive summary concludes 'Where differences were reported in clinical outcomes, these were not	Thanks for your comment. The EAG disagree that filter performance was consistent across studies: even within

			technological evidence	consistent across studies'. Coloplast believes this statement to be factually incorrect, due to the EAG misreading the table provided in an evidence request to Coloplast (comment 16). We therefore believe this sentence should be amended to: "Where differences were reported in clinical outcomes, only filter performance seemed consistent across studies". This should be amended to represent that there were in fact consistency in outcomes for filter performance.	the same study, a change in filter did not necessarily lead to consistent effects across outcomes that would be expected to be related to filter performance (e.g. ballooning, pancaking, odour control). The EAG consider the text in the executive summary to be factually correct and therefore have not amended this.
103	Coloplast	14	Executive Summary – Economic evidence and analysis	While Coloplast can understand the development of an economic model centred on the concept of EJP and not features, it is fundamental that the correct EJP calculations are used in decision making. In the section on eJP, it is concluded that: "a bag that completely eliminated complications was £3.89 for a flat bag and £4.33 for a convex bag". This is not reflective of the conclusions made on eJP on page 131, as these results are for the maximum impact complication only. The results on completely eliminating complications are £7.16 and £7.60 for flat and convex respectively. This misinterpretation is repeated throughout the section and should be amended.	Thank you for your comment. The wording has been amended to reflect what is presented in the results section: "The maximum eJP for a bag that for a bag which completely eliminates the chance of any one of the complications was...." This report section discusses overlap of complications and their impact within individuals and does not address bag features. Thank you for your comment about the potential problems that may arise associated with bag features, the EAG have added a comment about this in Section 2.

				The EAG report present results by individual complication assuming either a 100% or 50% improvement in tables 27 and 28 of their report and for all complications combined in table 29. The EAG also openly note on P131 of their report that there was an overlap between features within individuals and this was the justification for the development of the results in Table 29 of their report. What is not acknowledged is that the addition of some features can be detrimental to some patients, as they could result in adverse events e.g. allergy to baseplate additives. The EAG also state that the true EJP is somewhere between the two values reported in this table (corresponding to largest individual impact and additive cumulative impact) which Coloplast do not agree is factually correct as these values are calculated with absent evidence and flawed assumptions. Coloplast state strongly that we believe that the results in tables 27 and 28 should not form the basis for decision making and that committee should instead prefer to use the information in table 29 on which to decide on appropriate EJP values.	The report states that “the appropriate eJP would likely lie somewhere between the two results” in the context of either an additive approach to multiple complications or looking at the complication with the maximum effect only. The EAG have been clear in the report as to the limitations in our analysis caused by the poor quality of the evidence base.

104	Coloplast	15	Executive Summary – key points for decision makers	We believe that, because of the absence of evidence acknowledged by the EAG, the small amount of clinical effectiveness evidence assessed and the major uncertainties in both that and the modelling, that the statement: “The evidence did not appear to be sufficient to support price variation for any of the features considered” would be better expressed as: “More evidence is needed before any safe judgement can be made on appropriateness of price variations for bags with particular features.” This change is supported by the EAG’s consideration in Section 7.2.2 (p81): “Given the limitations of the evidence base for this analysis, as well as the lack of evidence to determine the effectiveness of specific features and/or bags to addressing these complications and patient preferences, the EAG cautioned that this analysis is suggestive only and that further research would be needed to inform pricing decisions for 1-piece closed bags for adults with a colostomy”.	The EAG disagree that the quoted statement is factually incorrect, as it’s true to say that the available evidence does not explain or justify price variations in bags.

105	Coloplast	15	Executive summary – key points for decision makers	The EAG concludes that ‘the evidence which did not appear to be sufficient to support price variation for any of the features considered’. In addition to our other comments on the conclusions reached in the report’s Executive Summary, we believe there are methodological issues about the eligible populations studies which may have resulted in not all of the relevant evidence being considered. Insufficient evidence was identified for the population subgroups detailed in the scope, and the review has assessed evidence in the broader colostomy population. As a result, the needs of the highly diverse colostomy group, has not been sufficiently assessed. The heterogeneity in preferences and clinical needs when determining the most appropriate bags is acknowledged by NICE in the supplemental user preference report, stating: • <i>Throughout the assessment, users highlighted the need for bags to be tested in various groups of people with different skin conditions, lifestyle, mobility levels and people with underlying health conditions to ensure a person can be confident</i>	Thank you for your comments about the availability of evidence, the importance of subgroups included in the NICE scope, the selection of comparators in research, and the complexities involved in choosing an appropriate bag for a person with a colostomy. As detailed in the report, the EAG used a comprehensive strategy to identify the available evidence for this assessment, and explored additional avenues for evidence that wasn’t explicitly included in the review protocol. The EAG were only able to consider the evidence available at the time of the assessment. As you note, the EAG have discussed these limitations in the report.

				<i>in the security and durability of their bag (page 19)</i> • <i>Throughout the assessment, users reiterated the importance of all identified criteria when choosing which 1-piece closed bag to use, as well as other factors unrelated to preference, such person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output, manual dexterity, visual impairment, mobility levels or other health conditions (page 20).</i> In its conclusion, the NICE report expresses that, due to the variability between stoma bag users, the choice of bag should be determined on a case-by-case basis, maintaining a wide product selection to meet the heterogeneous needs and preferences. • <i>The wide range of variability between people with a colostomy is reflected by the large number of products available for prescription in Part XI of the Drug Tariff and highlights the importance of individual reviews and maintaining a wide range of product choice (page 21).</i> The EAG report similarly acknowledges this variability, emphasising the	

				complexity associated with determining an appropriate stoma bag. The authors note that users' clinical needs and preferences may also change over time. <i>...there may be few suitable bags available for the person. Each person may be changing between multiple different bags at any one point in time, according to their needs (for example, they may use a different bag for sporting activities or certain social occasions). The bag that a person uses may also change over a person's lifetime as their needs and preferences change. An SCM also noted that people with multiple stomas may need to choose bags that fit comfortably alongside each other without overcrowding (EAG assessment report page 27).</i> Feedback from SCMs, including CNS in stoma care and people with lived experience, was that the consequences of using a bag that does not work effectively for a person or does not meet their needs could have a major impact on a person's physical and mental health. Negative outcomes that cause embarrassment for people with a colostomy, such as leakages or a lack of discreetness, may have a profound impact on a person's psychological	

				wellbeing and their confidence to socialise with others and engage in their usual activities, including struggling to work due to bag leaks or sore skin. Skin complications arising from leakages may also cause pain and discomfort in the short-term and may be challenging to resolve, meaning that these may continue to impact on people in the medium and long-term (page 28). As stated by the EAG, “Adults with a colostomy are a highly diverse group of people...The same bag will patently not be suitable for every person, and therefore may only ever be used by a subgroup of people with a colostomy (and never even tried in others). Within the population of people with a colostomy, this means that there are an unknown number of separate ‘indications’, i.e. groupings of people for whom a particular bag or set of bags may be appropriate. To the knowledge of the EAG, there is not a clear breakdown of these indications that could be used to guide study selection criteria, and given the high level of variation in needs, the EAG is unsure if this could be possible. This means that there are ‘appropriate’ and ‘inappropriate’ comparisons – i.e. some	

				bags should never be compared with others, as they are intended for different populations. It also means that a bag A may perform better than bag B in one population and worse than bag B in another population, meaning that the eligibility criteria in the studies are crucial for determining meaning in the results.” Additionally - the literature searches aimed to identify colostomy products. However, Coloplast’s products are designed for people with a stoma (see, specifically, ileostomies and urostomies) in general, and as such potentially relevant evidence may have been excluded as not directly relating to colostomies. Further, this is inconsistent with the approach taken to utilise studies used in the decision model that included studies that were otherwise considered out of scope: Nortoft 2019 for ‘cost of supporting product costs’ considers other types of ostomies. Bennett Institute for ‘the number of bags wasted per day due to prescription change’ considers other types of ostomies. Colwell 2018 (ADVOCATE RCT) was used for the ‘number of PSCs per	

				year’ and the ‘severity split’ for PSC, despite being considered out of scope as it was for 2-piece closed bags. Rolls 2023, despite being entirely for ileostomy patients, was used throughout for resource-use related parameters, albeit this was adjusted through consultation with CNS in stoma care.	
106	Coloplast	15	Executive Summary – key points for decision makers	Coloplast believe the user preference report brings up important perspectives of stoma care that are of high importance to the conclusion made in the LSA. We therefore suggest the user report is mentioned in the executive summary, including the statement: ‘The wide range of variability between people with a colostomy is reflected by the large number of products available for prescription in Part XI of the Drug Tariff and highlights the importance of individual specialist SCN reviews and maintaining a wide range of product choice.’	Thank you for this comment. The EAG agree the user preference report brings up important perspectives. These are reflected in this report which was produced by NICE as a separate parallel input to this assessment. The Committee have access to both sets of information and both reports will be published. Therefore the exercise of fully cross-referencing the user preference report has not been conducted.
107	Coloplast	15	Executive summary – research recommendations	Coloplast thanks the EAG for the carefully developed recommendations summarised here and explored in more detail in section 8.4 of the report. We support any effort to promote the development of high-quality clinical and economic evidence in ostomy care.	Thank you for this comment.

108	Coloplast	123-124	7.3.2	On page 123, the conclusion of the analysis is that pricing only partially explains variation in price, but it is also acknowledged that not all features are, or could be, included and that there is variation in the features. Therefore, it is not possible to know whether more variation in price could be explained by features that were not included and inference otherwise is factually incorrect. The standard error is 0.31 where the R-squared value is 0.42. There are no diagnostic plots so it is not possible to determine whether this model is even a good fit or should be deemed reliable. The SEs around individual variables are wide and adjusted R squared is low which infers it's not trustworthy, but this cannot be checked as diagnostic plots are not provided. The regressions are also not graphically represented so it is challenging to interpret. The adjusted R squared for convex bags is negative and no explanation is offered. Coloplast is not able to engage meaningfully in this process as the evidence is not supplied or described in completeness making it infeasible to critique this evidence or check its factual accuracy.	Thank you for your comment. The EAG's conclusion is that the potentially innovative features included in the NICE scope do not explain the observed prices. This is factually correct. We have clarified any wording in relation to the regression results to be clear we only looked at features in the NICE scope. The features in the NICE scope were consulted on and discussed at a scoping workshop. Diagnostic plots have now been added to a new Appendix (Appendix L). The EAG was not provided with a clear theoretical basis to justify why certain features would interact with each other to change the effect on the dependent variable (price), and considering the small number of observations, it would be impractical to check all interaction terms. Doing so would likely lead to overfitting, as the model would become too complex without a guiding theoretical framework. Overfitting can then lead to the model performing well on the current data but poorly on new, unseen data, limiting its generalisability and practical utility.

				Coloplast believes that the cost regression results presented in Tables 25 and 26 of the EAG report are misleading and potentially unhelpful from a decision-making perspective. As has been communicated consistently to NICE, it is not necessarily the impact of individual features that is important but the interplay and presence of multiple features within an individual bag (i.e. if Features A and B are both present, it is highly likely that the clinical impact will be greater than the sum of the individual elements. Converting this language into a more statistical argument, assuming that the correct main variables are included, it would also be important to include all relevant interaction terms into the analysis to get a meaningful result though this is not possible. Clinical evidence suggests that there are clinical differences between products, examples include: Virgin-Elliston et al. where it is shown that one filter outperforms the other, Welser and Riedlinger, where one product resulted in less unplanned changes and less seepage of stool under the baseplate than in the other tested product,	

			Kruse et al., where authors emphasize that the obvious product may not always be the best for the patients. They showed that the tested product provided various benefits for the participants: while being flexible and comfortable, it also improved appliance leakage and thus the feeling of security, hence being the overall preferred appliance in the study. Voergaard et al. where the overall performance of one ostomy product outperformed the other and resulted higher preference among patients than comparator and high percentage of patients wishing to switch to it from their usual bag (which also speaks to already mentioned individual preferences being an important aspect in Ostomy Care). and Teniere et al. with a conclusion that one of the products provides patients with a sense of more security and less problems related to changes. Thus, it is very important not to interpret the findings of the regression analyses as definitively showing a lack of a link between features and price. As mentioned above, based on the existing evidence, it is hard to attribute differences in clinical outcomes	

				to single features only, rather the clinical outcomes should be viewed holistically- as the result of presence of many features of the products together, nurse care and service provided.	
109	Coloplast	167 - 169	9	Coloplast are, in summary, very unsure about most of the conclusions drawn by the EAG given that they themselves rate the informing evidence as being of low quality (in Table 36) and because not enough detail has been provided for a full accuracy check. On P168, the EAG note <i>“the analysis also contained several limitations, almost exclusively driven by the lack of relevant data. In particular, there was a lack of data to quantify the clinical and economic benefits of specific features or types of bags... Furthermore, no published data were available on the impact of many complications of interest on either resource use or HRQoL”</i>. Fundamentally it should be concluded that there is not sufficient evidence to meet the stated aim of this LSA because without evidence to support clinical, economic, resource use or HRQoL outcomes it is not feasible to ascertain value. Therefore, the only appropriate and factually accurate conclusion should be that evidence is lacking and that the conclusions cannot be made, rather than infer that	Thank you for your comment. The assessment was done in line with NICE’s interim statement on late-stage assessment. The EAG have clearly highlighted the limitations of the assessment in their report. This information will be presented to the committee as part of the decision-making process.

				the conclusion is strong or that the eJP is known.	
110	Association of Stoma Nurses	13	Economic evidence	<i>You have stated pg 13 There was a substantial price difference between the cheapest and most expensive bags on the drug tariff, ranging from £1.85 to £3.84. However, there were no reliable data to quantify the cost-effectiveness of specific features or types of bags.</i> As clinicians we have welcomed the development of innovative products with features and benefits that have profoundly benefitted our patient population. We would hope the EAG acknowledge that with any product development the cost is going to be higher than older products to accommodate the research, ingredients and inflation. This fact does not appear to be reflected when you have compared your product listings and when looking at the range of costings there are factors such as older products and those with limited features and benefits that may be cheaper	Thank you for your comment. The EAG conducted the regression analysis to explore whether features (as specified in the NICE scope) drove differential pricing. We found that this was not the case (although data limitations mean this should be interpreted with caution). The EAG understand that development of innovative products costs money. However, a company's cost (and profit) function is not of concern to the NHS. The purpose of this analysis is to assess whether the added benefit of those features is proportionate to any additional cost, or whether the NHS could generate greater benefits for patients with the same resources deployed elsewhere (i.e. the aim is to establish whether the bags are cost effective).
111	Association of Stoma Nurses	15	Key points for decision makers	In view of the absence of evidence acknowledged by the EAG, it would be questioned that uncertainties exist to be able to support any decisions to support price variations for the features Fundamentally – a demand for further evidence is required to enable judgements	Thank you for your comment, the EAG agree with this conclusion.

				to be made on the effectiveness of specific features and justify pricing decisions of stoma bags	
112	Association of Stoma Nurses	64	5.4.7.2	This EAG states '<i>Overall, the paucity and limitations in the clinical effectiveness evidence for 1-piece closed bags for people with a colostomy meant that it was not possible to draw firm conclusions about the effectiveness of potentially innovative features of the bags, or about the relative or absolute effectiveness of any bag.</i>'- Surely this is paucity of evidence NOT that there isn't value in the innovations	Thank you for your comment. This already sentence states that the issue is the paucity and limitations in the clinical effectiveness evidence. The EAG have clearly stated the conclusions of their analysis in the Key points for decision-makers: "The evidence did not appear to be sufficient to support price variation for any of the features considered. This was due to an absence of evidence rather than evidence of no benefit associated with the bag features. In addition, current pricing did not appear to correlate with these features. This was not to say that these features were not of benefit to people with a colostomy."
113	Association of Stoma Nurses	66-67	5.5	It is stated within this report '<i>Feedback from CNS in stoma care and people with lived experience suggests that there are meaningful differences in outcomes between 1-piece closed bags, and that differences in bag related complications between bags may have significant implications for the lives of people with a colostomy. Further research is needed, however, to determine the direction and magnitude of these benefits across the 1-piece closed bags and bag features available on the NHS</i>' We very much are applauding this further evidence because anecdotally we would advocate there IS benefit	Thank you for your comment, the EAG agree further evidence collection is warranted.

114	Association of Stoma Nurses	71	7 economic evidence	PLEASE remember the central tenet of this piece, we are not simply discussing products and appliances we are discussing something that significantly effects individuals quality of life – which can be the difference between simply just existing or actually enjoying life. We are unable to see or comment due to the redacted study here – Cheapest is most definitely NOT good value for money Having limited user opinion means that the overarching value of the appropriate stoma bag has not been uncovered. Within a clinical practice of just one of the committee members who supports over 8,500 people with stomas and unsolicited and solicited feedback ensures that we understand the value of getting this right, offering choice and understand the varying and complex needs of this group. There is someone just trying to be ‘normal’ and live the best way they can at the end of this LSA and these are the people who will be impacted.	Thank you for your comment, the EAG are aware of the impact on quality of life.
115	Hollister Ltd	11/12	Executive Summary	The EAG commented on the paucity of evidence and as a result findings were highly speculative. To minimise the risk of this sort of situation arising in the future, it could be helpful if the Company RFIs were explicit as to the standard of evidence that would have been acceptable. From a company perspective a huge amount of work within very tight timelines was put into completing the RFI as completely and accurately as possible. ■	Thank you for comment. NICE has made a note of this for their lessons learnt process.

Scotland pricing					
116	BHTA	15, 141-143	7.4	Scotland DT prices are now aligned to England NHSBSA prices, this change was implemented in May 2023. The difference before this time was due to the fact the Stoma community agreement was not updated in 2020, in fact it was only updated in July 2024. Also, you mention other payments in England, this is also the case in Scotland	Thank you for the clarification. The text has been amended on relevant pages: Exec summary text added “In Scotland, ending sponsorship of stoma nurses in 2008 led to lower mean prescription item costs but also, anecdotally, a loss of nursing staff and skills, highlighting the complexity of pricing decisions. However, subsequent advice to the EAG was that prices in Scotland were aligned to those in England in May 2023.” P149: “From May 2023, pricing of stoma bags in the community in Scotland was aligned to match pricing listed by NHSBSA, ”. Also added to next paragraph P149: “Differences in which bags are promoted by companies and selected by patients will also lead to a difference in the mean price per bag between England and Scotland.”
117	Convatec	15	Exec Summary	In Scotland, ending sponsorship in 2008 led to lower bag prices: This is a flawed argument on the basis that Scotland DT prices are on parity with England DT. The NP contracted price may be lowered but as this represents such a low % of overall spend then is of little significance. The negotiated community agreement	Thank you for the clarification. Please see the response to comment 116.

				Drug Tariff prices. Thus, since that time in primary care all prices charges for colostomy bags have been the same in England, Wales, Scotland and Northern Ireland.	
120	Hollister Ltd	15	Executive Summary	There is statement that there are lower bag prices in Scotland. In community, Scotland prices are now fully aligned with the English Drug Tariff i.e. same price.	Thank you for this comment. Please see the response to comment 116.
121	Hollister Ltd	144	7.4	It may be worth revisiting the comparison with pricing in Scotland. In community Scottish prices are now fully aligned with the English Drug Tariff prices. In the acute setting, the vast majority of products are supplied free of charge to hospitals in England, actual sales will be very minimal whereas in Scotland there is no sampling and products should be purchased by hospitals.	Thank you for this comment. Please see the response to comment 116.
122	Coloplast	15	Executive Summary – key points for	‘In Scotland, ending sponsorship of stoma nurses in 2008 led to lower bag prices’ Coloplast don’t believe this statement is factually correct. Lower bag prices were negotiated/imposed by NHS Scotland when they stopped following Drug Tariff guidance. Therefore, on top of this bags saw no yearly price increases as applied to the English Drug Tariff - hence the price differential was due to two factors neither of which was sponsorship.	Thank you for this comment. Please see the response to comment 116.
123	Coloplast	143	7.4	‘as well as products from any manufacturer, subsequently benefiting people with a colostomy’	Thank you for highlighting this survey. This has been added to the report: “A survey conducted in 2023 by the Scottish Stoma Forum (an industry body) found a number of patients

				Evidence from Scottish Stoma Forum Specialist Nurse and Patient Survey 2023 suggests stoma care has deteriorated in Scotland SSF-Nurse-Patient-Survey-2023.pdf (b-cdn.net) ‘The Patient Survey results showed that, overall, most respondents reported some degree of satisfaction with the support and services they had received. However, some of the data and, particularly, many of the patient views demonstrate extremely concerning gaps in service and the resulting negative impacts on the lives of ostomates’ And nurse comments included: ‘I personally feel undervalued and most of the time left holding the service together. There is an overall shortage of staff everywhere, but experienced staff are getting thinner on the ground and see the colorectal service as struggling whilst other specialties are able to get extra staff, but we are not. Due to the reduction in staff over the last few years satellite clinics have been disbanded and therefore patients do not always have access to clinic within their own locality. This is something we hope to address in the near future’	reported dissatisfaction with the services they received in Scotland, although it is unknown how this compares to satisfaction rates in England.” (P145)

124	Coloplast	144	7.4	'the EAG noted that the price per bag was substantially lower in NHS Scotland Coloplast believe this statement is factually incorrect. Lower bag prices were negotiated/imposed by NHS Scotland when they stopped following Drug Tariff guidance. Therefore, on top of this bags saw no yearly price increases as applied to the English Drug Tariff - hence the price differential was due to two factors neither of which was sponsorship. Scotland DT prices are now aligned to England NHSBSA prices, this change was implemented in May 2023. The difference before this time was due to the fact the Scotland Stoma community agreement was not updated in 2020, it was only updated in July 2024.	Thank you for this comment. Please see the response to comment 116.
Structured expert elicitation					
125	Coloplast	201	Appendix D	<i>Linear Opinion Pooling Description</i> • When describing the aggregated distribution in Appendix D, the EAG states (page 201): • <i>The probability distributions are aggregated by the session leader which then effectively becomes the leader's judgement about the relative plausibility of different values, following consultation with the experts.</i>	Thank you for your comment. This wording has been amended to be clearer to: "The probability distributions are aggregated and used as an input into the decision model for the unknown parameter." The EAG used linear pooling in line with the MRC protocol. This is stated in Appendix D: "Then these will be pooled, assuming

				•While the methods used to generate an aggregate distribution are not explicitly reported, this statement does not reflect the description of linear opinion pooling presented in the MRC protocol (cited as the basis for the elicitation study). •Linear opinion pooling is the most frequent and (and preferred) aggregation approach adopted in healthcare decision-making, as it does not require experts to converge to a group distribution, allowing between-expert variability to be reflected in an overall distribution. •The aggregate distribution reflects the arithmetic average of the individual fitted distributions and does not necessarily reflect the session leader's judgement (presumably, the study lead). •Clarity should be added to appropriately describe the conduct and to frame the results.	that each expert contributed equally to the group overall distribution.”
126	Coloplast	208	Appendix D	<i>Fitting and Aggregation Methods</i> •No information is presented about the statistical analyses surrounding fitting and aggregation (page 208). The EAG does not describe which	Thank you for your comment. Amendments have been made to the Appendix to clarify the analysis conducted. “The statistical best fit distribution will be selected from Normal, Student t,

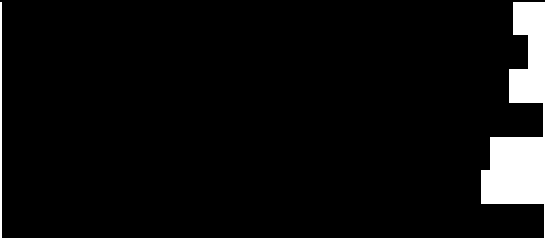
				methods were used to fit distributions to the experts' CDFs or how the best fitting distribution was assessed. •As such, it is not possible for the company to check these for factual accuracy.	Skew Normal, Gamma, Log Normal, Log Student t, and Beta distributions. Distributions were fitted for each expert individually, with the best fitting distribution determined by the smallest sum of squared errors, in accordance with the recommendations provided in the Sheffield Elicitation Framework (SHELF). Once the best fit distribution was identified for each expert, the fitted distributions were linearly pooled to produce the aggregated distribution."
127	Coloplast	202, 204, 92, 93, 118	Appendix D	<i>Direct Elicitation of Utility Decrements and Gains</i> • The EAG cites the Medical Research Council (MRC) protocol and SEE resources (STEER), developed by the Centre for Health Economics (CHE). The quantities of interest include health-related quality of life expressed as utility decrements and gains (page 202). • In Appendix D, the EAG reports (page 204): • <i>The choice of quantity considers the following three objectives: fitness for purpose; directly observable and homogeneity in the quantities elicited.</i> • Per the MRC protocol and	Thank you for your comment. The EAG has been clear about the limitations of the SEE for provision of information in relation to utilities already in the report. Given the complete absence of evidence in the literature the alternatives were all less robust than this option. In order to pilot the format of the exercise all experts participating were emailed with a sample of the planned question wording and questions to inform the exercise design. Their input was used to finalise the exercise. The EAG was clear about the difficulties in completing the survey in relation to disutilities experienced by some participants in Section 7.2.5: "Of the seven responses received, five supplied answers that suggested a potential misunderstanding of the questions related to disutilities (i.e.

				STEER recommendations, for a quantity to be a suitable target of SEE, it must be observable. Experts must be able to estimate the unknown quantity as a simple function of observed data. Complex parameters should be decomposed into related quantities that are simpler and observable to experts. • Health-related quality of life expressed as utility values are not directly observable to (or commonly encountered by) experts in clinical practice. The materials provided in STEER ('Structured Expert Elicitation for Healthcare Decision Making: A Practical Guide') state: • <i>It may not be feasible to elicit certain quantities and be confident that these represent experts' beliefs e.g. non-observable or complex quantities. For example, health state utility values are not encountered in day-to-day clinical practice and the long-term survival of patients</i>	submitted disutility estimates that lacked face validity, including inconsistency relative to their other responses) and were contacted to provide additional support and given the opportunity to revise their answers; three experts took this opportunity and two did not respond." The follow-up meeting was attended by 6 experts and was facilitated by a facilitator experienced in structured expert elicitation. All participants were given the chance to comment on each question. The slides used are now provided in Appendix K. The EAG would note that the level of detail already provided within the report exceeds that usually provided in NICE appraisals and therefore consider the allegation of procedural obstruction to be unwarranted. The rationale statements supplied by the two experts providing outlier values which were excluded are as follows: "There are degrees of pancaking, sometimes it causes leaks which would be distressing, sometimes it doesn't cause any further problem and is only a nuisance" "Pancaking may be very debilitating to patients as it may cause leakages, skin damage "

				<i>receiving a novel intervention may be very difficult for experts to predict.</i> • A pilot exercise was not conducted to ensure task comprehension and the suitability of the quantities of interest per the MRC protocol. Moreover, post-workshop feedback concerning the difficulty of the encoding task, question phrasing and observability of the quantities was not reported. • The EAG states (page 92 and 93): • <i>Of the seven responses received, five supplied answers that suggested a potential misunderstanding of the questions related to disutilities (i.e. submitted disutility estimates that lacked face validity, including inconsistency relative to their other responses) and were contacted to provide additional support and given the opportunity to revise their answers; three experts took this opportunity and two did not respond. In sum, the final sample size was five experts for questions relating to disutilities and seven experts for the other questions.</i>	

				<i>In addition to the steps planned within the protocol, a call was organised with the clinical expert (25th June 2024) to agree the estimates, given the discrepancy between some of the results. Changes were made to three outputs (the disutility for pancaking and proportion switching to a new type of bag for ballooning and pancaking); otherwise, the initial estimates were considered reasonable.</i> The cited sections indicate limited task comprehension. Little information is provided about the procedures employed in the follow-up meeting, including the level of interaction between experts and how those interactions were facilitated (if any), and questions, materials and data presented to the experts during re-elicitation. Thus, the company cannot assess the appropriateness of the methods used in the follow-up, including, for instance, which measures were implemented to manage bias or whether task	

				comprehension had improved sufficiently that the experts possessed the necessary normative expertise to describe their uncertainty surrounding the quantities of interest. As such, Coloplast is procedurally obstructed from engaging in meaningful critique of evidence and security of its factual accuracy. • Exclusion of two experts displaying outlier responses (page 118) also reduced the sample size below that recommended by the MRC protocol (≥ 5). The reason for exclusion – to avoid double-counting the impact of leakage – is valid. However, the rationale statements referred to for exclusion are not reported, preventing the company from assessing the appropriateness of exclusion.	
Sponsorship					

128	Convatec	19	1	Report states that there are several influencing factors that affect the judgement of potentially innovative nature of bags features, but neglect to include the sponsorship status of the CNS Stoma Nurse, which as seen from market distortion is a hugely influencing factor alongside features.	Thank you for this comment. The EAG have edited the text: to acknowledge that stakeholder comments to the EAG also noted that sponsorship status of the CNS in stoma care may also affect judgements.
129	Convatec	26	3	Complications: Agree that complications are high in this patient population & there is an unmet need to improve bag options for patients. What is not called out is how bag options made available to patients is heavily skewed by the sponsorship model.	Thank you for this comment. The EAG have added comments to the section on 'choice of bag': "Comment received by the EAG also suggested that the choice of bag may also be heavily influenced by the sponsorship status of the CNS in stoma care."
130	Convatec	26	3	Choice of Bag: Again, no mention of how the sponsorship model limits the choice of bag made available to the patient population.	Thank you for this comment. Please see the response to comment 129.
131	Hollister Ltd	29	3	Sponsorship Arrangements: Commercial sponsorship ensures that stoma departments are resourced appropriately to provide optimal patient care. The level of additional support services that sponsoring companies and DACs provide ensures high quality care is provided.	Thank you for this comment. The EAG feel the paragraph already makes clear the range of services sponsorship provides.
132	Hollister Ltd	29	3		
133	Coloplast	15	Executive Summary – key points for decision makers	'which might affect overall value for NHS patients and taxpayers' Additional services provided by companies are a fundamental bedrock of	Thank you for this comment. The EAG feel the paragraph makes this point as written.

				stoma care in the UK. NHS has handed a large burden of care over to companies over the last 30 years. Any changes to product availability/pricing will have significant taxpayer implications and therefore patient impact as companies, NHS, taxpayer and patients are in a symbiotic relationship.	
134	Coloplast	142	7.4	'Several respondents (28%) highlighted areas where the relationship works well, but a greater number (35%) highlighted concern' We know that DHSC and NHSE are looking into sponsorship as it is the NHS that issues the tenders, and industry chooses to respond, and NHS protocols are followed.	Thank you for this comment. The paragraph relates to a survey rather than NHS policy.
135	Coloplast	144	7.5	'Finally, the analysis did not consider the impact of sponsorship and additional services provided by manufacturers and DACs. It was unclear whether the net value of such arrangements represents a net benefit to NHS patients in England and value for money for the taxpayer. This was beyond the scope of this assessment.' The LSA report sponsorship and services are not part of the evaluation, yet the scoping workshop and a large following section of the report go into the details of the importance of these services. As mentioned in comment 33, an increase to the cost effectiveness	Thank you for this comment. Please see the response to comment 116 on sponsorship.

				threshold should have been applied to account for the value of these services.	
136	Association of Stoma Nurses	15	Economic evidence	By excluding or not considering the implications of the financial benefits of sponsorship and additional services to the NHS, cost savings will not have been accurately costed Without sponsorship – costs to the NHS will dramatically increase – these would include but not limited to not only the financial contributions to stoma care departments, training, educational materials for patients, free samples to hospitals, We contest your statement In Scotland, <i>ending sponsorship of stoma nurses in 2008 led to lower bag prices</i> - we request the EAG to quantify this statement – as all bags in scotland are now the same price in drug tariff as England	Thank you for this comment. The EAG feel we have outlined the limitations of our analysis, including consideration of sponsorship.
137	Association of Stoma Nurses	144	7.4	Discussion about sponsorship within this EAG is deemed to be out of scope for this document this LAS is about 1pc closed bags However, we would wish to highlight the significant number of company employed stoma care nurses- who the majority work in partnership with NHS SCN departments to provide ongoing specialists support and care to patients. It was clearly demonstrated during covid – where SCN's were relocated, high levels of sickness occurred that the company employed SCN's continued to be instrumental in providing ongoing care to	Thank you for your comment. As stated, detailed analysis of the market around sponsorship, and whether it is a net benefit to NHS patients is beyond the scope of this analysis.

				patients with a stoma within primary care. All company nurses are bound by the NMC code of conduct, they are professionally and personally very aware of their responsibilities, accountable actions and take decision making during their specialist assessment to a degree of rationalisation and justification for product choices	
138	Convatec	109	7.2.8.5	Relevant to the reference made to free samples, provided by the manufacturers; how was the provision of free samples accounted for in the cost analysis and the suggested eJP?	Thank you for your comment. The eJP states the maximum reasonable price to pay for a bag. A bag provided for free will, by definition, be below this maximum price. It is for companies to agree commercial arrangements that take into account the proportion of bags used by people with a colostomy that are provided for free if they so desire. No edit made to report.
139	Convatec	147	7.4	Given the uncalculated additional value and investment offered by Industry, the validity of the economically justifiable price is brought into question within the EAG findings.	Thank you for this comment. The eJP focuses on the benefits in terms of the performance of the bag at resolving complications, not sponsorship arrangements. No edit made to document.
140	Coloplast	141	7.4	'Manufacturers also reported providing training, education, and patient advice to assist in product selection' Firstly, manufactures can be different entities from DACs. In relation to the above sentence, we ask NICE /EAG to be clearer in their understanding: many manufacturers provide training, education, and patient advice on more than product selection. Each	Thank you for this comment. The EAG feel the full sentence in the report provides a comprehensive summary of the services offered.

				manufacture does this at different level of expertise.	
141	Convatec	141	7.4	As the table is redacted, we are unable to validate the correlation between market share and sponsorship, however in the avoidance of doubt, please note that Convatec do not offer Sponsorship across England, Wales or Scotland. Convatec wholeheartedly support freedom of patient choice as outlined within NHS Constitution.	Thank you for your comment. The EAG have removed the redaction in relation to your company as it was not marked as confidential.
General comments					
142	Hollister Ltd		Executive Summary	General Comment: Clearly a very detailed and thorough piece of work undertaken by the EAG.	Thank you for your comment.
143	Hollister Ltd	25	3	'The lost ostomate.' Yes, undoubtedly an issue though the scale as noted in the report is of course difficult to assess. Hopefully as the general subject of ostomies gains more profile (social media influencers, a number of recent news articles etc) then the number of lost ostomates will reduce.	Thank you for your comment.
144	Hollister Ltd	27	3	Role of the CNS – totally agree, absolutely crucial to ensuring the best outcomes for users. Whatever market changes may happen in the future, it is vital that nursing resource is maintained/increased.	Thank you for your comment.
145	Hollister Ltd	82	7.2.3	As noted, typically bag features/innovations will address multiple complications, not a single complication.	Thank you for your comment.
146	BHTA		General point	We are surprised that there appears to be no mention of Value Based Procurement principles in the EAG report as this is a	Thank you for your comment. The purpose of the regression analysis was to determine whether there was a link

				major drive from DHSC and NHSE. It appears the report does not mention the underlying value of the products in supporting patients to lead a good quality of life.	between pricing and features intended to deliver improved outcomes. This was already noted in Section 7.2.1. We have amended the executive summary to make this link clearer. “The EAG attempted to explore whether the principles of Value Based Procurement were being followed within the prices paid for bags. Exploratory analysis of bag price vs. the presence of features intended to deliver additional benefit showed little association between current pricing and potentially innovative features included in the NICE scope.”

Section B: Comments on the User Preference Report

Comment no	Organisation	Page no	Section no.	Comment	Response from NICE
1	Convatec	7	2	Whilst encouraging that we had a consistent level of engagement across all workshops from expert Clinicians and users, the representation in numbers is low to reach consensus conclusion about prioritisation of features on behalf of such a diverse user population.	Thank you for your comment. NICE acknowledged that a limitation of the user preference assessment is volunteer bias. Users volunteered to take part in the assessment, and so the sample of CNS in stoma care and people with lived experience may not be fully representative of the wider population. NICE publicly advertises its specialist committee member roles and encouraged companies, professional organisations and patient organisations to nominate or share this opportunity. In addition to this stakeholder comment period, NICE holds public consultation on the draft

					recommendations and associated documents. So, other healthcare professionals and users can provide additional comments. The user preference assessment is not intended to supersede the outcome from the clinical and economical evaluation. It is intended to compliment it and provide a transparent insight into the preferences identified by the users involved in the assessment.
2	B Braun Medical	General		One of the “users” consulted for the UPR was a patient advocacy group, rather than an individual with lived experience. While it is understandable that they could comment, their views may not be representative of all ostomates and therefore they should not be presented as a “user”. We are also concerned that 8 users is not enough to accurately represent the colostomate population.	Thank you for your comment. Please see NICE’s response to comment 1. NICE have amended the report to ensure that is clear that the user has knowledge of using 1-piece closed bags, rather than lived experience themselves.
3	B Braun Medical	15	Table 3	Some of the measures seem difficult to monitor or prove and will very dependent on many patient variables and some will be very subjective – as highlighted by committee when trying to decide what is acceptable.	Thank you for your comment. As highlighted by in the report for some outcomes, users noted that acceptability may vary between users and other patient factors could impact outcomes.
4	B Braun Medical	15	Table 3	Leakage is presented as a criterion alongside bag fit and bag size, despite these factors being intrinsically linked. They should not be presented as separate issues.	Thank you for your comment. This work is based on consensus opinion of the group of users consulted. Users did acknowledge that there is overlap in the criteria but agreed to these criteria based on what was important to them.

5	B Braun Medical	15	Table 3	Time taken to change a bag is highly user-dependent, for example patients with PSCs or dexterity issues will naturally take longer to change their bags.	Thank you for your comment. NICE have amended the report to highlight that the time agreed by users may vary depending on other factors.
6	CliniMed			The matrix is very complicated to understand and should have been issued with some instructions or not shared. This approach negatively affects small to medium sized companies, favouring larger organisations.	Thank you for your comment. NICE is committed to ensuring our outputs are accessible and clear. We will continue to review and update our outputs during the late-stage assessment pilot process.
7	CliniMed	30 / 31	Appendix D	Can a group of 8 patients cover all levels of diversity (age, sex, racial and ethnic demographic characteristics)? Would a larger group not be more reliable to prevent any bias? Are 8 users really speaking 200,000 patients. There is limited inclusion of Quality-of-Life measures, as some patients will live a lifetime with a stoma.	Thank you for your comment. Please see NICE's response to comment 1.
8	Hollister Ltd			General Comment: Our findings on user preferences very aligned with the findings in this report.	Thank you for your comment.
9	Hollister Ltd	9/10	3.1	Interesting to see all 16 criteria considered important although ranked, indicating the complexity of developing ostomy products to meet user needs.	Thank you for your comment.
10	Hollister Ltd	18	4	Report discusses many factors that can affect bag choice. This emphasizes the need to have as wide a range as possible of products available to ostomates. (This point is reinforced in section 5, page 21.)	Thank you for your comment.
11	Hollister Ltd	21	5	Volunteer bias as a potential issue is noted in the report. Users may only have their own	Thank you for your comment. NICE acknowledge that volunteer bias

				experience to draw on which may not necessarily be fully reflective of the wider ostomate population.	may be a limitation. However, a number of users are actively engaged within the stoma community, including voluntary work supporting other people with a stoma, and so have a knowledge base wider than their own.
12	Coloplast	1	Title page	UP report finished 7 th August – why have NICE only shared this with us 12 th August?	Thank you for your comment. NICE shared the documentation with stakeholders on the agreed date. As there are a number of documents prepared for stakeholder consultation, some are finalised earlier than others.
13	Coloplast	3	1	Based on the title of this HTE10045 Colostomy bags - it would be suggested that additional charities should be represented within your user preference assessment, for instance Ileostomy and Pouch Association, Crohn's & Colitis, Bowel Cancer UK and others also work in this area of healthcare and could have brought additional perspective.	Thank you for your comment. Patient organisations were invited as stakeholders as part of NICE's public involvement programme. Recruitment of specialist committee members for people with lived experience (or knowledge of lived experience) was publicly advertised and so anyone with relevant experience was able to apply. A full list of patient and carer organisations contacted for the assessment can be found in the final scope. The Ileostomy and Internal Pouch Association was not contacted as the assessment focuses on people with a colostomy only.
14	Coloplast	3	1	'Colostomy UK survey with 3742 responses (69% of responders having a colostomy)' We are concerned about the reliance on findings from this survey	Thank you for your comment. Colostomy UK kindly provided interim results of their research as part of their patient organisation submission. The patient organisation

				because we understand this report will not be published until later in 2024, so we are unable to verify the information cited. For instance, we do not have visibility of the age range of survey respondents. How did these come to their surgery? Are these 69% people with a colostomy only? Of these colostomists – there is a high probability many of the people with a colostomy may be wearing a drainable bag. Based on your literature exclusion criteria – this survey potentially would be excluded.	submission will be published alongside the report. In terms of the user preference report, this information was used as contextual information to aid the understanding of readers who may be non-experts in the area of stoma care.
15	Coloplast	4	1	‘Colostomy UK survey found that 31% of people with a stoma reported that they were not actively involved in choosing their stoma bag.’ what does ‘actively involved’ mean? Again, in view of the context of this survey not being publicly available this cannot be understood. It would be considered users immediately post-surgery (especially if an emergency) would not have any insight or understanding at this point of the differences in the features of a bag in relation to their individual needs.	Thank you for your comment. Colostomy UK have confirmed that ‘actively involved’ means whether they were given a choice in the product they were initially prescribed. The report has been amended to ensure this is clear.
16	Coloplast	4, 6	1, 2	<i>Criteria Identification</i> The authors asked users to identify their perceived most important	Colostomy UK kindly provided interim results of their research as part of their patient organisation submission which included the 31% figure. This survey was sent to a

				factors when choosing a stoma bag (page 6) despite approximately one-third of people (31%) reportedly not being actively involved in choosing their stoma bag (page 4). • <i>Due to the large number of products available, there is a wide range of options for clinical nurse specialists (CNS) in stoma care and adults with a colostomy to choose from. Decisions can be shared and are made due to clinical need and personal preference. But the Colostomy UK survey found that 31% of people with a stoma reported that they were not actively involved in choosing their stoma bag.</i> • <i>Users were asked to identify key factors that are important when choosing a 1-piece closed bag. A list of criteria and definitions were identified and agreed on during an online workshop with users.</i> • <i>It is plausible that the users omitted otherwise important criteria they were unaware were available, violating the completeness principle noted in the ISPOR task force report (cited by NICE).</i> • An evidence brief outlining types of stoma bags and/or validation of the features and outcomes highlighted in the NICE scope by the stakeholders may have mitigated potential availability bias during selection. • Clarity should be added to the report to ensure that it is accurately	wide UK audience with 3742 responses and does not mean that 31% of the users recruited for this user preference work have no involvement in the choice of their stoma bag. NICE reiterates its guideline on shared decision-making which says that people have the right to make informed decisions about their care and should understand the choices available to them. NICE encourages this as best practice but acknowledges that this may not be reflective of current care. NICE's methods for collecting user preferences are informed, where appropriate, by MCDA best practices. Please see the LSA interim methods and process document for more information. The outcome of the user preference assessment is intended to reflect the views of the sample of users who took part and what is important to them. We are unable to ascertain what our participants do not know. However, all those who took part had access to the project scope and most were involved in the scoping process. In addition, in the first workshop the list of features under evaluation was presented to the group. This means they were all aware of the features under evaluation in this LSA.

				reflecting weakness in the study robustness due to conduct.	In addition to the recruitment of engaged people with a colostomy, NICE also recruited a range of specialist nurses in stoma care who are knowledgeable about of the range of stoma bags available.
17	Coloplast	7	2	The report is based on 7 people who have a stoma (and at times only 6 were available / at meetings). Knowing the heterogeneity of the population mentioned throughout the LSA, Coloplast don't believe this is a significant number of people for decision making with the large potential impacts to people with a stoma.	Thank you for your comment. Please see NICE's response to comment 1.
18	Coloplast	8	3	'Bag that can be used with minimal amount of supporting products' In principle, this is a good idea, and we understand why that would be favourable – but is this a realistic description, and would that leave too much to interpretation by the participant?	Thank you for your comment. This description was decided by consensus opinion of users. They did not feel a definitive description was appropriate, given the variation in needs across the colostomy population.
19	Coloplast	8	3	'Durability of baseplate definition The definition for "durability of the baseplate" can easily be misinterpreted by the participant as it is unclear whether the bag change is due to the bag filling, or due to leakage/seepage.	Thank you for your comment. This criterion name was decided by consensus opinion of users involved in the assessment. They have also provided an associated description which states that baseplate durability is 'the bag to be changed as required by an individual's poo rather than baseplate failure'.
20	Coloplast	9	3	'Easy to attach the baseplate to the skin' Coloplast believes this should have been described as good useability/ ease of use.	Thank you for your comment. This criterion name was decided by

					consensus opinion of users involved in the assessment.
21	Coloplast	9	3	'Baseplates available in pre-cut or cut to fit options that come in a variety of shapes (such as round, oval, square, flower, diamond) and sizes.' This is a problem, it's not about a shape alone, it's about body profile, which is fit. This should be higher in the list as it relates to leakage and seepage	Thank you for your comment. This criterion was decided by users who said they would want availability of different baseplate shapes and sizes. This was then ranked by users and deemed to be less important than some of the other factors considered. NICE and users are aware that there is some overlap between criteria considered important to them. Users involved in the assessment rated preventing leakage and seepage as the most important criteria to them, it cannot be changed retrospectively.
22	Coloplast	10	3.2	The stoma nurse weighting should be important when it comes to leakage as they will see a number of patients, whereas the patient only knows themselves and their leakage generally	Thank you for your comment.
22	Coloplast	15	3.2	'Unable to reach consensus on acceptable levels of leakage, seepage or use of supporting products' This is not necessarily surprising as a person either leaks or seeps, or they don't. Ideally the only acceptable level would be none – but this isn't the reality.	Thank you for your comment.
23	Coloplast	15	3.2	'Does the baseplate maintain integrity during storage until it's expiry date?' This is about packaging and storage – not the baseplate?	Thank you for your comment. This is the opinion based on the experience of the users involved in the assessment, and further information is provided on page 11 of the user preference report.

24	Coloplast	15	3.2	Does the baseplate cause skin tears or damage when removed? This could be user error / lack of training also when removing. Skin should be held etc	Thank you for your comment. This is the opinion based on the experience of the users involved in the assessment.
25	Coloplast	15	3.2	Does the baseplate fit around the stoma taking into account body shape? The exact fit is made by cutting to size, this is manual or machine. If this is about sticking to the body profile, then this is about level of convexity / concave or flat	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively.
26	Coloplast	16	3.2	'No level of a bag losing the ability to hold poo, coming away from the baseplate, disintegrating or puncturing was considered acceptable.' Agreed, but after what length of wear 'losing ability to hold poo' is different from fraying of fabric?	Thank you for your comment. As this was the opinion of the users involved in the assessment, additional detail to the performance rules cannot be added retrospectively.
27	Coloplast	16	3.2	Is additional adhesive needed to apply the baseplate? It would not be expected that an additional adhesive is required – with the current innovative advancements of quality baseplates additional adhesives are not recommended or used. This can be seen within the prescribing data	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively. NICE acknowledges some products are now considered redundant (such as adhesive sprays) due to advances in the bag technology as stated on page 19 of the report.
28	Coloplast	16	3.2	Time to secure adherence of the baseplate on application (less than 3 minutes considered acceptable) Why three minutes. What about if a person has dexterity issues, or have steps to take, need to cut the bag, put paste on etc?	Thank you for your comment. Please see the response to comment 5.

29	Coloplast	17	3.2	Easy to remove the film or covering from the baseplate Would ease of use not have been a criteria – e.g. coloured tabs to show what to fold or remove? Especially in terms of disability – visual and or dexterity.	Thank you for your comment. As this was the opinion of the users involved in the assessment, the criteria definitions cannot be changed retrospectively.
30	Coloplast	19, 20	5	<i>Sample Size and Population Heterogeneity</i> Overall, 18 people were included in the study, seven of which were people with lived experiences using stoma bags and one charity worker (eight in total). We appreciate that someone who works for a charity and actively supported people with a stoma could be judged to have relevant insights. But if the report infers that all eight were people with a stoma (which is stipulated in the methods on page 5 and implied by the title on page 30 '<i>People with lived experience of using 1-piece closed bags</i>') then can NICE clarify these numbers in all relevant sections of the report. We would question the representation and validity of the small sample size in respect of the size of the user population. With such a small user group where only seven individuals with lived experience are present, these can be influenced strongly by dominant individuals – it would be suggested separate workshops are of benefit to eliminate group influence	Thank you for your comment. We have amended the report to ensure that is clear that the user has knowledge of using 1-piece closed bags, rather than lived experience themselves. Please see NICE's response to comment 1 on the sample size. Group discussions and workshops are a standard part of NICE's guidance development process. As part of the user preference assessment, users were also contacted by email after the workshops and given the chance to follow up with additional comments if they wanted to add further detail or felt uncomfortable discussing in a group setting. Where this took place, the opinion of users was highlighted in the report. NICE facilitated the workshops to allow all users to contribute and comment. This including giving time for people to state if they did not agree with the opinion. Both people with lived experience and clinicians

			and gain a consensus. NICE acknowledges the heterogeneity observed in users' needs unrelated to preference affecting their choice of stoma bag: <i>Throughout the assessment, users highlighted the need for bags to be tested in various groups of people with different skin conditions, lifestyle, mobility levels and people with underlying health conditions to ensure a person can be confident in the security and durability of their bag (page 19).</i> <i>Throughout the assessment, users reiterated the importance of all identified criteria when choosing which 1-piece closed bag to use, as well as other factors unrelated to preference, such person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output, manual dexterity, visual impairment, mobility levels or other health conditions (page 20).</i> Thus, given the heterogeneity noted by the participants and the small sample size, the representativeness of the findings may be limited beyond that due to volunteer bias acknowledged by NICE. The current report does not accurately acknowledge the limitations and should be edited. It should also be noted that all of the	were in agreement with the decisions made. All users were able to follow up with email if they had any concerns. Any NICE decisions made by the committee are made by consensus opinion by standing and specialist committee members. NICE routinely utilises expert insight (clinical and people with lived experience) as part of its decision-making process. The user preference assessment is a formal way to collate valuable expert insight into the technologies being evaluated.

				clinical nurse specialists and all but one of the lay members who contributed to the user preference assessment are also specialist committee members, and therefore decision-makers, for this evaluation. Please can NICE clarify how this will be taken into account during committee decision-making, so that the evidence is judged fairly and independently?	
31	Coloplast	18	4	You have highlighted in this report that <i>'Some areas have local formularies to provide guidance to prescribers on the supporting products (in addition to quantity but not type of stoma bag) that can be used in their area. The aim of these formularies is to guide where there are cheaper alternatives' ...these are not intended to restrict patient access to products if they are needed'</i> However, there appears to be a significant variation in formularies depending on whether a SCN has been involved in the development of the formulary – some appear to be price driven, others are based on a review. As you state these are not intended to restrict access, but they do impact on choice	Thank you for your comment. NICE have amended the report to clarify that formularies may vary depending on local area.
32	Coloplast	20	4	'The economic analysis of the external assessment report also found that bags preventing peristomal skin complications and leakage may have the biggest	Thank you for your comment, this is a summary of an academic opinion stated in the external assessment report. The uncertainty with 'may' is

				improvement to quality of life and may be worth paying a higher price for'. Why only 'may' if this is the most important criteria and also the one, we know costs the NHS	due to the uncertainty in the evidence to prove benefit.
32	Coloplast	20	4	'Throughout the assessment, users reiterated the importance of all identified criteria when choosing which 1-piece closed bag to use, as well as other factors unrelated to preference, such person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output, manual dexterity, visual impairment, mobility levels or other health conditions.' This is one of the reasons Coloplast believes that conclusion made by this LSA are not fit for purpose, and not meaningful for decision makers.	Thank you for your comment. NICE's committee will consider all information provided in the assessment report and user preference report, in addition to expert opinion when making their recommendations.
33	Coloplast	21	4	'The wide range of variability between people with a colostomy is reflected by the large number of products available for prescription in Part XI of the Drug Tariff and highlights the importance of individual specialist SCN reviews and maintaining a wide range of product choice.' Coloplast agrees to the statement and would like this clearly reported in the executive summary of the LSA.	Thank you for your comment. The assessment report (containing the executive summary) is based on an independent review of the evidence by an external assessment group.
34	Coloplast	21	4	You have excluded CNS' in stoma care that are employed directed by companies – However, as the majority of hospitals in England (we believe to be over 75%) have a	NICE have followed its policy on declaring and managing interests for NICE advisory committees for recruitment of specialist committee members and reviewing conflicts of

				formal sponsorship agreement or non-formal agreement in place with stoma appliance suppliers or manufacturers. Many of these specialist nurses will therefore be the at the forefront of providing the essential care to patients for the NHS, running the NHS stoma care services within the acute and primary care settings This user preference work has been undertaken as a consensus opinion and therefore all CNS in stoma care should be considered for their opinion regardless of their sponsorship arrangements. You must acknowledge that the NMC code of conduct that each nurse professionally adheres to is respected.	interest. Clinical nurse specialists in stoma care were not recruited to the specialist committee member role if they are directly funded by a manufacturer included in the evaluation. NICE acknowledge the majority of hospitals in England have some sponsorship arrangement (reported as 84% by the StoMAP report), and so have included clinical nurse specialists who work at hospitals with a sponsorship agreement. NICE have tried to seek as much independency as possible whilst also ensuring it had valuable clinical insight.
35	Coloplast	30	Appendix D	'People with lived experience of using 1-piece closed bags' EAG should clearly identify those who did not have a colostomy and those who have 'experience' through interacting with patients with colostomy i.e. charity workers, as this could have impacted results.	Thank you for your comment. Please see the response to comment 5.
36	Association of Stoma Care Nurses UK	3	intro	2 piece products are an imperative option for people living with a colostomy this has been excluded here with limited rationale. You acknowledge the need for 2pc closed pouches in your EAG	Thank you for your comment. Two-piece closed bags were outside of the scope of this assessment. Clinical evidence for them was considered in the external assessment report due to the limited of evidence on one-piece closed bags.

37	Association of Stoma Care Nurses UK	3	intro	The Colostomy UK survey has not been published and is not in the public domain to comment on You have highlighted from the colostomy UK survey leakage, pancaking, skin irritation, ballooning and odour are impacting stoma management – all these issues require assessment and options of a colostomy pouch to contribute to solving these issues – highlighting the need for unique features of pouches to meet these individual needs. the opportunity for a specialist assessment by SCN and choice of another suitable appliance would significantly improve these issues As highlighted above in the EAG of the respondents only 69% had a colostomy – due to the lack of transparency of this survey – we do not know how many were wearing a 1 pc drainable bag or a2pc You have referenced the significant variation in provision of support and follow up - It would be suggested a review of the areas where regular follow up was provided, these issues may be reduced	Thank you for your comment. Colostomy UK kindly provided interim results of their research as part of their patient organisation submission. As their analysis is ongoing we currently do not have more detailed breakdowns available. The patient organisation submission will be published alongside the report. In terms of the user preference report, this information was used as contextual information to aid the understanding of readers who may be non-experts in the area of stoma care. In regard to follow up, this was information presented in a published report. Reviewing the structure of the service provision is outside of the scope of this report
38	Association of Stoma Care Nurses UK	4	intro	Study by Nafees et al 2015 – has not been included in your reference list- the context of the conclusion is potentially misleading in your user preference as this study was focused on discrete choice and willingness to pay The conclusion states “improving comfort and elastic flexibility and risk of skin problems were the most important aspect of appliances”	Thank you for your comment. The Nafees et al. (2015) study has been referenced in the introduction of the report to provide context of previous studies focussing on preferences only. NICE acknowledges that the methods used in this study are different from NICE’s user preference assessment.

39	Association of Stoma Care Nurses UK	4	intro	You reference colostomy UK survey stating 31% reported not actively involved in choosing their stoma bag - the paper has not been published yet so we would wish to review the data before making comment on this	Thank you for your comment. Please see NICE's response to comment 37.
40	Association of Stoma Care Nurses UK	5	method	there are limited users identified (7or 8) - this is just 0.008% population, therefore not statistically significant so is NOT representative for a consensus One of the users we believe representing the voluntary association is not a user by lived experience – so reduces the numbers to 6 at stage 1 & 4	Thank you for your comment. Please see NICE's response to comment 1.
41	Association of Stoma Care Nurses UK	5	method	Although you state CNS(n=10) in the user engagement group – in stage 4 there were only 7 CNS present This is not representative of the 600+ reported SCN in UK. 10 SCN equates to only 1.5% of the estimated population of SCN is UK, this is not statistically significant – so the process is essentially flawed There appears to be disparity in those chosen as experts V panel CNS's - from the conflict of interest declaration form. There are now changes in job roles we note in the declarations of COI and indeed a reduction in CNS in stoma care From the list of panel experts we would wish to see a greater number of practising SCN 's who have regular exposure to clinical practice . In addition some of these “perceived experts” have less than 5 years of experience	Thank you for your comment. Please see NICE's response to comment 1. The Association of Stoma Care Nurses were invited to nominate potential clinical experts (who were not employed directly by a stoma bag manufacturer) to take part in this process. The specialist committee role was also publicly advertised and companies were asked to nominate non-conflicted experts to apply for this role. The clinical specialist committee members have or have had experience as working as a clinical nurse specialist in stoma care with ongoing knowledge in the area.

				We would welcome further contact with our membership to invite a greater representation in further studies or opinion/consensus	
42	Association of Stoma Care Nurses UK	6	Stage 1	with such a limited user group this would benefit by having a 2nd group to compare and contrast the criteria so not biased as potential to be influenced by a dominant individual within a group The analysis is focused on the user feedback and unbalanced with the CNS responses	Thank you for your comment. Please see NICE's response to comment 1.
43	Association of Stoma Care Nurses UK	7	Ranking criteria	The fact the top 6 features were aligned between the user group and CNS demonstrates the importance of these criteria and reflects the key features of appliances to meet these needs is a requirement of a pouch manufacture. All of the features do have a strong physical element to them, psychological factors are often overlooked when asked by users about key features,	Thank you for your comment. The focus of the user preference assessment was the features of technologies. Psychological factors were linked to some features such as bag appearance. Psychological impact is also considered as part of the external assessment report.
44	Association of Stoma Care Nurses UK	11	Criterion 1	The literature states the negative impact of leakage and QOL - so surely there would not be an acceptable level – as is stated in the last sentence of this paragraph. It is also noted within the literature that often patients do not perceive themselves to have a problem and live with PSC until they visit CNS who re-assesses skin and suggests alternative product that alleviates PSC.	Thank you for your comment. As you have mentioned, users said that no leaks would be ideal but, for some people, this may not be possible and they may accept a certain amount of leakage as their normal. Users said that no level of worsening to the peristomal skin was considered acceptable and all baseplates should maintain or improve skin integrity. But, it is acknowledged that not all people with a stoma will seek help for problems associated with their stoma bag.

45	Association of Stoma Care Nurses UK	11	Criterion 2	Users identified baseplate lifting would lead to leakage/ seepage. From a SCN specialist assessment this most likely would be due to a poor fit/inappropriate product, hence why a specialist assessment is required to review the fit of an appliance	Thank you for your comment.
46	Association of Stoma Care Nurses UK	12	Criterion 4	It is inferred that baseplate failure has occurred However, there may be a possibility that the individual did not have the correct baseplate for their body profile or they have not applied / positioned it correctly But it is also the size of the stoma and length of spout that will dictate the fit of the baseplate in additiona to flexibility against the body profil	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively.
47	Association of Stoma Care Nurses UK	12	Criterion 5	Collectively as a group of 6 specialist SCN's – we have never come across the bag contents or certain undigested food types puncturing holes in the bag lining, Equally although we accept some issues with product manufacturing occur, it is very rare for the bag to become "detached" from the baseplate in a 1 pc pouch.	Thank you for your comment. As this was the opinion of the users involved in the assessment, and it was based on their experiences, it cannot be changed retrospectively.
48	Association of Stoma Care Nurses UK	13	Criterion 7	It very much depends on the complexity of the stoma to how long it can take to change the pouch, as well as how long the person has had their stoma.	Thank you for your comment. Please see the response to comment 5.
49	Association of Stoma Care Nurses UK	14	Criterion 9	The bag will always remain intact on removal, its the baseplate that may be affected and leave residue on the skin	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively.
50	Association of Stoma Care Nurses UK	15	3.2	Skin tears or damage – could be down to the individuals technique	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively.

51	Association of Stoma Care Nurses UK	16	3.2	It would not be expected that an additional adhesive is required – the newer developments in adhesives and baseplates has led to adhesives not being used – this can be seen within the prescribing data	Thank you for your comment. As this was the opinion of the users involved in the assessment, it cannot be changed retrospectively. NICE acknowledges some ‘products are now considered redundant (such as adhesive sprays) due to advances in the bag technology’ as stated on page 19 of the report.
52	Association of Stoma Care Nurses UK	18/19	4. Additional considerations	You identify and we concur that bag choice is driven by clinical need for features agree that bag technology advances have impacted on some supporting products now being redundant, however you have not considered wear time at all in any analysis and yet a lot of the gathering evidence talks about increase in PSCs will reduce wear time and increase costs	Thank you for your comment. The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. Wear time was not a consideration raised by users in this assessment.
53	Association of Stoma Care Nurses UK	19	conclusion	CNS=10 and users= 8 On reviewing each stage of your study – not all users were present in each stage. Such numbers are so low – not representative of the population of CNS or users	Thank you for your comment. Please see NICE’s response to comment 1.
54	Association of Stoma Care Nurses UK	20	conclusion	This fundamental statement to all of this review is: as this EAG states that a person’s confidence in creating and maintaining a leak free seal when using their bag is key to successful management and maintaining quality of life. <i>In conjunction with the economic analysis of the external assessment report also found that bags preventing peristomal skin complications and leakage may have the biggest improvement to quality of life and may be worth paying a higher price for -</i>	Thank you for your comment.

				We agree it is a vital consideration to ensure we have research to demonstrate this imperative outcome	
55	Association of Stoma Care Nurses UK	21	Conclusion	We would agree with the statement in your conclusion <i>“this user preference work is done on consensus opinion and CNS in stoma care are knowledgeable about a range of products, the impacts of sponsorship should be minimal.”</i> As you have identified that this is the case it is extremely disappointing for ASCN UK not to have been given full eyes on this document and NOT a redacted version- regardless of where/who we work for and how we are paid, we do ASCN as volunteers, there is NO gain for us and this is the hat we wear. Any CNS has a professional responsibility to abide to their NMC code of conduct to offer rationale justification and choice	Thank you for your comment. None of the user preference report was redacted and so all the information was made available. In relation to the external assessment report and in line with NICE’s Health Technology evaluations manual, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement.
56	Association of Stoma Care Nurses UK	22	Conclusion	You acknowledge the limitation of the user group - but from your COI declaration it is unknown what contact and engagement the users would have in the colostomy community - there is a high probability they are influenced by their own experiences	Thank you for your comment. Users volunteered to take part in the assessment and NICE has acknowledged this as a potential limitation in its report. NICE reviews users experience based on relevance to the assessment when they are recruited. The conflict of interest declaration form is a standard format for NICE’s HealthTech guidance topics, any additional personal information about the users are not formally shared.

Section C: Comments on the economic model

Comment No	Organisation	Issue	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
1	Convatec		EJP does not account for Industry investment in support to patients, and NHS Institutions	A full audit is conducted of level of investment to include sponsorship, free samples offered to hospitals, education and clinical and counselling support to patients.	Should the EJP include these additional value support features alongside the prioritised bag features, the risk of complications would be lowered (towards 100% avoidance of complications)	Thank you for this comment. The eJP focuses on the benefits in terms of the performance of the bag at resolving complications, not sponsorship arrangements. No edit made to document
2	B Braun Medical	7.5	The EAG states that a ■ relative reduction in ballooning events was observed in Voergaard (2007) but does not state what the observed relative reduction was in any of the other complications.	Clarify what the highest observed relative reduction was in the literature for the other complications.	Manufacturers will now have to justify their prices based on the expected reduction in complications from their products. Transparency in the reduction in all complications would allow manufacturers to better understand how to position (and justify) their pricing relative to expected reductions in complications.	Thank you for your comment. The following text has been added: "As noted previously, the only other outcome for which a difference was demonstrated for bags on the Drug Tariff was pancaking where a ■ difference was observed."

3	B Braun Medical	7.2.3.3	<i>“Chance of the patient choosing a different bag and cost of associated wastage of unused bags from their old prescription”</i> – this is included in the modelling for several complications. This is important, however, it is unclear how this wastage was modelled. For example, if a patient had only used one bag before switching there would be almost an entire prescription wasted, compared with very little waste if a patient had used the majority of their prescription before switching.	Provide further clarity on the quantity of wastage modelled.	Greater transparency of the economic model, allowing the modelling to be checked or critiqued by other modellers.	Thank you for your comment. The EAG report states that they assume that on average people change prescription half-way through their old prescription (see Table 20 for example).
4	B Braun Medical	Table 18	Disutilities are only elicited from clinical expert opinion for ballooning, pancaking and odour.	Disutilities for these complications should also be elicited from patients themselves, as there can be disparities between dis/utilities attributed to health states by patients and clinicians.	Strengthening of the economic model.	Thank you for your comment. The EAG agree that data collected from people with a stoma would be preferred in line with the NICE reference case. Responsibility for data collection to demonstrate the added value of products falls to the manufacturers of those products.

5	B Braun Medical	Table 18	The probability of hospitalisation and stoma re-siting is only gleaned from clinical expert opinion.	Real world data sources (e.g. Hospital Episodes Statistics) and/or published evidence of these probabilities should be sought to verify expert opinion.	Strengthening of the economic model.	Thank you for your comment. The EAG agree that the use of data is preferred over expert opinion. The EAG would however note the concordance of the opinion gained via the Rolls (2023) study and the expert elicitation exercise conducted for this appraisal in respect of stoma re-siting. Real world data (primarily Clinical Practice Research Datalink [CPRD] although also linkage to HES) was considered for this evaluation. However, due to variability in how care is delivered such as through CNSs in stoma care working predominantly in a secondary care setting, varying involvement of GPs in prescribing, the outsourcing of care to prescribing hubs, and the relevance of the outcomes

						available within primary care data, it was deemed that CPRD data would not contain the information required to inform the economic model. Additionally identification of the relevant codes for the complications would not be straightforward.
6	B Braun Medical	7.2.7	<i>“However, for the purposes of this analysis we identified instances where outcomes differed meaningfully between bags compared within the same study.”</i> It is not stated whether this means clinically meaningful or statistically significant.	Clarify whether outcomes between bags were clinically meaningful or statistically significant.	Greater transparency of the economic model, allowing the modelling to be checked or critiqued by other modellers. Greater transparency of the data interpretation, allowing clinical experts to assess the appropriateness of this interpretation.	Thank you for your comment. This comment does not relate to the economic model. Studies identified in the clinical review as providing a meaningful difference in outcomes were carried through to the economic model.
7	B Braun Medical	7.2.10	The decision analytic model should have a complication event frequency for the comparator; there is only a frequency reported for PSC (2.4 per year – 44% mild, 48% moderate, 8% severe) and not for the	Provide event frequencies for the other complications.	Greater transparency of the economic model, allowing the modelling to be checked or critiqued by other modellers.	Thank you for your comment. The event frequency for other complications is included in the health state definition. For leakage – 3 different frequencies are modelled. For

			other complications. Section 7.3.2 states “<i>The incremental eJPs for fully preventing a particular complication in those who would otherwise experience it...</i>” but it is unclear how the EAG modelled the frequency at which those patients “would otherwise experience” them.			ballooning, pancaking and odour the definition used was regular, at least once weekly.
8	B Braun Medical	Table 27	The proportion of ostomates experiencing complications was taken from a survey by Colostomy UK. The sample size of this survey is good, however it is unclear whether the EAG have assessed the representativeness of the sample. For example, those responding to a survey about complications may be those who experience more frequent or severe complications and therefore are more inclined to respond to a survey about complications. They may also be patients who are more cognisant of their own stoma/peristomal health.	Consider and critique the representativeness of the Colostomy UK survey sample. Consider additional data sources alongside this survey.	Strengthening of the economic model.	Thank you for your comment. Colostomy UK kindly provided interim results of their research as part of their patient organisation submission. The patient organisation submission will be published alongside the report. This information has been used to provide context due to a lack of other appropriate data sources.

9	B Braun Medical	Table 27	The same proportion of patients (53%) is applied to all leakage frequencies: 2 times yearly, monthly, and 4 times monthly. This is not mathematically possible.	An additional data source should be sought for the proportion of patients experiencing each frequency of leaks.	Strengthening of the economic model.	Thank you for your comment. This information is provided for context to interpret the results of the economic model. The EAG do not have data on the proportion of people with a stoma in the UK experiencing leaks with each of the modelled frequencies.
10	CliniMed	1	Too complex to understand.	Instructions on how the model was created and is being used.	Organisations would understand the model and be able to comment.	Thank you for your comment. The model is described in full in the EAG report.
11	CliniMed	2	Have the EAG considered that some manufacturers may already be offering better VFM by introducing more modern lines at similar prices to previous lines, thereby removing any increase in cost should an ostomate move from an older product to a newer product? In line with this manufacturers are supporting users who prefer existing lines, even though overall usage is declining, even when the	To review where companies have added enhancements to their older products but kept them at the same price, even though they cost more to manufacturer. Have the statisticians done any work on the distribution of products relative to their pricing, and how these fit in with their pricing models?		Thank you for your comment. The remit of the EAGs analysis was to determine whether or not the price charged for the features listed in the scope was justifiable according to the benefits provided by those features. If manufacturers introduce products with better outcomes at a similar cost this becomes more likely. The regression

			manufacture of lines become less viable.			analysis presented explores the relationship between product features and price.
12	Coloplast	Structural issue	Overall, the aim of this decision model was to aid decision making. However, due to fundamental issues with the economic analysis, specifically the lack of evidence that is available to inform it, Coloplast believes that there is a very high risk that its use in decision making, in its current form, will negatively impact patients and the healthcare system.	To consider that this model cannot be used to justify a decision being made on the use of 1- piece closed stoma bags in the NHS.		Thank you for your comment. The report clearly states throughout that there is an absence of evidence and discussed the implications of this.
13	Coloplast	Model usability	Coloplast were not able to engage fully with the LSA process and confirm the factual accuracy of the economic model for several reasons. In order to determine whether the decision model has been developed appropriately for the	We propose that all values are clearly labelled as inputs prior to use in the calculations sheet to ensure that all stakeholders are able to properly evaluate the model. We further propose that the input parameters and	Unknown as the source and use of these values is not clear in most instances.	Thank you for your comment. A response is provided to each of the points raised.

			current evaluation in the timelines allowed, the model must have a minimum level of user friendliness. The EAG model developed for LSA 2 was, in general, very difficult to follow and there was a high level of obstructive practice with the following examples noted: • Multiple instances of hard-coded numbers in calculations (trace) sheets and live Parameters sheet that were not referenced and so could not be cross-checked by Coloplast. Instances include: ○ in the wastage from change of bag type in all sheets where the	sources are made clear, stored and labelled in a consistent way given the time frame available with which to review the model and there being no procedural ability to engage the EAG within the time frame. We would also welcome consistent formatting for ease. As the model may be used to construct scenarios, we would also welcome removal of the module that resets to the base case each time. We then propose that the amended model is made available to stakeholders again.		The EAG disagree and state that the named ranges are used throughout the model to specify parameters. The comments provided below have no relevance to model functionality or ability to review. The reason for division by 2 is that the EAG assume on

			time is divided by 2 and then the switch_PSC_mild is divided by 100 ○ supportive product costs for ballooning where the month to week parameter is divided by 1 with no explanation. • Parameters sheet, G90, the cost is multiplied by 7 when time parameters are included in the model to avoid this confusion. • Parameters sheet, G127 and G128 are both hardcoded values, not linked to an input sheet. • Named parameters feeding from sheets that would not be			average prescriptions are changed half-way through. This is stated in Table 20 in the report. On the reason for division by 100 of chance of switch parameters is to convert it from %. Division by 1 occurs as the parameter was already in the correct format. A specific parameter to go from daily to weekly is not really required for most people. This is a stylistic point only. The source of the values is clearly presented in the parameters sheet. No errors identified.

			expected to have important parameters on with no purpose, citation or explanation offered. An example is observed where all disutilities from the SEE exercise are fed to the trace sheet from the SEE sheet except for one that goes to the parameter sheet, is made negative and then comes to the trace sheets. • Naming conventions not being followed consistently. This can be seen in the parameter sheet where some utilities are prefaced as "u_" and some as "ut_"			No errors identified.

			• Lack of consistent formatting meant that the decision model was difficult to interpret as it was not clear which values were costs, proportions, QALYs etc. • Blank cells were present in the trace sheets that feed into results calculations with no indication of whether this was intentional and for what purpose. • A macro (sub Results settings()) that copies results from other sheets (for no discernible reason) and automatically resets to the base case prior to displaying results			No errors identified. No errors identified. Macro was written for the convenience of the EAG in producing tables for the report. The user is free to interact with the model as

			regardless of whether this is what the user wished to view results for, and then sets the starting health state back to 'Mild' regardless of whether the user had intended this from an unnamed module (Module 8). • The utility decrement for 'bad odour' is positive (when all other decrements are negative) on the SEE Results sheet. This parameter is then made negative on the Parameter sheet, but it is the only of these utility decrements that work this way for no explained reason. • A very impactful cost parameter			they wish. The output from the SEE came in this format. No error identified.

			(cost of supporting products) is CIC in the EAG report and was removed from the decision model because it was CIC but other elements that are also described as CIC in the EAG report were not removed in the model.			Marking has been amended to align model and report.
14	Coloplast	Calculation error	In both 'Engines' in the model, the 'Cost per Health State cost' is set to equal two sources, but when those sourced are not selected, the cost is set to have a failed 'IF()' function. We are therefore unable to determine whether Health State costs are an input or an output, as described in the EAG report under Table 20.	Coloplast believes that this is a programming error in the model that should be corrected such that all of the potential health state costs are options in the economic model. As the model was delivered to stakeholders, only two are available for selection (in practice) and because one of the three unavailable options was selected, the formula defaults to zero health state costs which is not anticipated to be correct.	It is anticipated that health state costs may increase though as noted elsewhere, we are not able to recreate the base case so it is unknown.	Thank you for your comment. Cost per health state is only used when those specific sources are selected as no cost breakdown was available for those sources. That total costs are used for the two scenarios is clearly stated under Table. No error identified.

15	Coloplast	Calculation error	The EAG Report Table 20 reports the following information and sources were used, but the base-case model does not reflect this, so the EAG reported information is factually inaccurate, or the model is set-up incorrectly and the results in the EAG Report are incorrect. The following parameters could not be evaluated on their applicability: The 'Number of 1-piece closed bags per day' is stated to be sourced from 'Clinical expert opinion (2 CNS in stoma care)', however in the model this is actually sourced from 'Berger (2018)' in the model, which has a lower number of bags used	Please could the EAG clarify the parameters used. Once this is clear Coloplast would be able to check the model and report for factual accuracy. This is also a comment on the EAG report section, as it was not possible to understand which set of inputs are correct.	Unknown.	Thank you for your comment. Each of the bullets are addressed individually: - Thank you for spotting this. This has been amended in the updated model and report - There are two cost per bag parameters in the model. <code>c_costperbag_comp_source</code> is used in the results to present the eJP versus a reference bag – this is the one that correctly uses the lowest cost 2023. The other parameter <code>c_costperbag_source</code> is the one described in the report in relation to how wastage is costed and

			per week - please could the EAG clarify which parameter is utilised here for the base-case analysis? • The 'Cost per bag' parameter is described in the EAG Report as being sourced from 'Bennett Institute average bag cost 2023', however in the base-case model it is set to 'Lowest cost 2023', which is £1.85 (rather than £3.02). Which is used in the analysis and is the report correct here? • The 'Cost per CNS in stoma care consultation' is described as being sourced			correctly uses Bennett Institute 2023 • Thank you for spotting this. This has been amended in the updated model and report • Thank you for spotting this. This has been amended in the updated model and report The EAG has done a full cross-check of the model switches versus the report as it has become clear that some were overwritten when running the scenario analysis macro. Changes made to the model are listed below: • The addition of the variables from item 15

			from a mix of the National Cost Collection and PSSRU, but in the model this input is set to 'Berger (2018)' instead of 'EAG'. Which cost is correct for this parameter as this is inconsistent between the model and EAG report? The 'Stoma resiting' proportion in Table 20 is described as being sourced from 'Rolls (2023) HCP survey', but in the model 'Proportion of patients undergoing resit - Severe Health only' it is set to 'Expert Elicitation' in the			downwards, in the "Scenarios" sheet (look for cell enabled the model to fully return to the base case In addition we noticed that an older version of the code to complete the scenario analysis tables had been included in the model and have rectified this to allow the tables to be produced automatically. The changes to the model resulted in an increase to the total eJP for bags reducing the chance of PSC (from £3.89 to £4.24 for a flat bag) and a change of 1 pence to the total eJP for a bag reducing the chance of leaks for people experiencing these

			model. Which of these two parameters should be used? The 'number of PSC episodes' in Table 20 has no impact on the model, as the 'Source of resource use for PSC' option is set to 'EAG', which means that the 2.4 used in the table does not impact the costs in any way. Is this intended? If so, this means there is no recurrence of the complications, meaning costs and HRQoL impacts are underestimated.			2 times yearly. There were no other changes to the total eJPs. This is not correct as the number of PSC episodes impacts on the health state occupancy (see Columns G to I) in the engine sheets. For simplicity the EAG models recurrent episodes as occurring back-to-back as the time horizon of this model is only one year and there is no discounting included.
16	Coloplast	Calculation error	The 'Intervention Engine' applies the cost of people switching bags due to events (such as odour, leakage etc.), as 100% of people have their bags replaced. The Comparator arm has the same calculation, however this is applied	Coloplast believes that this is a programming error in the model that should be corrected.	It is anticipated that costs will increase in the comparator arm and decrease in the intervention arm.	Thank you for your comment. This is not an error. In order for a new intervention to be used on the intervention arm it is clear that 100% of people would need to switch bags. Whereas on the

			to the proportion who would replace it due to an event (from the SEE Results sheet). However, those people who do not have their bag replaced due to the event do not have a future bag replacement (wastage) cost applied. This results in a higher cost in the Intervention arm due to bag replacement (wastage) than the comparator arm, which is illogical. The Comparator arm should also have a wastage cost applied to 100% of people from the point at which they have a bag confirmed, as that is the underlying assumption with the bags (replaced even if no event). This currently underestimates the costs in the Comparator arm, resulting in a lower EJP for each complication			comparator arm not all people may need to switch bags to resolve their complication as there are other pieces of advice (such as from a CNS) which may work (see the report for a detailed description of these for each complication).

			(except for discreteness/appearance/comfort, that was not included in the SEE Results).			
17	Coloplast	Utility values	The model requires health state utilities for PSC and leakage. It is understood that Nichols (2019) did not report utilities for leakage. However, Rolls (2022) reported utilities for both leakage and PSC.	It is recommended that the same source be used across both Leakage and PSC, as to ensure internal consistency when interpreting the quality of life inputs and outputs. Inconsistent use of sources to inform parameters with no justification is tantamount to 'cherry picking'.	The impact is not known as it is not possible to assess the current base case.	Thank you for your comment. The EAG has clearly justified which source has been selected for each complication in detail in the report. Having data reported directly from people with a stoma is preferred as it is considerably more robust than conducting vignettes with the general population, a practice which is subject to considerable bias and therefore not included in the NICE reference case.
18	Coloplast	Cost associated with feature	There is no cost associated with the new features that go on the comparator bag during	Coloplast propose that there should be a suitable additional cost applied during the period	It is expected that the cost of the comparator arm is currently	Thank you for your comment. This is assuming that the additional features

		s/complication s	the period when the complications are applicable. This assumes that the features included in the comparator arm to fix the complication are of no extra cost to the payer. This is a very conservative approach, as it would be paid to be fixed via a supplemental component.	where the complication is assumed to occur in the comparator arm.	underestimated and that this would increase if amended as identified.	required to fix the complications come at an additional cost. The EAG's pricing regression analysis clearly demonstrates there is very little link between current pricing structures and features and therefore this assumption is flawed. Use of the mean cost per bag in these circumstances is justified.
19	Coloplast	Complication implementation	The complications are assumed to be resolved after a defined period of weeks. Then there's no instance of this complication returning. This is a fundamentally flawed assumption, as the complications come and go. There is no way to capture this in the current analysis therefore the model does not reflect clinical reality.	Coloplast propose that an option be built into the model for complications to reoccur so that the committee are able to review realistic scenarios and that the cost of switching products in the comparator engine incur an additional bag cost.	The comparator engine heavily underestimates the cost of complications.	Thank you for your comment. For PSC multiple episodes are included as noted in previous responses. For other complications no data exists on propensity for the complication to reoccur. Scenarios were explored around longer time to resolution for these complications to

			Furthermore, can the EAG please explain how the assumption was made for the comparator engine, that it would be possible to switch the population to a different, similarly costed product, and resolve the issue experienced by the population? This inherently means the bag used in the comparator engine has a 100% effectiveness at resolving the complication.			explore the model sensitivity to this. The EAG assume that a combination of switching bag, using additional supporting products and trying tricks and tips given by CNS resolves the complication not change of bag alone. This is stated in the report.
20	Coloplast	Reference error	In section 7.3.4 a comparison is made between Moderma Flex and SenSura based on the Voergaard 2007 study. The reference product used in the study was Nova1, not Moderma Flex.	Replace Moderma Flex with Nova1. The Nova1 bag is priced at £2.84.	No change to conclusion.	Thank you for this correction. The model and report have been amended. The EAG note that on the version of the Drug Tariff used for the report the Nova1 is only listed as a convex bag. We have therefore used the price of the Nova bag (£2.84) as the study states that no participants were using convex bags.

						We agree there is no change to the conclusion.
21	Coloplast	Treat ment time	The treatment time (weeks) for ‘Discreteness, appearance and comfort’ in the model and report is set to 3 weeks, along with all other treatment times for the complications. However, the source for this is stated as ‘Assumption based on SCN statement that for most people they can resolve issues within 2-3 consultations and they wait 2 weeks between consultations’. However, this input is relevant for a complication, and not a benefit. Therefore, the input for 2-3 consultations until the discreteness, appearance and comfort is resolved may not be reflective, as this benefit may not appear as quickly as a more	To increase the time for the resolution of discreteness, appearance and comfort complications, or to discuss with relevant clinical experts on how long the aspect would take to ‘resolve’.	Higher costs and lower QALYs in the comparator arm would be expected, the extent of which will depend on the approach and value taken.	Thank you for your comment. For discreteness and appearance the source was not completed in the model. The EAG have now completed to match the report: “The CNS in stoma care noted that it is likely to take a few contacts and free samples being sent to find a comfortable bag (although this may take a little longer than identifying a bag based on appearance).” For all complications the assumption is that the final consultation is confirmed the person is happy

			tangible complication with the bag.			not to make further amends in line with CNS expert input.
22	Coloplast	Effectiveness	The effectiveness ("Number of episodes reduction") is set to be equal across all complications. I.e., setting 100% effect removal applies this to all complications, not just a specific one, which is a substantial assumption. We would expect that certain bags would reduce the impact on one complication by X% and another complication by Y%, as not all complications are resolved equally. This was not adjustable in the model without modification which was not feasible in the time frame allowed by this process.	Include the ability to alter the effectiveness in each complication, such that variation can be seen in scenarios. This aligns more with a features-based approach.	More relevant applicability per product that does not assume equal efficacy across all features.	Thank you for your comment. No data was available to the EAG to inform how different features or bags might reduce the change of complications differentially and therefore this functionality was not included in the model. Results are already presented for individual complications.
23	Coloplast	Stoma resit utility decrement	The utility impact (decrement) of a stoma resiting is 0.25 and is from a weak source that Coloplast consider as not	To confirm with patients receiving a stoma resiting if this utility decrement is accurate.		Thank you for your comment. The 0.25 is a QALY decrement not a utility decrement. The

			reflective of the negative impact of a stoma resiting. It does have an impact on results, from initial checks, approximately a ~£0.05 impact on EJP per bag for PSC. So not a non-zero impact.			source chosen by the EAG was the only source identified in the literature review. The EAG agree that the quality of evidence available in this area, as in most others, is low.
24	Coloplast	Inconsistency with the User Preference Report	As noted in the comments relating to the User Preference Report, there is internal inconsistency in the utility decrements associated with the presence of bleeding due to a PSC and the likelihood of switching stoma bags.	Ensure consistency across the report and decision model.		Thank you for your comment. These two parameters are not expected to be perfectly correlated as there are other ways to resolve a complication than switching bags and there is a known population of people who have complications who do not seek support.
25	Coloplast	Non-colostomy bag studies used	Colwell 2018 (ADVOCATE trial), the Bennett Institute and Nortoft 2019 were used to populate the parameters in the model, despite including populations that were not solely colostomy patients. Further, Rolls 2023 was used (ileostomy	Ensure that inclusion/exclusion of studies is consistent across the EAG report and decision model.		Thank you for your comment. The EAG has clearly described the limitations of using data from mixed and ileostomy populations and adjusted data based upon expert input where possible.

			patients) for resource use parameters, but this was consulted and adjusted with CNS in stoma care.			
26	Coloplast	New available data	The most recent (2024) National Cost Collection is now available to be used, albeit at the time of producing this work it was not. However, many costs used will change substantially if the latest document is used instead.	Update using the new National Cost Collection data available from NHS England.	Alter the costs and ensure the most recent data is used.	Thank you for your comment. This data was not available at the time the report was produced and at the time of writing this response the 2024 costs were withdrawn by NHSE as an error was identified in them.
27	Coloplast	GP visits	No GP visits were included in the treatment pathway for PSC. The “GP referrals” in Rolls 2022 also covered GP visits due to stoma complications. The LSA economic modelled assumed a highly optimistic pathway, where people with a stoma would always contact their stoma care nurse in	GP visits should be included in the PSC costs as part of the treatment pathway at the level suggested in Rolss 2022.	Increased cost of PSC	Thank you for your comment. None of the GPs consulted by the EAG had ever had contact with a patient in regards to stoma complications. They indicated that stoma care nurses and DACs were the primary places where contact would be made. Given this the EAG reduced the level of GP contact from Rolls

			case of difficulties. In reality, due to lack of pathways and differences of care across locations, many will contact their GP with stoma related issues.			(2022) and increased the level of CNS contact. If GP contact were to be reintroduced to the model then CNS contact should be reduced.
28	Coloplast	GP and prescription costs	If GP visits are not included in the pathway, please consider the following: The proportion of patients referred for GP was, identified as including prescription requests, so this proportion was set to 0% in the. However, prescription costs do carry a cost, as reported in the PSSRU (£1.51 per prescription request done online). Could this cost be captured in the decision model?	Include the cost of prescription-related call instead of GP-related costs.	Increase ongoing costs and resource use.	Thank you for your comment. The cost of prescriptions applies to both arms in the decision model. Given how small this cost is it was not considered relevant to include. The EAG note this has the impact of the EJPs presented being minorly optimistic as a small percentage of people would require an additional prescription on the intervention arm.
29	Coloplast	Cost of hospita	A cost of hospitalisation aligns with the US study	Use a non-elective stay cost instead of day case	The cost of hospitalisations will	Thank you for your comment. This

		lisation	‘Taneja (2017) for the risk of hospitalisation for PSC. However, the EAG have used a ‘day case’ cost from the National Cost Collection, when the Taneja (2017) study states that the mean readmission length of stay for colostomy with PSC was 7 days. This indicates that it is a lengthy admission, so a non-elective stay cost may be more appropriate in this instance.	for readmission.	increase in both arms of the model.	study only includes patients within the first 120 days of surgery and therefore is not representative of the overall population. The increased inpatient care in this study relates to additional requirements to treat PSC developing prior to hospital discharge from initial stoma surgery. The authors also caution against drawing a causal link between PSC and increased hospital stay.
30	Coloplast	Utility values for leakage	Table 27: Can the EAG please explain how the total QALYs for people experiencing 4 leakages per month in the comparator group (0.8007) is higher than those experiencing 2 leakages per year in the	Reassess the calculations in the ‘leakage’ section in both the Comparator and Intervention Engines. The Table 28 results will also need recalculating.	Decreased impact of leakages twice per year, but increase for more frequent leakages.	Thank you for your comment. The EAG has explained this in the report: “Additionally, for leakage, a larger eJP was predicted for twice yearly leaks compared to

			comparator group (0.7853)? The assumption that people experiencing leakage twice per year are not seeking help, and the assumption that complications are fixed by switching to a similarly costed bag, means the model results are too theoretical to be useful. We suggest including recurrence of issues in the model, to better reflect that experiencing leakages onto clothes 4 times per month naturally would have a higher impact on QALY and cost			monthly leaks, as the model assumed (based on clinical expert feedback) that people experiencing less frequent leaks would not seek support from CNS in stoma care to resolve the issue. This meant that they experienced reduced costs compared to monthly leaks, but their complication would not get resolved and the impact on HRQoL applied for the full year.” No data has been provided to implement the alternate suggestion of including recurrence for leaks.

31	Coloplast	Basic bag cost flat	The choice of basic flat bag comparator does not reflect current clinical practise, as the bag is not prescribed. A total of just 6,960 1-piece closed NaturFit flat bags, were prescribed in the calendar year 2023 (PCA 2023). The same was true for Protea Vital with filter (28,530), SuperFlat (30), Ultramax (1,230) and Confidence Gold (15,570). SuperSoft was not relevant as it was a convex product.	The cheapest relevant product should be Dansac Nova which has a price of 2.80 and a volume of 1,511,439.	The maximum justifiable price would increase.	Thank you for your comment. Selection of a comparator in this area is challenging. CNS were consulted to see if a “basic bag” could be defined to use as a comparator. Whilst a number of bags were suggested the pricing of these bags was variable with some bags classed by CNS as “basic” being above the average price. This reflects the lack of a link between price and features of a bag demonstrated in the regression analysis. Given this the EAG chose to use the cheapest bag as the reference for the economic analysis as this is objectively

						definable. Basing the bag price for presentation of the EJP on the cheapest bag with a minimum level of sales as proposed would also include additional assumptions i.e. what should that minimum level of sales be? The EAG also note that if the Committee or stakeholders wish to use a different price to which to apply the incremental eJP they are able to do so with the information provided in the report.
32	Coloplast	Basic bag	The choice of basic convex bag comparator	The cheapest relevant product should be Dansac	The maximum justifiable price	See response to comment 31.

		cost conve x	does not reflect current clinical practice, as the bag is not sufficiently prescribed. A total of just 3,800 1-piece closed NaturFit Convex bags, were prescribed in the calendar year 2023 (PCA 2023). The same was true for Confidence Soft Convex (38,050), Ultramax Atlas Convex (40), Assura Colostomy Seal Convex (2,060) and Emperor Convex (0). SuperSoft was not relevant as it was a convex product.	Nova 1 which has a price of 3.02 and a volume of 145,950. Alternatively, Esteem+ Soft Convex with a volume of 239,581 could be used as it has more significant volumes.	would increase.	
33	Coloplast	Model input	Appendix 1 – model input. The parameters “two leak event per year (mild), one leakage event per month (moderate) and 4 leakage events per month (severe), has a value of 52, 3 and 3 respectively. These values seem to describe the treatment times related to different			Thank you for this comment. The report has been amended to clarify that these are treatment times.

			leakage event frequencies. It is unclear to us what these values reflect.			
34	Coloplast	Uncertainty in modelled parameter inputs	While there is scenario analysis, there is no uncertainty in the modelled parameters which means that the direction and magnitude of uncertainty in the decision cannot be qualified or quantified. This is not acknowledged in the report and values are inferred to be known. As such, the uncertainty in the results may be small or large, it may be related to some parameters or all; it is not known. (figure 5 is a clear example of the uncertainty issue relating to parameters but it is not acknowledged in the decision analysis)	We propose that the uncertainty associated with all of the input parameters is accommodated so that the range in potential eJP can be shown to decision makers. Once this has been implemented, we would welcome the opportunity to check the results for factual accuracy.	Coloplast expect that there be a very wide range of potential eJP values which should be reviewed and discussed.	Thank you for your comment. Due to the poor quality of the evidence available to populate the decision model quantification of the magnitude of parameter uncertainty was not possible for the majority of parameters. This is acknowledged in the report in Section 7.2.3 "Results are presented deterministically as there was insufficient evidence to support a probabilistic analysis." The EAG have provided

						quantification of uncertainty via scenario analysis where possible and have clearly indicated which factors are model drivers in the report.
35	Coloplast	Cost of hospitalisation	A cost of hospitalisation aligns with the US study 'Taneja (2017) for the risk of hospitalisation for PSC. However, the EAG have used a 'day case' cost from the National Cost Collection, when the Taneja (2017) study states that the mean readmission length of stay for colostomy with PSC was 7 days. This indicates that it is a lengthy admission, so a non-elective stay cost may be more appropriate in this instance.	To include an updated cost for hospitalisation that reflects the longer stay.	The cost of hospitalisations will increase in both arms of the model.	Thank you for your comment. This study only includes patients within the first 120 days of surgery and therefore is not representative of the overall population. The increased inpatient care in this study relates to additional requirements to treat PSC developing prior to hospital discharge from initial stoma surgery. The authors also caution against drawing a causal link between PSC and increased

						hospital stay.
36	Coloplast	Number of PSCs per year	Based on reported prevalences of PSCs in the literature, it seems unlikely that the rate of PSCs would be limited to 2.4 per year. In Colwell 2018 (the source of the 2.4 per year), 41 people out of 74 in the control arm have a PSC in 12 weeks. Number of PSCs is therefore calculated as an incidence of at least one PSC occurring within 12 weeks, rather than the repeated incidence during this 12-week period. It is plausible that PSC could occur more than once during this 12-week period, particularly due to the high risk of occurrence. This number has no bearing on the results in the base-case analysis, albeit if it is, it's likely underestimated.	The model should allow recurrence of PSC in the comparator arm. The PSCs per year should be increased to 7.5, in accordance with Martins 2012 and Meisner 2012.	Current costs are underestimated. This would result in a higher cost for PSCs.	Thank you for your comment. The estimate of 7.5 in Martins 2012 and Meisner 2012 is based solely on speculation not data. The EAG agree that data to inform this parameter is limited.

			Although research is limited, existing evidence strongly suggests that peristomal skin complications are the most prevalent of the stoma-related complications (Gray et al, 2013). From the Martins and Meisner, the treatment period is estimated as 6-8 weeks. As recurrence is likely to happen again after this period, individuals could experience 7.5 PSCs per year (52.177/7). A higher incidence rate would also be supported by available evidence, as mentioned in the LSA, the incidence is likely between 36-73% (page 91).			
37	Coloplast	Cost of leakage	Based on figure 7 on page 132, it looks as if leakage only incurs supporting product cost and not increased bag	Either break up the supporting product cost and increased bag use, or include the additional changes mentioned in De	Inaccurate reporting or underestimated costs of leakage.	Thank you for your comment. Yes, this is because these two parameters were merged as

			use. Is this because these two parameters were merged in the model? If not, costs relating to leakage based on increase in bag usage should be included, or the figure should be amended. Increased bag use related to leakage is well described in literature (De Fries Jensen 2023 and Jeppesen 2022), that one of the primary ways people try to manage leakages is by increasing the change frequency i.e. in Jeppesen 54% of users reported increasing their change frequency.	Fries Jensen 2023.		the source used for supporting costs also included the costs of increased bag use.
38	Coloplast	Cost of leakage (HCP costs)	HCP costs related to leakage is reported as very low on a yearly basis. It seems the model assumes leakage is fixed after one visit, when in fact, leakage is a recurring problem, which may have a large cost impact to the NHS over time.	Make leakage impact recurring, e.g. repeat every 3 months, to better capture the continuous issues experienced by users. It should at least be recognised that the De Fries Jensen only accounted for a single Stoma Care Nurse Consultation. Evidence has shown that at least 2-3 are		Thank you for your comment. The proportion of people consulting with a HCP in De Fries Jensen was low (21.4%). The EAG do not have data on recurrence frequency for leakages with which to inform alternate

				required based on stoma care nurse own feedback, Down et al 2021 – Perception of leakage.		assumptions.
39	Coloplast	Results table input	The total costs for “leakage 4x monthly” total costs refer to the variable “Calc_QALYs_Leakage_int” for comparator and “Calc_costs_Leakage_comp” for intervention. The output variables should be checked for accuracy.	Variables should be checked	Unknown	Thank you for your comment. The costs pulled through to the results tables have been checked and are correct.
40	Association of Stoma Care Nurses UK		This is hugely complex document and we do not feel given the timescale we can offer further comment on this economic model			Thank you for your comment.

**HealthTech Programme
Late-stage assessment**

**One-piece closed bags for adults with a
colostomy: late-stage assessment**

User preference report

Produced by: NICE

Authors: Amy Barr, Technical analyst

Charlotte Pelekanou, Technical adviser

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1 Introduction

This late-stage assessment focuses on 1-piece closed bags for adults with a colostomy. Colostomy surgery is an operation to divert 1 or both ends of the colon through an opening in the abdomen ([NHS, 2020](#)). This opening is called a stoma. A bag (also known as a pouch or appliance) can be placed over the stoma to collect bodily waste (poo). Although people with a colostomy can use 2-piece or drainable bags, this assessment focuses on adults with a colostomy that use 1-piece closed bags only.

Colostomy surgery may be needed during the treatment of conditions including, but not limited to, anal cancer, colorectal cancer, vaginal or cervical cancer, ovarian cancer, diverticular disease, Crohn's disease, endometriosis, Hirschsprung's disease, birth defects, faecal incontinence or trauma.

Some people with a colostomy will experience complications ([Burch, 2021](#)). Common issues are bag leakage and peristomal skin complications which can be painful and difficult to manage. Colostomy surgery and related complications can significantly impact a person's psychological and emotional health. But, each person's journey to their colostomy may vary. For example, a person may feel more positively about their colostomy if it can relieve negative symptoms that they were experiencing beforehand. Whereas people experiencing fewer symptoms before their surgery, or have an emergency procedure may have more difficulty adjusting. Interim results from a Colostomy UK survey with 3742 responses (69% of responders having a colostomy) found that 34% of people believed their mental health had worsened since their surgery. The survey found that a number of factors contributing to this were linked with stoma management. The survey reported that 53% of people were impacted by leakage, 48% by pancaking, 44% by skin irritation, 39% by ballooning, and 28% by odour.

In community and primary care, 1-piece closed bags are supplied using an NHS prescription for bags listed in Part IXC of the Drug Tariff under the 'colostomy bag' subgroup. The colostomy bag subgroup has over 15 companies listed as suppliers with over 1,500 product variations available.

The products available can vary in the features offered including ranges of

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sizes, colours, baseplate shapes, additives and adhesives, as well as the bag material (a full range of feature categories are listed in the [published scope](#)).

Due to the large number of products available, there is a wide range of options for clinical nurse specialists (CNS) in stoma care and adults with a colostomy to choose from. Decisions can be shared and are made due to clinical need and personal preference. But, the interim results of the Colostomy UK survey found that 31% of people with a stoma reported that they were not given a choice in the stoma bag that they were initially prescribed. A Coloplast funded report ([Advancing Stoma Care Services: evidence-based proposals for a best practice pathway](#)) also highlights the significant variation for the provision and funding of care, support and follow-ups in stoma care services across the country and how this impacts product use as well as quality of life for people with a stoma.

Previous studies related to preference found that comfort and flexibility ([Nafees et al., 2015](#)) and reducing the number of leakages ([Bonnichsen, 2011](#)) were the most important factors impacting bag choice.

NICE is looking at user preferences when choosing a 1-piece closed bag for adults with a colostomy alongside the evaluation of the clinical and cost benefits. This user preference assessment considers the following:

- the criteria that are important to users when choosing a 1-piece closed bag
- the relative importance of the criteria
- and how the criteria can be measured.

This report presents the key findings of this user preference assessment. It should be read alongside the external assessment group's (EAG) assessment report.

2 Methods

This user preference assessment was done in line with [NICE's Interim methods and process statement for late-stage assessment](#). The aim of

capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. Users are defined as those who will use the technology and are directly involved in the decision to choose one technology over another.

For this assessment, users were identified as people with lived experience, or knowledge of using 1-piece closed bags (referred to as people with lived experience throughout the report) and clinical nurse specialists (CNS) in stoma care (or people previously in this role with ongoing knowledge of the area). Users were recruited in line with [NICE's Interim methods and process statement for late-stage assessment](#). [NICE's policy on declaring and managing interests for NICE advisory committees](#) was considered during the recruitment process. Users who were directly employed by a company whose technologies are being evaluated were excluded from the process. A declarations of interest register will be published alongside the guidance document on [NICE's topic page](#).

The user preference assessment has been designed with Multicriteria Decision Analysis (MCDA) principles ([ISPOR Task Force Report, 2016](#)). The user preference assessment was done through participation in 2 online workshops and 2 email tasks. This was split into the following 4 stages:

- Stage 1: identifying and defining criteria (workshop 1)
- Stage 2: ranking criteria in order of importance (email task 1)
- Stage 3: weighting criteria (email task 2)
- Stage 4: developing performance rules (workshop 2)

Stage 1: identifying and defining criteria

Users were asked to identify key factors that are important when choosing a 1-piece closed bag. A list of criteria and definitions were identified and agreed on during an online workshop with users.

Stage 2: ranking criteria in order of importance

Users were then asked to rank the criteria in order of importance to them via email. Ranked lists from all respondents were collated, averaged and ordered from most important to least important, creating a final ranked list of criteria and definitions (using the SMART ranking technique; [see appendix C for a detailed definition](#)).

Stage 3: weighting criteria

Users were asked to weight the top 10 criteria to show how much more important 1 criterion was compared with the criterion ranked below (using the swing weighted technique, [see appendix C for a detailed definition](#)). Users were asked to weight the top 10 criteria only to ensure the weights assigned were meaningful. To weight the criteria, users were asked to give each criterion a score from 0 to 100%. A score of 0% meant that there was no difference in importance between a criterion and the criterion ranked below, and a score of 100% meant that it was considered twice as important. Weighted lists for all respondents were collated, averaged and weights were calculated.

Stage 4: developing performance rules

During the second online workshop, performance rules were created by consensus for each criterion. To do this, users were asked how they would measure performance of the technology against each criterion. For rules with multiple answers, users were asked what would be considered acceptable or unacceptable levels of performance. In some cases, a level of acceptable performance could not be reached due to variation in opinion. Where this was the case, it was highlighted in table 3.

User engagement for all stages of the assessment is in table 1.

Table 1: Overview of user engagement at each stage of the assessment

Stage	People with lived experience [n=8]	Clinical nurse specialists in stoma care [n=10]
1	7	8

2	8	10
3	8	9
4	7	7

3 Results

3.1 Identifying and ranking criteria

A total of 16 criteria were identified and defined by users during the first workshop. Users were then asked to rank the criteria in order of importance. The average rank is shown in table 2. Anonymised individual responses from the ranking exercise and the comparison between user groups is in appendix A (tables 4 and 5).

The top 3 criteria to consider when choosing a 1-piece closed bag relate to maintaining and promoting healthy peristomal skin. The most important criterion was preventing leakage and seepage. This was followed by the durability of the baseplate and a baseplate that maintains and promotes skin health.

When comparing the ranking between CNS in stoma care and people with lived experience, the top 3 criteria were the same but ranked in a different order of importance. CNS in stoma care ranked preventing leakage and seepage as the most important criteria, whereas people with lived experience ranked the durability of the baseplate as the most important factor to consider when choosing a 1-piece closed bag. People with lived experience ranked a filter that remains functional during use and the durability of the baseplate as more important than the CNS in stoma care. But, CNS in stoma care prioritised the fit of the baseplate and comfort of the bag against the skin as more important factors. The appearance of the bag and availability of baseplate sizes were ranked lower in the list for both user groups. But, the availability of different bag sizes was a slightly higher priority for people with lived experience. Both user groups ranked having a reduced environmental impact as the least important factor in the list of 16 criteria. However, it is

important to note that although this outcome was ranked lowest, people with lived experience did find the quantity of packaging they received with their products to be unnecessary (particularly cardboard).

Table 2: Criteria ranked in order of importance

Order of importance	Criteria	Definition
1	Prevents leakage and seepage	A bag that prevents leakage (poo coming outside of the baseplate) or seepage (poo coming onto the skin under the baseplate), helping to prevent skin damage and odour. A bag that can be used with minimal use of supporting products.
2	Durability of the baseplate	A baseplate that securely adheres to the skin around the stoma without lifting during activity, when wet, in different temperatures and humidities, allowing the bag to be changed as required by an individual's poo rather than baseplate failure.
3	Baseplate that maintains and promotes skin health	A baseplate that doesn't tear the skin when being removed, doesn't cause irritation or skin sensitivities and can be used with a variety of skin conditions.
4	Fit of baseplate	A baseplate that has appropriate flexibility, follows the natural movements of skin and doesn't pull on the skin when moving.
5	Durability of the bag (external fabric and plastic inner lining)	A bag that keeps its form and holds poo under different conditions (such as when it is wet, in different temperatures and humidities, when it is full) when undertaking different activities until a person is able to change it.
6	Filter that remains functional during use	A bag with a filter that allows air to be released, doesn't cause ballooning, controls odour, prevents pancaking and remains functional during use when it is wet (externally with water and internally with poo).
7	Easy to attach the baseplate to the skin	A bag that can be attached with minimal effort and adheres well to the skin.
8	Comfort of bag against skin	A bag that has material (both the fabric and edging) that is comfortable against the skin such as it doesn't rub and doesn't itch when it's empty or full and is quick to dry.
9	Easy to remove	A bag that remains intact when it is removed and has a low risk of leaving residue (such as adhesive) on the skin.

10	Easy to remove the film or covering from the baseplate	A baseplate with an indicator (for example a coloured tab) to show where to remove the plastic film from the baseplate quickly. A film that comes off intact and allows the baseplate to retain its shape, integrity and adhesiveness.
11	Reduces noise	A bag made of material that makes minimal noise when moving.
12	Availability of different baseplate shapes and sizes	Baseplates available in pre-cut or cut to fit options that come in a variety of shapes (such as round, oval, square, flower, diamond) and sizes.
13	Availability of different bag sizes	A bag that is available in a variety of sizes (such as mini, midi or maxi) or has adaptable sizing (for example, can be folded to appear smaller).
14	Appearance of the bag	A variety of colours and shapes available. A bag that is minimally obtrusive and visible, such as a bag with a low profile that reduces dragging when filling, less bulky material and material that doesn't become see through when wet.
15	Easy to cut	A baseplate that is easy to cut without damaging the bag and has a film or covering that can be used as a template for cutting without disintegrating or distorting the baseplate shape.
16	Reduced environmental impact	A bag that strives to be more environmentally friendly (for example, uses less plastic and cardboard in the manufacturing of the bag and packaging). A reduced carbon footprint in manufacturing process.

After the workshop, a number of users wanted to highlight that, although they had carefully ordered the criteria in order of importance to them, all 16 criteria should be considered important when choosing which bag to use. Some users suggested that criteria could be merged to allow the weighting task to cover the full criteria list. One user said that they would not be willing to compromise on a bag that could not fulfil the majority of the 16 criteria.

3.2 Weighting criteria and creating performance rules

Weighting criteria

The top 10 criteria were weighted by users and are shown in the performance matrix (table 3). Anonymised raw data of weighting scores and the comparison of weighting between user groups is in appendix B (tables 6 and 7).

In total, 16 out of 17 users weighted at least 1 criterion as equally as important as another. A total of 7 users weighted over half of the criteria as equally as important as another.

Nearly a quarter of the total weighting score was given to preventing leakage and seepage (22.5%). This was supported by 2 users explicitly stating preventing leakage and seepage was by far the most important criterion. One of the users noted that they would have liked the ability to weight this outcome more than was possible during the weighting exercise, to highlight that leakage and seepage was much more important than the other criteria considered. CNS in stoma care weighted preventing leakage and seepage as slightly more important (23.5%) than people with lived experience (21.2%). Similarly to the ranking task, people with lived experience weighted a filter that remains functional during use as slightly more important (8.2%) than CNS in stoma care (7.0%). The remaining weights given to criteria showed minimal variation between user groups.

Creating performance rules

During the second workshop, users were given the choice to create performance rules only for criteria with a weight of more than 5%, or for all 10 criteria. Users agreed that rules should be created for all criteria and stated that they are all important when choosing a 1-piece closed bag. Performance rules are listed in table 3.

Users were able to create multiple performance rules for all criteria. Some rules can be answered as a simple yes or no answer whereas others may have a number of answers. For those with a number of answers, users were

asked to state acceptable or unacceptable levels of performance. This was achievable for some rules but for others, a consensus could not be reached.

Criterion 1: Prevents leakage and seepage

Performance rules included whether leakage or seepage occurred, whether the skin was assessed as intact and the amount of supporting products used to help prevent leakage and seepage over time. A consensus could not be reached on what would be considered acceptable or unacceptable levels of leakage, seepage or supporting product use. Users highlighted that the lack of consensus was due to varying levels of what may be considered acceptable between individuals. Acceptable levels of leakage and seepage could be impacted by multiple factors including lifestyle, time of day, other health considerations, the consistency of a person's poo, manufacturing issues (leading to bag or baseplate failure), individual tolerance level and what is generally considered normal for that person. Some users may consider manufacturing issues as a product complaint rather than associate this with poor performance of the stoma bag itself. Although a consensus could not be reached, users stated that no amount of leakage or seepage would be considered the ideal performance from a bag.

Criterion 2: Durability of the baseplate

Performance rules included if the baseplate has lifted and whether the baseplate is able to maintain integrity (both when being used and during storage until its expiry date). Users would want a baseplate to not lift during use (including during activity, when wet, in different temperatures and humidities) and maintain integrity during use and when in storage. Users noted that some baseplates get a slime like texture when wet, causing the bag to slide and become less secure. Users agreed that baseplate lifting can often lead to leakage or seepage. They also noted that the integrity of a baseplate can deteriorate over time, impacting the durability, and that it was important for this not to happen before a products expiry date. Users also stated that storage conditions (such as temperature) can impact the durability of a baseplate.

Criterion 3: Baseplate that maintains skin health

For criterion 3, users identified 3 performance rules to measure if the baseplate tears or damages the skin upon removal, causes or worsens peristomal skin complications and maintains or improves skin integrity. Users stated that no amount of skin damage or worsening in the condition of peristomal skin when using a bag would be considered acceptable. They stated that all baseplates should aim to maintain or improve skin health and integrity.

Criterion 4: Fit of baseplate

For this criterion, lifting and fit of the baseplate around the stoma were highlighted as important performance measures, alongside the flexibility of the baseplate across all dimensions when still, moving or changing position. Users noted that lifting of the baseplate was thought to relate to both fit and durability. Users said that the appropriate level of flexibility for a baseplate cannot be specified, as this may differ depending on the type of baseplate (flat or convex), shape of a stoma or a person's body shape and profile. Appropriate levels of flexibility could also be different depending on mobility levels.

Criterion 5: Durability of the bag (external fabric and plastic inner lining)

Measures of performance for criterion 5 included whether a bag keeps its form and holds poo until a person can change it, whether the bag stays intact and attached to the baseplate, and whether it begins to disintegrate or puncture when in contact with undigested food. Users said that it was unacceptable for a bag to lose the ability to perform any of these functions. They stated that bags may lose the ability to hold poo or come away from the baseplate due to manufacturing issues, and disintegration or puncturing may be caused by the acidity of the bag contents or certain undigested food types puncturing holes in the bag lining.

Criterion 6: Filter that remains functional during use

Users agreed performance rules to measure whether the filter releases air to help reduce ballooning and control odour without creating a vacuum, as well

as remaining functional when wet. Users agreed that no level of odour was acceptable, and that the presence of odour would likely lead the user to change the bag. Users were unable to reach a consensus on the rates of ballooning, creating a vacuum or filter malfunction when wet that are considered acceptable. As with leakage and seepage, users highlighted that a lack of consensus was due to varying levels of what may be considered acceptable between individuals.

Criterion 7: Easy to attach the baseplate to skin

Performance rules included whether additional adhesive is needed to apply the baseplate, whether the baseplate maintains its shape during application and the time taken to secure the baseplate to the skin. Users agreed that the acceptable time place the baseplate around the stoma and secure it to the skin is less than 3 minutes. Stakeholder comments highlighted that this may vary depending on factors such as having visual impairment, manual dexterity issues, the complexity of the stoma and how long a person has had their stoma. Users stated that they did not want to have to hold the baseplate down for too long to make it stay in place securely. They stated that if the baseplate did not stick properly, it may lead to leakage or seepage.

Criterion 8: Comfort of bag against the skin

Performance rules related to comfort of the bag included time to dry, whether the bag material causes or prevents skin discomfort or irritation and whether the bag material changes in feel or texture during use. For the time to air dry, some users stated that they would want a bag to air dry quickly after getting it wet, without using other means of drying the bag (such as using a hairdryer) or having to change the bag. Users agreed that an acceptable time for a bag to air dry is less than 5 minutes. Users also highlighted that the texture of bag material can sometimes change during use. Users said that these changes (such as bobbling) can lead to skin irritation or pulling on clothing, making bags more uncomfortable.

Criterion 9: Easy to remove

Performance rules included whether the bag remains intact when removed and if adhesive residue is left on the skin. Users agreed that it unacceptable

for a bag to not remain intact during removal and a single event would likely lead to a user requesting to change bag. But, they were unable to reach a consensus on the amount of residue left on the skin that may be considered unacceptable due to the variation between individuals on what may be considered 'normal'. One user noted that they always experience residue left on the skin after removal.

Criterion 10: Easy to remove the film or covering from the baseplate

Performance rules included whether a baseplate had indicators to show where to remove the film, whether the film comes off the baseplate intact, whether the baseplate retains its shape, integrity and adhesiveness and the time taken to remove the film from the baseplate. In relation to the time it takes to remove the film from the baseplate, users said that removing the film can sometimes be challenging as it can break off into pieces. This can increase the time it takes to remove the film, delaying application of the bag around the stoma. Users agreed that an acceptable time to remove the film from the baseplate is less than 1 minute. Similarly to attaching the baseplate to the skin, stakeholder comment notes that this may be longer for certain people, such as people with visual impairment or manual dexterity issues.

Table 3: Performance matrix

Order of importance	Weight (%)	Criteria	Performance rule (how to measure criteria and levels of performance considered acceptable)
1	22.4%	Prevents leakage and seepage	- Does leakage occur? - Does seepage occur? - Is the skin assessed to be intact? - Supporting products used to help prevent leakage or seepage over time Unable to reach consensus on acceptable levels of leakage, seepage or use of supporting products
2	17.6%	Durability of the baseplate	- Does the baseplate lift? - Does the baseplate maintain integrity during storage until it's expiry date? - Does the baseplate maintain integrity during use?
3	14.9%	Baseplate that maintains and promotes skin health	- Does the baseplate cause skin tears or damage when removed? - Does the baseplate cause or worsen peristomal skin complications (such as irritation, sensitivities, skin tears or damage) - Does the baseplate maintain or improve skin integrity? No level of worsening to the peristomal skin was considered acceptable and all baseplates should maintain or improve skin integrity.
4	11.4%	Fit of baseplate	- Does the baseplate lift? - Does the baseplate fit around the stoma taking into account body shape? - Is the baseplate flexible across all dimensions when still, moving or changing position?

5	9.5%	Durability of the bag (external fabric and plastic inner lining)	• Does the bag keep its form and hold poo until a person is able to change it? • Does the bag stay fully attached to the baseplate and intact (such as seams staying together around the edge of the bag and the edge of the filter) during use? • Does the bag begin to disintegrate or puncture when in contact with poo (for example, due to acidity or undigested food)? No level of a bag losing the ability to hold poo, coming away from the baseplate, disintegrating or puncturing was considered acceptable.
6	7.6%	Filter that remains functional during use	• Does the filter release air helping to reduce ballooning? • Does the filter allow air to be released without causing a vacuum? • Does the filter allow air to be released whilst controlling odour? • Does the filter remain functional when wet? No level of odour was deemed acceptable. Unable to reach a consensus on the rates of ballooning, creating a vacuum or filter malfunction when wet that are considered acceptable.
7	6.7%	Easy to attach the baseplate to the skin	• Is additional adhesive needed to apply the baseplate? • Does the baseplate maintain its shape during application? • Time to secure adherence of the baseplate on application (less than 3 minutes considered acceptable)
8	4.6%	Comfort of bag against skin	• Time to drying (less than 5 minutes for air drying considered acceptable) • Does the bag material cause skin discomfort or irritation? • Does the bag material prevent or reduce skin irritation? • Does the edging of the bag cause skin irritation?

			Does the bag material change in feel or texture (such as developing bobbles) during use?
9	3.5%	Easy to remove	- Does the bag remain intact when removed? - Does the bag leave residue on the skin when removed? It was considered unacceptable for a bag to not remain intact during removal. Unable to reach a consensus on amount of residue that may be considered acceptable.
10	3.0%	Easy to remove the film or covering from the baseplate	- Does the baseplate have an indicator to show where to remove the film? - Does the film come off the baseplate intact? - Does the baseplate retain its shape, integrity or adhesiveness when the film is removed? - Time to remove the film from the baseplate (less than 1 minute considered acceptable)

4 Additional considerations

During the user preference assessment, users reiterated that choosing a 1-piece closed bag is driven by multiple factors that will vary from person to person. Alongside preferences, bag choice is also driven by a clinical need for certain features.

Bag choice can be influenced by a person's body shape or stoma anatomy. For example, a person with curves or creases around their stoma may need a bag with a convex or concave baseplate to ensure secure adhesion to the skin without lifting, preventing leakage and seepage. Bags of certain shapes and sizes may not be suitable for people with limited abdominal space, such as people with multiple stomas, people with abdominal hernias, people who need their stoma re-siting due to complications or people who require additional abdominal surgery. Users also highlighted that bag choice can be influenced by the formation and consistency of a person's poo, how many bag changes are needed per day and a person's skin type and integrity, which are individual to each person and can change over time.

Some people may need additional support or may find that they are unable to use certain bags. Users noted that people who use a wheelchair, people who are sat for long periods of time or people with excessive sweating may struggle with the durability and security of certain bags. People with visual impairment or manual dexterity issues may need a bag that has indicators to show where the film can be removed from the baseplate and can be more easily attached around the stoma.

Some people use supporting products (such as flange extenders, adhesive remover sprays or wipes, barrier sprays or wipes) to provide additional security, help to secure or remove the baseplate from the skin or to help maintain skin condition. Some areas have local formularies to provide guidance to prescribers on the supporting products (in addition to quantity but not type of stoma bag) that can be used in their area. These formularies may vary between areas. The aim of these formularies is to guide where there are cheaper alternatives (such as an adhesive remover spray instead of wipes for GID-HTE10045 One-piece closed bags for adults with a colostomy: late-stage assessment User preference report August 2024

those able to use them), suggest quantities needed for items such as adhesive remover sprays, or guide where products are now considered redundant (such as adhesive sprays) due to advances in the bag technology. These are not intended to restrict patient access to products if they are needed. During the assessment, people with lived experience stated that the need for supporting products, such as adhesive removers or skin protecting products, varies from person to person and an acceptable amount of use cannot be specified. Some said that they would not want to remove their bags without using adhesive removers and would not want to stop using skin protecting products. Although CNS in stoma care did agree with this to an extent, they highlighted that there is variation in practice in who is given supporting products, particularly adhesive removing products. CNS in stoma care stated that some people may not need them but other people, for example people changing their bags more regularly or those with skin complications, may be more likely to need products such as adhesive removers. CNS in stoma care also stated that they would preferentially look for alternative bags before offering supporting products if leakage or seepage is the main concern.

Throughout the assessment, users highlighted the need for bags to be tested in various groups of people with different skin conditions, lifestyle, mobility levels and people with underlying health conditions to ensure a person can be confident in the security and durability of their bag.

5 Conclusion

Ten CNS in stoma care and 8 people with lived experience took part in this user preference assessment to identify what is important to users when choosing a 1-piece closed bag. A total of 16 criteria were identified, defined and ranked in order of importance. The top 10 criteria were given weights and performance rules were created to show how performance for each criterion could be measured.

The top 3 criteria (agreed by both user groups) were all linked to maintaining and promoting healthy peristomal skin (prevents leakage and seepage,

durability of the baseplate and baseplate that maintains and promotes skin health). They were also considered to be considerably more important than the other criteria with a combined weighting of over 50%. Preventing leakage and seepage was continually reported as the most important criteria to users and accounted for nearly a quarter of the weighting. This is reflected in other completed pieces of research. For example, [Advancing Stoma Care Services: evidence-based proposals for a best practice pathway](#) states that a person's confidence in creating and maintaining a leak free seal when using their bag is key to successful management and maintaining quality of life. Interim results from a survey on people with a stoma done by Colostomy UK also aligned with this as 53% of respondents reported that they were impacted by leakage. The economic analysis of the external assessment report also found that bags preventing peristomal skin complications and leakage may have the biggest improvement to quality of life and may be worth paying a higher price for.

For the remaining criteria, order of importance varied slightly, with people with lived experience prioritising a filter that remains functional during use and the durability of a baseplate more than CNS in stoma care. Potential variation in what is important between user groups reiterates the importance of shared decision making when choosing which bag to use. [NICE's guideline on shared decision-making](#) says that people have the right to make informed decisions about their care and should understand the choices available to them.

Throughout the assessment, users reiterated the importance of all identified criteria when choosing which 1-piece closed bag to use, as well as other factors unrelated to preference, such as person's body shape, skin type, skin integrity, stoma construction, stoma position on the abdomen, stoma output, manual dexterity, visual impairment, mobility levels or other health conditions. Users highlighted the difficulty of ranking and weighting criteria, when they are all considered important, which was reflected in the weighting exercise as all but 1 user ranked at least 1 criterion as equally important as another. Users also chose to create performance rules for all 10 criteria (rather than just those weighted above 5%) to emphasise this importance. Some users also

note that, although there were separate criteria for a number of outcomes, they can be interrelated. For example, leakage and seepage can be impacted by baseplate durability. One user also noted that you would want a durable baseplate with a durable bag so that you can have a bag that is fully functional.

During the second workshop, users were able to create performance rules for all of the top 10 criteria. For some criteria, it was clear that performance could be measured by a yes or no answer. For example, whether the baseplate lifted during use. But, for other criteria users could not reach a consensus on levels of acceptable or unacceptable performance for a number of rules that had a range of possible outcomes (such as frequency of leakage or seepage acceptable) due to the variation in what is considered normal from person to person. The wide range of variability between people with a colostomy is reflected by the large number of products available for prescription in Part XI of the Drug Tariff and highlights the importance of individual reviews and maintaining a wide range of product choice.

Engagement in the assessment was extremely high, with only a small number of users unable to attend the online workshops and only 1 user not responding at stage 3. Users employed directly by companies whose products are being evaluated were excluded from the assessment. But, as the majority of hospitals in England have a formal sponsorship agreement or non-formal agreement in place with stoma appliance suppliers or manufacturers, some CNS in stoma care nurses work in sponsored hospitals. As this user preference work is done on consensus opinion and CNS in stoma care are knowledgeable about a range of products, the impacts of sponsorship should be minimal.

A limitation of the user preference assessment is volunteer bias. NICE recruited a sample of users that volunteered to take part in the assessment, and it is likely that the sample of CNS in stoma care and people with lived experience is not fully representative of the wider population. The people with lived experience are actively engaged with the colostomy community and may have more awareness of product features, potential problems, and be more

willing to seek advice or switch products. But due to this engagement in the colostomy community they do also have increased awareness of problems faced by the wider community and their views may represent this wider population more accurately. Both user groups highlighted that there are a number of people with a colostomy that often do not present to their local service when experiencing issues and try and cope with these at home.

Despite this, the assessment highlights the importance to users of bag security, preventing leakage and seepage and maintaining healthy skin around the peristomal area in allowing people with a colostomy maintain their quality of life.

Appendix A: individual responses and variation in criteria ranking

Table 4: Individual user responses for criteria ranking

Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	Mean	SD	Final Rank
Prevents leakage and seepage	1	3	2	1	5	3	2	2	1	1	1	1	2	7	1	4	8	1	2.56	2.09	1
Durability of the baseplate	3	2	1	2	2	5	3	3	3	3	3	2	1	6	3	1	2	3	2.67	1.25	2
Baseplate that maintains and promotes skin health	2	1	4	3	4	1	4	1	2	2	7	4	7	2	2	3	5	2	3.11	1.79	3
Fit of baseplate	4	6	6	4	3	2	9	4	4	7	4	10	5	9	5	8	3	6	5.50	2.24	4
Durability of the bag (external fabric and plastic inner lining)	6	8	3	5	7	6	5	15	9	4	8	3	3	4	9	6	1	11	6.28	3.28	5
Filter that remains functional during use	11	5	5	9	9	13	10	6	5	5	2	5	4	10	6	2	4	4	6.39	3.08	6

Easy to attach the baseplate to the skin	8	9	9	10	1	7	6	8	6	6	6	6	6	14	4	9	6	5	7.00	2.67	7
Comfort of bag against skin	5	4	7	6	6	4	1	5	10	14	10	9	10	5	14	13	9	7	7.72	3.56	8
Easy to remove	10	10	8	11	15	8	16	13	15	10	11	8	9	13	7	10	7	8	10.50	2.75	9
Easy to remove the film or covering from the baseplate	9	12	11	13	8	9	7	7	7	13	15	7	11	15	13	12	11	14	10.78	2.74	10
Reduces noise	14	7	12	14	10	12	11	9	11	8	13	15	8	12	8	14	10	10	11.00	2.36	11
Availability of different baseplate shapes and sizes	7	14	16	7	12	10	12	11	14	12	5	13	12	8	10	15	15	15	11.56	3.10	12
Availability of different bag sizes	15	13	15	8	13	14	8	12	13	15	16	14	13	1	11	5	14	12	11.78	3.817	13
Appearance of the bag	12	11	13	15	11	15	14	16	12	9	14	11	14	3	16	11	13	9	12.17	3.04	14
Easy to cut	13	15	10	12	16	11	15	10	8	11	12	12	15	11	15	16	12	13	12.61	2.24	15
Reduced environmental impact	16	16	14	16	14	16	13	14	16	16	9	16	16	16	12	7	16	16	14.39	2.58	16

SD: standard deviation

Table 5: Comparison of ranking between user groups

Rank	Clinical nurse specialists in stoma care (or people previously in this role with ongoing knowledge of the area)	People with lived experience of using 1-piece closed bags
1	Prevents leakage and seepage	Durability of the baseplate
2	Baseplate that maintains and promotes skin health	Prevents leakage and seepage
3	Durability of the baseplate	Baseplate that maintains and promotes skin health
4	Fit of baseplate	Filter that remains functional during use
5	Comfort of bag against skin	Durability of the bag (external fabric and plastic inner lining)
6	Filter that remains functional during use	Fit of baseplate
7	Easy to attach the baseplate to the skin	Easy to attach the baseplate to the skin
8	Durability of the bag (external fabric and plastic inner lining)	Easy to remove
9	Reduces noise	Comfort of bag against skin
10	Easy to remove the film or covering from the baseplate	Availability of different bag sizes
11	Easy to remove	Reduces noise
12	Easy to cut	Appearance of the bag
13	Availability of different baseplate shapes and sizes	Availability of different baseplate shapes and sizes
14	Appearance of the bag	Easy to remove the film or covering from the baseplate
15	Availability of different bag sizes	Easy to cut
16	Reduced environmental impact	Reduced environmental impact

Appendix B: Individual responses and variation in criteria weighting

Table 6: Individual responses to criteria weighting

Criteria	1	2	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	Mean importance	SD	Weight (%)
Prevents leakage and seepage	0	0	0	0	0	80	0	100	100	100	0	0	0	25	50	10	0	27.35	41.01	22.4
Durability of the baseplate	25	0	50	0	0	0	0	0	100	50	0	75	0	0	0	5	0	17.94	31.43	17.6
Baseplate that maintains and promotes skin health	75	0	50	0	50	50	0	0	50	25	0	75	0	0	50	25	80	31.18	30.49	14.9
Fit of baseplate	50	0	50	0	0	0	0	50	50	0	30	0	0	0	25	0	90	20.29	28.09	11.4
Durability of the bag (external fabric and plastic inner lining)	50	0	0	0	50	0	50	50	100	0	0	75	0	25	10	15	0	25.00	31.57	9.4

Filter that remains functional during use	20	0	50	0	50	0	50	75	50	100	0	0	0	50	80	5	25	32.65	33.03	7.6
Easy to attach the baseplate to the skin	0	0	50	0	50	0	0	50	80	0	0	100	0	0	10	5	75	24.71	34.71	5.7
Comfort of bag against skin	0	0	50	0	75	0	25	100	25	100	10	20	0	25	30	50	0	30.00	34.10	4.6
Easy to remove	0	0	0	0	0	0	0	0	100	100	0	20	100	50	0	75	0	26.18	40.99	3.5
Easy to remove the film or covering from the baseplate																				3.0

SD: standard deviation

Table 7: Comparison of weighting between user groups

Criteria	Weightings for clinical nurse specialists in stoma care	Weightings for people with lived experience
Prevents leakage and seepage	23.5%	21.2%
Durability of the baseplate	17.9%	17.2%
Baseplate that maintains and promotes skin health	15.0%	14.8%
Fit of baseplate	11.5%	11.2%
Durability of the bag (external fabric and plastic inner lining)	9.4%	9.5%
Filter that remains functional during use	7.0%	8.2%
Easy to attach the baseplate to the skin	5.3%	6.2%
Comfort of bag against skin	4.2%	5.0%
Easy to remove	3.2%	3.9%
Easy to remove the film or covering from the baseplate	3.0%	3.0%

Appendix C Glossary

Term	Definition
SMART ranking technique	A multi-criteria decision making technique that allows criteria to be ordered by importance. Individual responses from each member of a group are collated and averaged, ensuring equal say among the group (Von Winterfeldt D, Edwards W. (1993) Decision analysis and behavioural research. Cambridge: Cambridge University Press).
Swing weighting technique	A technique used for calculating and reporting the relative importance (weight) of each criterion from a ranked list. Each member of a group provides individual responses deciding how important each criterion is over the criterion below it (on a scale of 0-100%). Individual responses from each member of the sample are collated, averaged and weights are calculated (Von Winterfeldt D, Edwards W. (1993) Decision analysis and behavioral research. Cambridge: Cambridge University Press).
Performance rule	A rule (or rules) describing how users would measure the performance of a technology in relation to each criterion.
Performance matrix	A table reporting the criteria most important to users when choosing a technology and the associated performance rules.

Appendix D Participants in the user preference assessment

Clinical Nurse Specialists in stoma care (or people previously in this role with ongoing knowledge of the area)

Amelia Palmer, clinical nurse specialist in stoma care, Kingston Hospital NHS Foundation Trust

Emma Gaunt, clinical lead – continence, urology and colorectal service, Leeds Community Healthcare NHS Trust

Gabrielle Thorpe, associate professor, University of East Anglia School of Health Sciences

Heather Ilett, lead stoma nurse, Herts and West Essex integrated care board

Jennie Burch, head of gastrointestinal nurse education, St Mark's Hospital

Michelle Boucher, lead stoma care clinical nurse specialist, Salisbury NHS Foundation Trust

Natasha Rolls, lead stoma care clinical nurse specialist, University Hospitals Bristol and Weston NHS Foundation Trust

Petya Marinova, lead nurse practitioner – pouch and stoma care, St Mark's Hospital

Rali Marinova, nurse practitioner – stoma and internal pouch care, St Mark's Hospital

Rebecca Wootton, colorectal clinical nurse specialist, Sheffield Teaching Hospitals NHS Foundation Trust

People with lived experience, or knowledge of using 1-piece closed bags

Giovanni Cinque, Colostomy UK representative

Caroline Knight

Deborah Meredith

Emma van Eeden

Holly Broomfield

Malcolm Oswald

Scott Keir

Vicky Buckley

HealthTech Programme

Patient organisation submission

One-piece closed bags for adults with a colostomy: Late Stage Assessment

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on patient experience of using the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.

Your response should not be longer than 10 pages

Information about your organisation	
Organisation name	Colostomy UK
Colostomy UK is a national charity that supports, empowers, and advocates for people living with a stoma throughout the UK. We funded through a mixture of donations from individuals, fundraising income, grants from charitable trusts and foundations, and trading income through advertising on our print and digital platforms. We are not a membership organisation but engage with approximately 50,000 people.	

Declarations	
Do you have any conflicts of interest? Please let us know if you have a question on the NICE policy on declaring and managing interests. No	
How did you gather information about the experiences of patients and carers to include in your submission? A combination of the results of our recent beneficiary survey, and also individual case studies.	
Are you willing for this submission to be shared on our website?	Yes ☒ No ☐
We may invite you to a scoping meeting and/or committee meeting where this technology is to be discussed. Would a member of your organisation be willing to join such a meeting (this may be in person or virtually)?	Yes ☒ No ☐
Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?	Yes ☐ No ☒

Impact of the symptoms, condition or disease on patients and / or family and carers

1. What is it like to live with the condition? What do carers experience when caring for someone with the condition?

Living with a stoma is life changing but it is also life enabling. For those living with chronic conditions like IBD, it can give them control of their life again.

However, people can face major physical and psychological challenges coming to terms with what is major surgery, as well as practical challenges around stoma management, which can also impact on well-being. People worry about whether they will be able to go back to doing the things they used to, they worry about the attitudes society has to people with stomas too.

Results from our beneficiary survey which we conducted between December 2023 and March 2024, which had 3742 responses highlighted that 33% believe their physical health has got worse since stoma surgery while 27% believe it has got better, and 40% said there was no change.

When it comes to mental health 34% believe it has got worse since stoma surgery, while 13% believe it has got better and 53% see no change.

When asked if they feel in control of their lives 49% said no.

Some of the things that can have the biggest negative impact on quality of life are directly linked to management of their stoma. For example, 53% reported that they were impacted by leakage, 48% by pancaking, 44% by Skin Irritation, 39% by ballooning, and 28% by odour. Evidence also shows that at least 50% of people living with a stoma will develop a Parastomal Hernia. Failure to manage these issues can lead to people stopping doing things like going to work, socialising etc which leads to feelings of loneliness and isolation. However, when stomas are managed successfully people will return to living life to its fullest.

Carers will experience the multitude of emotional and physical challenges that many can face post stoma surgeNry, as mentioned above. Challenges over stoma management are often difficult especially when faced by recurring cases of leakage, and skin irritation, or parastomal hernia, when there is often difficulty in accessing support from a stoma nurse.

Experiences and availability of current health technologies

2. How do the existing health technology/ies play a role in managing the condition, and what are their advantages and disadvantages?

Stoma bags and accessory products are necessary in allowing people to live a normal life post-surgery. Once people become used to and confident in a 'different way of going to the toilet' they are able to return to work, play sport, travel etc.

The disadvantages that can arise come when bags and accessory products do not provide the security and comfort needed which leads to people suffering from leakage, skin irritation, ballooning, odour etc, which in turn hugely impacts negatively on quality of life, making people more reluctant to leave home, and work, socialise etc.

Equality issues

3. Are there any groups of people who might benefit more or less from the technology than others?

No, having the right stoma bag, and any necessary accessory products is equally important for all those living with a stoma.

4. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

People who live with a stoma and Dementia may need extra consideration the following document gives more guidance

<https://www.colostomyuk.org/wp-content/uploads/2022/06/CUK056-01v02r00-Caring-for-a-person-with-a-stoma-and-dementia.pdf> Those with dexterity issues may also need further consideration due to challenges around being able to change their bag without support from carers. In both cases leakage especially could be more likely.

5. Are there any potential **equality** or **health inequality** issues that should be taken into account when considering this condition and the technology?

The main health equality issues that need to be considered is that access to stoma care technology in the UK is not uniform across the country, with local formularies differing so what may be accessible in one part of the country isn't.

Sponsorship arrangements with stoma care departments can also mean that not all patients are involved in identifying the best product for themselves. They may end up with the best product from the sponsoring company. Our survey highlighted that 31% of people were not actively involved in choosing their stoma bags.

Additional information

Th6. Please include any additional information you believe would be helpful in assessing the value of the technologies.

If patients are seen on a regular (annual) basis by a stoma nurse specialist for a review which includes making sure the bags they are using are the most appropriate for them still, we believe there will be a considerable decrease in leakage and skin irritation issues. Post surgery people's bodies change shape. They could lose or put on weight, develop hernias etc so the bag they had when they were discharged may not be the most suitable one now leading to greater chances of stoma management problems. According to our survey only 34% of people saw a stoma nurse in a clinical setting in the last year. So access to a relevant healthcare professional we believe should be factored in to overall assessments, as while a product may be highly proficient at managing potential stoma management complications, it's success will be less if it is not the right fit for the person using it.

Key messages

In up to 5 bullet points, please summarise the key messages of your submission. bullet points.

- Leakage, skin conditions, Ballooning, odour, and parastomal hernias are all major stoma management challenges for people, and having the correct bag hugely influences the impact these can have.
- However people living with stomas need to have access to the right products, at the right time, from the supplier of their choice, and free from commercial influence
- Regular contact with a Health Care professional (Stoma Nurse specialist) is vital in ensuring that patients are using the right bag for them regardless of its quality. Changing in circumstances such as body shape etc hugely impact product reliability and need to be taken in to account

HealthTech Programme

Patient organisation submission

One-piece closed bags for adults with a colostomy: Late Stage Assessment

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on patient experience of using the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.

Your response should not be longer than 10 pages

Information about your organisation	
Organisation name	Ovacome Ovarian Cancer Charity
Brief description of the organisation, such as: - who funds it - How many members does it have - What region your organisation represents Ovacome is the national UK ovarian cancer charity focused on providing support and information to anyone affected by ovarian cancer. This includes people who have either been diagnosed with the disease or think that they might be at risk, as well as their friends and family and healthcare professionals. We currently have 5276 members and we have 18 members of staff. We are funded through charitable donations, trusts and foundations donations, community fundraising donations and earned income.	

Declarations
Do you have any conflicts of interest? Please let us know if you have a question on the <u>NICE policy on declaring and managing interests</u>. No

How did you gather information about the experiences of patients and carers to include in your submission?

We used our knowledge and experience from providing support to those affected by ovarian cancer and those who have a stoma as a result of surgery for ovarian cancer.

We requested feedback from our members via our 'My Ovacome online community, from our monthly stoma support group attendees and through our social media channels.

We also created a short survey to provide people with the opportunity to share their experiences and feedback. This was shared on our 'My Ovacome' online community and with those who are registered for our monthly stoma support group.

We subsequently amended the survey to add 3 questions to ensure that the people who responded had or have had a stoma as a result of ovarian cancer, live in the UK and use or have used one piece closed stoma bags. The survey was then shared more widely on our social media channels.

Our survey questions were as follows:

- Approximately how many different types of stoma bags did you need to try before you found one that worked well for you?
- What features of the bag made it your preferred choice?
- Have treatments for ovarian cancer had an impact on the stoma products you have used?
- What are the top 3 most important features of a stoma bag to you personally? You may wish to consider: • baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH buffering system) • modified baseplate shape (e.g. flower shaped, oval shaped, tapered) • modified baseplate adhesive (e.g. to improve adhesion, reduce residue or improve peristomal skin condition) • modified bag

shape (e.g. to be more discrete or allow water to drain off more easily) • modified filters (e.g. to improve gas release or reduce odour) • modified material (e.g. to be more discrete, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence) • flushable disposal – Have you ever been made aware of a stoma product you would like to have tried, but they have not been available to you through your local suppliers? – What stoma bag features would you like to see in the future? We had 20 responses in total, after screening there were 15 completed surveys.	
Are you willing for this submission to be shared on our website?	Yes ☒ No ☐
We may invite you to a scoping meeting and/or committee meeting where this technology is to be discussed. Would a member of your organisation be willing to join such a meeting (this may be in person or virtually)?	Yes ☒ No ☐
Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?	Yes ☐ No ☒

Impact of the symptoms, condition or disease on patients and / or family and carers	
1. What is it like to live with the condition? What do carers experience when caring for someone with the condition? Ovarian cancer has a significant impact on quality of life. The majority are diagnosed at Stage III when it has already spread outside of the pelvis. This	

means people can experience symptoms impacting their health and quality of life, such as ascites.

People with ovarian cancer are commonly treated with surgery which is most usually a total abdominal hysterectomy and bilateral salpingo-oophorectomy. This operation can have long term effects on abdominal organs. For a proportion of people who have surgery to treat ovarian cancer, this surgery will result in the formation of a stoma. This may be a permanent stoma or a stoma that is reversed at a later date.

People may have surgery for ovarian cancer not knowing for certain if they will wake up with a stoma or not. In addition to recovering from major surgery and managing the impact of the surgery which may include immediate surgical menopause, fatigue, changes to body image and changes in sexual function, people may also need to learn to live with a stoma and to manage the emotional, psychological and practical aspects of this.

Experiences and availability of current health technologies

2. How do the existing health technology/ies play a role in managing the condition, and what are their advantages and disadvantages?

12/15 people who responded to our questionnaire had tried 2 or more stoma bags before they found one that worked well for them. 8/15 responders had tried 3 or more bags. This illustrates how important it is that there is a variety of stoma bags available with different features to ensure that people have the opportunity to find a bag that meets their current needs and provides choice as needs evolve over time.

In response to our questions 'What features of the bag made it your preferred choice' the following were mentioned more than once: comfort, no leakage and the colour of the bag. Other features highlighted included:

- Micro skin makes it flexible when you bend or sit,
- Bags that are easier to wear and use, adhesion,
- The bag being flushable,
- Manuka honey base plate for skin and adhesive with ceramide for very sensitive skin.

Two people who responded said that their preferred bag was suggested by their stoma nurse. 'It was the stoma nurses decision - she felt it was the best fit'. One person responded to say that they had no other bag offered.

Two people responded who had moved on from one piece closed stoma bags:

'I moved from a closed bag following surgery to a convex drainable bag. The convex bag fitted the contour of my abdomen and the drainable made it easier to be out and about than the closed bag'

'Light convex reduced the risk of leaks. I went from a one piece to a two piece as my abdominal wound opened and I have stayed with a 2 piece as I have found it more convenient I am not having to take a bag fully off two to three times a day I can just click on a new pouch'.

One person commented that 'The ones that can be emptied feel like they may open and the plastic sticks in my leg!'

In response to our question 'What are the top 3 most important features of a stoma bag to you personally?' the following features were the most popularly identified:

- Discreteness under clothing, less noise and reduced rustling
- Comfort
- Odour control
- Modified materials
- Modified filters
- Modified baseplate adhesive/Baseplate adhesive
- Ease of disposal or flushable. However, one person commented 'I've been very happy with the adhesion, I don't think that trying to make them flushable is at all possible or advisable, we should not be putting extra things into our sewage systems'

Other responses included:

- Leak proof
- Manuka honey base plate
- Ceramic base plate additive
- Kind to skin/ anything that would help with skin condition
- Impact of indentation around stoma from convex shape
- More confidence to swim, shower
- Fit
- Shape and size of bag
- Better water resistance

Additional comments included:

'Baseplate adhesive impregnated with manuka honey is excellent, but the bag sometimes causes soreness, also the noise is embarrassing'.

'Adhesive qualities as I suffered from leaks to start with. Drainable bag so I can empty when necessary and get rid of wind.'

Another person contacted us by email to share 'So I have used open, or drainable, closed, one piece and two piece. I currently use a two piece system and change the bag regularly. I have found the one piece drainable system is too hard because of my output'.

In response to our question 'What stoma bag features would you like to see in the future?', the following features were mentioned:

- Reduced noise would be an advantage, less noise from rustling
- Bags that do not leak
- Smaller bag option that fits my stoma circumference
- Less indentation from convex
- One with an adjustable hole so that you can get a really good fit to reduce leakage on to the surrounding skin
- Colours to match skin tone
- Easier to drain if you have diarrhoea as difficult to empty and clean.
- A soft, flat baseplate which is as protective as a convex bag.
- Improved adhesive to prevent leaks and odours
- Bag impregnated to stop soreness
- More biodegradable for environmental reasons
- An improved idea of a stoma cap that could be worn during intimacy that is not medical looking or a band of fabric that would cover the pouch that doesn't look medical
- Discreet, disposable, hide noise and thin

One person commented 'Happy with current products but always appreciate new and improved features.'

Another person shared through a telephone conversation that their stoma bag is a well thought out item however:

- Size – mini and standard available, it would be good to have a smaller one ie extra mini
- Different colours – brown/black/white available – a wider range would enable wearer to hide nicely under outfit and underwear
- Filters can get stuck
- Nicer smelling adhesive remover would be better

This person added that 'it would be good to have a broader range available including swimming bags and flushable bags which currently aren't widely available – not available from the company I'm with, had to order separately'

Equality issues

3. Are there any groups of people who might benefit more or less from the technology than others?

4. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

People with ovarian cancer typically receive additional treatment following surgery which may have an impact on their stoma and the products that they need. These treatments may include chemotherapy and maintenance therapies. People may also receive additional treatment should they experience a recurrence. Of the 15 people who responded to our survey, 7 people shared that subsequent treatment for ovarian cancer had an impact on the types of stoma products they used. One person commented who moved from a closed bag following surgery, to a convex, drainable bag: 'Yes some of my treatments have caused diarrhoea so the drainable bag has been essential'. Another person commented 'Yes as the chemotherapy made my psoriasis flare and my skin more problematic sticking the flange to it'. Someone else shared 'I currently use a midi size, but following 2nd debulking surgery I requested a larger sized bag & bags I could cut to size'

In terms of problems accessing stoma products, in our survey we asked 'Have you ever been made aware of a stoma product you would like to have tried, but they have not been available to you through your local suppliers?' 1 person responded yes, 12 people responded no and 1 person responded don't know. One respondent commented 'I was seen post initial surgery by stoma nurse 3 times. I then had no contact with stoma nurse for 4 years and this was following second surgery whilst in hospital'.

For people who are using stoma bags that include features that are important for their individual needs, it is important that these continue to be available in order to enable confidence in managing their stoma and the best choice regarding physical effects, to maximise their quality of life when living with a stoma.

5. Are there any potential equality or health inequality issues that should be taken into account when considering this condition and the technology?

We know that some people with ovarian cancer can struggle to access treatments if they don't fully understand treatment options and choices. This may include people with learning disabilities, people who have English as a second language or who have low levels of literacy.

It is important that all patients have equal access to the variety of stoma bags available and are made aware of what products are available to ensure that they are able to live well with a stoma and have a good quality of life. It is essential that all patients' needs are assessed on an individual basis and that conversations around selecting stoma products should take place in an appropriate and accessible manner.

Additional information

6. Please include any additional information you believe would be helpful in assessing the value of the technologies.

Enter text.

Key messages

In up to 5 bullet points, please summarise the key messages of your submission. bullet points.

- It is important that people have access to and a choice of a range of stoma bags with different features to ensure that they are able to benefit from products that meet their own individual needs
- The use of the correct stoma bag is vital for ensuring best management of the physical effects of a stoma and also the psychological effects (such as confidence in use and in reliability of the bag), to enable someone to have a good quality of life
- When people have a stoma as a result of treatment for ovarian cancer, the stoma products that they need may change over time.
- It is important that all patients have equal access to the variety of stoma bags available and are made aware of what products are available to ensure that they are able to live well with a stoma and have a good quality of life. For this to happen, information needs to be provided in an appropriate and accessible way, taking into account individual patients needs.