NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

One-piece closed bags for colostomies: late-stage assessment

Guidance development process

Late-stage assessment (LSA) guidance evaluates categories of technologies that are already in widespread use within the NHS. It assesses whether price variations between technologies in a category are justified by differences in innovation, clinical effectiveness and patient benefits. This will support NHS commissioners, procurement teams, patients and healthcare professionals to choose technologies that maximise clinical effectiveness and value for money.

Find out more on the NICE webpage on late-stage assessment (LSA) for medtech.

NICE is producing this guidance on one-piece closed bags for colostomies in the NHS in England. The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If the committee meets again, it will consider the evidence, this evaluation consultation document and comments from the stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on one-piece closed bags for colostomies. The recommendations in section 1 may change after consultation.

More details are available in NICE's health technology evaluations: the manual and NICE's late-stage assessment interim process and methods statement.

Key dates:

Closing date for comments: **6 March 2025**

Second committee meeting (to be confirmed): **17 April 2025**

1 Recommendations

1.1 Stoma care services should have access to the full range of one-piece closed bags available for prescription in the NHS, so that adults with a colostomy can have the most appropriate bag for them.

1.2 A healthcare professional and the person with a colostomy should decide together which one-piece closed bag to use.

1.3 There is not enough evidence to determine whether price variations between different one-piece closed bags for adults with a colostomy are justified. So, try using the least expensive bag if more than 1 bag is:

- clinically appropriate
- meets the preferences and needs of the person with a colostomy (including preventing leakage, seepage and peristomal skin complications).

What information is needed

More information is needed to determine whether price variation can be justified between one-piece closed bags for adults with a colostomy. Key outcomes and information that should be captured include:

- leakage and seepage
- peristomal skin complications
- impact on psychological and social outcomes
- health-related quality of life
- healthcare resource use, particularly the number of appointments with clinical nurse specialists in stoma care
- the specific bag used
- how long a person uses one range or brand of bag before switching to another
- supporting products used.

A core outcome set and validated patient-reported outcomes should also be developed to help consistency in outcome-reporting across studies. Evidence should be generated across different groups of adults with a colostomy who have complex needs.

This information could be collected through real-world evidence generation or formal research studies. For more detail, see sections 3.20, 3.21 and 3.22 of the guidance.

What this means in practice

Considerations for procurement and commissioning

- Between April 2023 and March 2024, one-piece closed bags prescribed in primary care cost the NHS almost £92 million. There is a large difference in price between the cheapest and most expensive bags available on the drug tariff (£1.85 to £3.84; April 2024 pricing).
- Based on the external assessment group's analysis, between 59.7% (for flat bags) and 77.5% (for non-flat bags) of the price of bags cannot be accounted for by the presence of potentially innovative features. There was also not enough clinical evidence to justify price variation.
- One-piece closed bags with features that can be proven to improve or prevent leakage, seepage, peristomal skin complications and related psychological and social outcomes may be worth paying more for.
- The maximum additional cost per bag that could be added to a baseline cost to completely prevent complications most important to users is £1.22 for regular leakage (4 times per month) and £2.39 for peristomal skin complications. Fully preventing complications is unlikely, so a maximum additional cost for a 50% reduction in complications is £0.59 for regular leakage and £1.15 for peristomal skin complications. But, these values are uncertain and do not consider an overlap of complication resolution.

Considerations for healthcare professionals

- Choosing a one-piece closed bag should be free from sponsorship influence.
- It should be a decision that is shared with the person with a colostomy and follow the principles of NICE's guidance on shared decision making.
- Consider the quality of the clinical evidence when prescribing new bags with claimed innovations.
- While clinical appropriateness and preferences and needs of the person with a colostomy should be prioritised, if there are multiple options which

could be suitable then the least expensive bag should be tried first. This is because there is no evidence to support the price variation.

Considerations for people with a colostomy

- Choosing a bag should be a joint decision between you and your healthcare professional to make sure a bag is clinically appropriate and meets your needs and preferences. Not all one-piece closed bags will be appropriate for you. You should be provided with information about those that are.
- If there is more than 1 bag that is clinically appropriate and meets your needs and preferences, your healthcare professional may consider trying the least expensive bag first. This is because this assessment found no evidence to show why one bag should cost more than another.
- Seek support from a healthcare professional if the one-piece closed bag you are using is causing complications such as leakage and skin irritation, to see if changing the bag type (or supporting products) may help reduce these.

Why the committee made these recommendations

The clinical evidence available on one-piece bags for adults with a colostomy is limited, low-quality and does not consistently report on outcomes important to users. There is not enough clinical evidence to show whether different bags (or their features) would benefit people with a colostomy. But the user-preference assessment found that having features that can reduce leakage, seepage and maintain peristomal skin health were most important when choosing a one-piece closed bag.

There is not enough evidence to determine whether differences between bags or features of bags justify the differences in costs. The cost-effective price is highly uncertain because of the lack of good-quality evidence. The economic evaluation found that bags or features that can prevent peristomal skin complications and leakage may have the biggest impact on costs and quality of life.

More evidence is needed to show if bags with potentially innovative features are more effective, to justify differences in price. Evidence should be collected for outcomes that are important to users, and that allow clinical and cost benefits to be assessed. This evidence should be collected across different groups of people with a colostomy to reflect the variation in this population.

2 The technology

2.1 One-piece closed bags can be used by people with a colostomy to collect the bodily waste (poo) from their stoma. One-piece closed bags are made up of a baseplate (also known as a flange) that attaches to the skin around the stoma. This is attached to a bag that collects the poo. Baseplates are generally made from hydrocolloids. They are adhesive and come in flat, convex, concave and mouldable variations to suit different stoma and body shapes. Bags can also come in different sizes, colours and have additional features that may be considered innovative.

2.2 For this assessment, NICE considered one-piece closed bags available for prescription under the 'colostomy bag' subgroup on the NHS Drug Tariff Part IX. One-piece closed bags designed specifically for babies or young children were excluded from the assessment. Having flat and non-flat baseplate options was considered essential, and so were not evaluated as potentially innovative features for this assessment. Features identified as potentially innovative for the assessment included:

- baseplate additives
- baseplate shape
- baseplate adhesive
- bag shape
- filters
- bag material
- flushable disposal

- inspection window.

3 Committee discussion

The medical technologies advisory committee considered evidence on one-piece closed bags for colostomies from several sources to determine whether price variation between the bags could be justified by differences in their clinical, cost effectiveness or non-clinical outcomes important to users. These included a systematic review of the published literature, evidence submitted by the companies, responses from stakeholders and a user preference assessment. The committee also considered the economic evidence from a review of the published literature and an economic evaluation done by the external assessment group (EAG). Full details are available in the project documents for this guidance.

The condition

3.1 Colostomy surgery is an operation to divert 1 or both ends of the colon through an opening in the abdomen. This opening is called a stoma. 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
- organ nerve damage
- faecal incontinence
- trauma.

Colostomy surgery may be temporary and can be reversed, or it can be permanent. It is estimated that there are over 200,000 people with any type of stoma in the UK (Colostomy UK, 2024).

Impact of having a stoma

3.2 Colostomy surgery can significantly impact a person's quality of life. Patient experts explained that each person's journey to their colostomy may vary depending on the reason for surgery. They highlighted that getting a colostomy is often life-saving, but emphasised that it is always life changing. Patient experts explained that colostomy surgery can impact a person's psychological and emotional health, as well as other aspects of daily life. Modifications to diet, clothing, social life, work and hobbies may be needed as a result. Patient experts noted that people with a colostomy may need long-term support from healthcare professionals, counselling and stoma support groups.

3.3 Some people with a colostomy will experience complications related to their one-piece closed bag. Interim results from a Colostomy UK survey with 3,742 responses (69% of responders having a colostomy) found that 33% of people believed their physical health and 34% believed their mental health had worsened since their surgery. The survey found that several factors contributing to this were linked with stoma-related complications including leakage, skin irritation and pancaking. Another patient and carer organisation highlighted that using the correct bag is vital for ensuring the best management of the physical and psychological effects of a stoma and related complications. Clinical and patient experts highlighted that some people experiencing complications may not seek support, including to change bag type, and will experience ongoing issues. They stated that the proportion of these people, often referred to as 'lost ostomates', is unknown. The committee acknowledged the large potential impact of

complications and highlighted the need for further information about 'lost ostomates', to ensure that everyone with a colostomy can maintain their quality of life.

Current management

Variation in care pathway

3.4 There is a need for a standardised care pathway for people with a colostomy. After surgery, people with a colostomy will get their bags and other stoma supplies from local dispensing appliance contractors (DACs) or community pharmacies. Depending on local funding arrangements, ongoing support may be delivered by a clinical nurse specialist in stoma care (either in the community or hospital). Some people with a colostomy might also contact their DAC directly for support for managing their stoma. The Association for Stoma Care Nurses stoma care nursing standards and audit tool says that regular appliance use reviews should be offered to support appropriate use and good prescribing practice. But, these are not done consistently in all areas of England and can only be done by pharmacy contractors or a nurse working directly with a DAC, which are often linked with stoma appliance suppliers or manufacturers (Kettle, 2019). Clinical experts agreed that stoma care service provision is a 'postcode lottery' and that there is a lack of standardisation in stoma care pathways. A patient and carer organisation submission stated that regular contact with a healthcare professional is vital to ensure people are using the right bag for them. The committee acknowledged that people with a colostomy should have regular access to healthcare professionals and have the same level of care across the country. It concluded that more standardisation of the care pathway is needed.

3.5 Over 80% of hospitals in England have a formal sponsorship agreement (awarded by an NHS tender process) with stoma appliance suppliers or manufacturers (Kettle, 2019). These

agreements may include funding for clinical nurse specialists in stoma care, training, IT equipment and admin support. There is limited evidence discussing the impact of sponsorship in England with mixed opinions for both the advantages and disadvantages. NHS England's commissioned report Delivering Excellence in Stoma Care (2020) highlights that clinical nurse specialists 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. In the East of England it was reported that, for 12 out of 13 hospitals with formal sponsorship agreements, the sponsor was the market leader in product use (Kettle, 2019). The committee concluded that more information is needed to understand the true impact of sponsorship on one-piece closed bag choice in England.

Shared decision making

3.6 Choosing a bag should be a shared decision between a healthcare professional and the person with a colostomy. 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, 2022). Clinical experts explained that this initial choice is often led by clinical need. Clinical and patient experts stated that, over time, choosing a bag should be based on clinical need and the individual preferences of the person with a colostomy. Patient experts stated that the level of involvement in decision making related to bag choice can vary across services, and that they were not always aware of all the bags that were available to them. Patient and carer organisations highlighted that bag needs may change over time, such as because of changes in skin condition, stoma output or body shape. They highlighted the

importance of being aware of, and having equal access to, the variety of bags available to ensure a good quality of life. 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 committee concluded that choosing a one-piece closed bag should be a shared decision between a healthcare professional and the person with a colostomy and should consider the individual needs and preferences of the person, as well as clinical appropriateness.

User preferences

3.7 A user preference assessment was done and included both people with lived experience or knowledge of using one-piece closed bags, and clinical nurse specialists in stoma care (or people previously in this role with ongoing knowledge in the area). Users value bags with features that can reduce leakage and seepage, and maintain and promote healthy peristomal skin. The users identified and ranked a total of 16 criteria considered important to them when choosing a one-piece bag. Although users reiterated the importance of all 16 identified criteria, the top 3 criteria related to reducing leakage and seepage and maintaining and promoting healthy peristomal skin, and had combined weighting of importance of over 50%. Patient experts agreed that leakage, seepage and peristomal skin complications (PSC) have the largest physical and psychological impact on people with a colostomy. A patient expert also highlighted that leakages have a wider impact on daily life including on what a person can wear, their confidence to do everyday activities, and the cost of washing and replacing bedding and clothes. Clinical and patient experts agreed that all criteria are important. They noted that the user preference assessment was a robust process that captures the experiences of the users involved, and the population more widely. Interim results from a Colostomy UK survey (3,742 people with a stoma, 69% who have a

colostomy) found that 53% of responders reported that they were impacted by leakage and 44% by skin irritation. This reiterates the need for bags that reduce leakage and seepage and maintain peristomal skin. The committee concluded that people with a colostomy should have access to bags with features that meet most criteria identified as important, to ensure quality of life is maintained. There should be a particular focus on a bag that prevents or reduces leakage, seepage and PSC.

Equality considerations

3.8 The needs of people with a colostomy vary from person to person, and access to a wide range of bags is needed. People with a colostomy having cancer treatment, 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. 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 or people with sensory processing difficulties may also find certain bags unsuitable or may need additional support. People who are unable to read or understand health-related information (including people who cannot read English) may need additional support to understand the options available to them. People in a wheelchair, people who are sat for long periods of time, or people who experience excessive sweating, may struggle with the durability and security of certain bags. Changes in body shape or skin condition, such as because of pregnancy, aging or hormonal changes may also impact the type of bag that is needed. One-piece closed bags are mostly offered in beige, grey or clear colours. 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. A patient and carer organisation submission highlighted the importance of having access to, and a choice of, a

range of stoma bags with different features to ensure that people with a colostomy are able to benefit from bags that meet their needs. The committee understood that people with a colostomy are individuals with needs that change over time. It stated the importance of maintaining a wide range of product choice for people with a colostomy.

Clinical effectiveness

Clinical evidence included in the assessment

3.9 The evidence base for one-piece closed bags for adults with a colostomy is limited and of low quality. The EAG only identified 5 studies directly related to the decision problem in its evidence review. These included 4 crossover randomised controlled trials (RCTs) and 1 confidential internal company report. The 4 published crossover RCTs were based in Germany, Denmark or Denmark and France. All of the published studies were sponsored by Coloplast (with some authors having a financial conflict of interest) and evaluated the SenSura or SenSura Mio bags, with comparisons including each other or with bags from Hollister and Dansac (Nova 1 or Moderma Flex). The EAG highlighted concerns related to:

- small sample sizes (there were less than 100 people in the published evidence)
- using unvalidated measures to collect outcomes
- a lack of consistency in how outcomes are measured across studies
- short follow-up length (maximum of 2 weeks) and
- limited detail related to how people were assessed for inclusion in the studies.

Clinical experts noted that, in clinical practice, people would typically be followed up for 6 months to 1 year to assess

improvement in outcomes. They reiterated that short follow-up times may not be appropriate for key outcomes such as PSC. The committee acknowledged that the directly available evidence was limited and of poor quality. It stated that higher-quality evidence with validated outcomes and longer follow up would be needed to accurately assess certain key outcomes.

3.10 Because of the limited evidence base directly related to the decision problem, the EAG explored wider sources of evidence. This included evidence evaluating two-piece closed bags and evidence that used comparator arms including more than 1 range of bag. The EAG identified 8 additional studies that were relevant to the expanded evidence base. These included published before-and-after studies, RCTs, real-world evidence studies and unpublished studies. Studies on both two-piece bags and multiple bags in the comparator arm reported differences in outcomes relating to PSC and leakage or seepage. But, clinical experts noted that, for two-piece bags, the baseplate remains on the skin for longer. So, outcomes related to the baseplate for two-piece closed bags (such as leakage and PSC) may not be generalisable. For evidence with multiple bags in the comparator arm, the EAG stated that it is not possible to determine the extent of the impact of a bag or feature, because it may vary between comparator bags. The committee concluded that there are uncertainties around the generalisability of the evidence for two-piece closed bags and multiple comparators to the decision problem.

Evidence on potentially innovative features

3.11 The clinical evidence base included bags with potentially innovative features that could impact outcomes for adults with a colostomy. But the EAG stated that these findings were from low-quality studies and not conclusive because of the limitations highlighted in section 3.9. The results from the directly relevant published evidence showed improvements in some outcomes related to filter

function, such as ballooning. But other outcomes related to filter function, such as pancaking and odour control, did not show differences between the bags being evaluated. Other differences such as bag security, adhesion, ease of removal and comfort were not measured using validated scales and so the EAG considered the outcomes to be difficult to interpret and unreliable. No difference was reported in PSC or leakage in the published evidence base. Clinical and patient experts noted that the studies covered a small number of bags currently available for prescription on the NHS, and these were often not the most recent ranges from companies. The committee concluded that there is insufficient evidence to show whether any bags with potentially innovative features offer greater benefit for adults with a colostomy compared with other bags or bags without potentially innovative features.

Outcomes and populations

3.12 There is limited evidence reporting the impact of bags or bag features on the outcomes that are important to users. Only 3 published studies directly related to the assessment evaluated the impact of bags or bag features on leakage. Only 1 study reported the impact on PSC and no studies reported the impact on psychological outcomes. Patient experts highlighted that people with broken or damaged skin (such as those with PSC) were excluded from the 4 published RCTs in the direct evidence base. They reiterated the huge physical and psychological impact that PSCs have on people with a colostomy and highlighted the importance of collecting evidence for this group of people. The committee also noted that studies excluded people having chemotherapy or radiotherapy as part of cancer treatment, or those who irrigate their stoma. The committee concluded that more evidence is needed that focuses on the outcomes highlighted as important to users in populations that are generalisable to the colostomy population.

Excluded evidence

3.13 The EAG excluded a number of studies evaluating one-piece closed bags in people without a stoma and evaluations of bags or their features that were done in a laboratory, because they do not provide clinical outcomes relevant to this assessment. Evidence reporting outcomes for people with an ileostomy was also excluded because it was found not to be generalisable to people with a colostomy. Clinical experts stated that people with an ileostomy often have a more liquid and acidic stoma output compared with people with a colostomy. They agreed that the baseline characteristics for key outcomes (such as leakage and PSC) and the impact of bag features on these outcomes would not be comparable because of this difference. The committee agreed that excluding this evidence was appropriate for the assessment.

Economic evaluation

Regression analysis

3.14 Factors other than the presence of potentially innovative features may influence the current prices of one-piece closed bags. The EAG found that the variability in price accounted for by the presence of potentially innovative features was 40.3% for flat bags and 22.5% for non-flat bags (including convex, concave and mouldable bags). The feature that impacted price most was flushable disposal in flat bags. No other feature had a significant impact in the initial regression analysis. After removing a bag identified as a potential outlier from the analysis (Opus Natufit), baseplate additives and an inspection window were also significant predictors of bag price. The EAG stated that the results suggest that current pricing may not be driven by the presence of potentially innovative features. The committee acknowledged that the current pricing of one-piece bags may be driven by factors other than

potentially innovative features, which may include competitive pricing models.

Model structure and parameters

3.15 Because of the limited clinical evidence, the EAG could not evaluate the cost effectiveness of one-piece closed bags or features. Instead, the EAG constructed multiple discrete state transition models to calculate the maximum cost-effective price (economically justifiable price [eJP]) for a bag that can completely prevent specific bag-related complications. These were PSC, leakage, pancaking, ballooning, odour and discreetness, appearance and comfort. A total eJP was calculated by adding the cost of the cheapest bag available on the Drug Tariff at the time of the evaluation (flat bag £1.85, convex bag £2.30; Opus NaturFit range) to the incremental eJP per bag for resolving a complication. The cheapest bag was used as a comparator because there was not a specific bag that would be considered standard care. The EAG used a 1-year time horizon, representing an average year for a person experiencing a complication after they have adjusted to their colostomy.

Results of the economic evaluation

3.16 Bags with features that can improve PSC and leaks have the biggest impact on cost and quality of life. The incremental eJP per bag to completely prevent a single complication ranged from £0.37 for odour to £2.39 for PSC. When this is added to the cost of the cheapest bag, the total eJP for flat bags ranged from £2.66 for odour to £4.24 for PSC. For non-flat bags it was £2.66 for odour to £4.69 for PSC. The average mean bag price for all bags available on the Drug Tariff in 2023 was £3.02, which sits within the range of these total eJPs. The EAG highlighted that a 100% reduction in these complications is unlikely and also explored scenarios with lower reduction in complications. Although decreasing the

proportion of complications resolved decreases the incremental eJP, the change in the incremental eJP is not linear because some costs are unavoidable. The economic evaluation reported that improving PSC had the largest impact on costs and quality of life, followed by leakage, pancaking, ballooning, discreetness, appearance and comfort, and finally odour. The EAG looked at a number of scenarios and found that scenarios substantially reducing the total eJP included lower costs for resource use, a higher number of bags used per day for people with no complications, and a shorter time to resolution for complications. Increasing the impact of complications on utilities and increasing the time to resolution for complications was found to increase the eJP. Key model drivers were the unit cost, frequency of healthcare professional interactions, cost of supporting products and expected improvements in quality of life. The committee concluded that further evidence is needed to evaluate the cost effectiveness of bags with potentially innovative features. Bags with features that can improve PSC and leakage may have the biggest impact on costs and quality of life for people with a colostomy.

Model limitations

3.17 The model has a number of limitations and the results from the economic evaluation should be interpreted with caution. The EAG highlighted that the lack of evidence directly related to the assessment and uncertainty around the accuracy of model parameters is a key limitation. This is because some outcomes were obtained by structured expert elicitation, from published studies in mixed populations with a high proportion of people with an ileostomy. Some studies also used vignettes, which may be less accurate at capturing quality of life than patient-reported outcomes. The EAG also noted that the model used optimistic estimates for the resource use impact of PSC and leaks. The EAG used the cheapest bag available on the Drug Tariff as the bag price

comparator (which has less than 1% of the market share), with an assumption that this bag is priced appropriately and does not resolve complications. The EAG also stated that the model looks at complications discretely, and although it created a scenario for all complications being additive, it highlighted that the total eJP for preventing multiple complications is unknown. Patient and clinical experts confirmed that, in reality, the impact of a bag or features on complications will likely overlap. For example, leakage may lead to PSC, which may then impact the fit of the baseplate around the stoma, leading to further leaks. The EAG stated that the actual incremental eJP is likely between the incremental eJP for the single most impactful complication and the sum of the incremental eJP of all of the complications. The committee concluded that caution should be taken when interpreting the model results because of uncertainty in model parameters.

Justification for price variation

3.18 The committee concluded that it was not possible to determine whether the differences in cost of one-piece closed bags were justified by benefits derived from incremental innovations. The committee stated that the available clinical evidence was limited, of low quality, and did not consistently report how bags or features impacted outcomes that are the most important to users (leakage, seepage, PSC and psychological outcomes). The committee acknowledged that potentially innovative features may improve outcomes, but further evidence is needed to determine whether differences in price would be justified by these benefits. The committee agreed that bags with features that are shown to improve outcomes important to users may be worth paying more for than bags with features that do not.

Resource impact of reducing price variation

3.19 The impact of sponsorship on the price of one-piece closed bags is unclear. Because the value of sponsorship could not be quantified within the price of one-piece closed bags, the committee considered a hypothetical scenario that modelled a 10% reduction in mean bag price (reported as £3.02 from a mean of all bags available on the Drug Tariff in 2023) without considering potential clinical differences. It concluded that this overall cost reduction could result in the funding for about 1 band 6 clinical nurse specialist in stoma care per trust in England (141 acute NHS trusts), with residual savings to account for travel and non-pay costs. This scenario did not take into account a mixture of band 6 and band 7 nurses.

Evidence needed to demonstrate additional value

3.20 The committee concluded that further evidence is needed to justify price variation between one-piece closed bags. This research should be done in people with a colostomy (or a subgroup reporting for people with a colostomy) with a clear description of the included population. The committee acknowledged the difficulties of doing large-scale randomised studies, such as funding requirements, length of time to study completion and potential recruitment difficulties because of a person's potential reluctancy to try new bags if they are happy with their current bag. Clinical experts also noted that data is currently stored across care settings depending on how the service is set up. They highlighted the need for data to be collected, clearly coded and stored centrally to support the analysis of real-world data. The EAG noted that the current published evidence base directly related to the decision problem is sponsored by 1 company and studies often have authors with financial conflicts of interest. It highlighted the need for independence in those doing studies and reporting study findings. The committee agreed that independently run company funded

studies would be an appropriate solution and that clinical nurse specialists in stoma care should be encouraged to lead this research. It concluded that both formal research studies and real-world evidence collection may be appropriate to fill evidence gaps related to one-piece closed bags for adults with a colostomy.

3.21 A core outcome set, clear comparator and longer follow up is needed. The EAG explained that there is currently a lack of a core set of outcomes for adults with a colostomy, and that outcomes are not reported or measured consistently across studies. Clinical experts agreed that developing a core set of outcomes with definitions on how these should be measured would be beneficial and improve consistency in reporting. They also stated the need to develop psychometrically validated patient-reported outcome measures to measure bag-related quality of life. The EAG noted that a small number of stoma-related quality-of-life measures do exist, but these cannot currently be used to generate utilities. Both the EAG and clinical experts also highlighted the need for a more standardised or clearly justified comparator in future evidence generation, as well as longer follow-up times. The EAG noted that the longest follow-up length in the current evidence base is 2 weeks, whereas clinical experts explained that in practice, follow up for much longer is needed to evaluate the impact on complications. The committee concluded that further evidence should report on a core set of outcomes that are important to users, with longer follow up. Also, more work is needed to identify the appropriate comparator and develop bag-related patient-reported outcome measures.

3.22 Evidence should be generated across various different groups of people with a colostomy who have complex needs. Clinical and patient experts reiterated that the needs of people with a colostomy are individual and that not all bags will be suitable for everyone. Patient experts noted that the current published evidence base

excludes people with complex skin. They highlighted the need for evidence collection for this group of people because of the large incidence and impact. They also explained that other excluded populations may have different outcomes and should be considered separately. This includes people having chemotherapy or radiotherapy as part of cancer treatment, or those who irrigate their stoma. The committee concluded that evidence should be collected across different groups of people with a colostomy, to reflect their varying needs.

4 Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Specialist committee members

Emma Gaunt

Clinical lead – continence, urology and colorectal service, Leeds Community Healthcare NHS Trust

Gabrielle Thorpe

Professor of professional development in health sciences, University of East Anglia

Heather Ilett

Lead stoma nurse, Herts and West Essex integrated care board

Jennie Burch

Senior teaching fellow, Coventry University

Natasha Rolls

Lead stoma care clinical nurse specialist, University Hospitals Bristol and Weston NHS Foundation Trust

Rali Marinova

Advanced nurse practitioner, TWINS for iPouch & Stoma Patients Ltd

Rebecca Wootton

Colorectal clinical nurse specialist, Sheffield Teaching Hospitals NHS Foundation Trust

Caroline Knight

Lay specialist committee member

Deborah Meredith

Lay specialist committee member

Emma van Eeden

Lay specialist committee member

Giovanni Cinque

Lay specialist committee member

Holly Broomfield

Lay specialist committee member

Malcolm Oswald

Lay specialist committee member

Scott Keir

Lay specialist committee member

Vicky Buckley

Lay specialist committee member

Clinical experts

Amelia Palmer

Clinical nurse specialist in stoma care, Kingston Hospital NHS Foundation Trust

Michelle Boucher

Lead stoma care clinical nurse specialist, Salisbury NHS Foundation Trust

Petya Marinova

Advanced nurse practitioner, TWINS for iPouch & Stoma Patients Ltd

ISBN: [to be added at publication]