National Institute of Health and Care Excellence

HealthTech Programme

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

Draft guidance consultation comments

There are 208 consultation comments from 17 consultees, including companies (n=8), trade organisations (n=1), patient and carer organisations (n=1), professional organisations (n=1) and other stakeholders (n=6).

The comments are reproduced in full, arranged in the following themes (some comments contain multiple issues and have been split):

- Recommendations: comments 1 to 25
- Economic model: comments 26 to 55
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No.	Stakeholder	Section	Comment	Response
Recommendations				
1	Consultee 1 Individual	1.3 1 Recommendations	Should professionals not also be advised to be fully transparent with patients on the cost issue?	Thank you for your comment. The recommendations have been amended to make it clear to people with a colostomy and healthcare professionals that if more than one bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be chosen. This is reiterated in the 'what this means in practice (considerations for people with a colostomy)' section of the guidance.
2	Consultee 2 Hollister Ltd	1.3 Considerations for procurement and commissioning	Although comment is made as to the price differences between bags, there is no reference to which bags are actually used in the real world. Typically these would not be cheaper products as these do not offer the same user benefits/QoL experience.	Thank you for your comment. The aim of late-stage assessment (LSA) is to assess if the value added by incremental innovation justifies the price variation of a group of products. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and peristomal skin complications (PSC) may be worth paying more for. Additional detail has also been added to section 3.19 of the guidance to reflect that clinical experts stated, from experience, some less expensive one-piece closed bags were of lower quality and led to worse outcomes. But, that they acknowledged that

				there is a lack of evidence to demonstrate this.
3	Consultee 3 Coloplast	1.3 Considerations for procurement and commissioning	This makes no consideration or allowance for the fact that body shape and type continually change. There is a cost burden on the NHS when patients re-visit their HCP to address leakage. This is no fault of the bag or the HCP but rather individual body shape.	Thank you for your comment. Recommendation 1.3 and the 'what this means in practice (considerations for people with a colostomy)' section have been amended to include that needs and preferences change over time. This is also reiterated in section 3.6 and 3.8 of the guidance.
4	Consultee 3 Coloplast	Not specified	In addition to our comments on the text in the draft guidance, we ask NICE to explain why the recommendations have not been drafted using NICE's standard approach used for all medicines and healthtech guidance, as described on this page: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/types-of-nice-recommendation This is because, although sections 4.35 and 4.36 of the interim processes and methods for late-stage assessment state that the recommendations may address price variation, the evidence considerations for colostomy bags are comparable with topics in other guidance streams. In such cases, products are recommended for use with evidence generation – with a plan similar to that being advised for colostomy bags - but without recommending the lowest acquisition cost product. In some topics handled as early value assessments, the products evaluated have been available for much longer than in this LSA. At a time when it is seeking to	Thank you for your comment. The recommendations presented on the 'Types of recommendation NICE can make' webpage referred to in the comment relate to NICE's existing guidance products. These recommendations are made in the context of evaluating technologies for adoption by the NHS. LSA evaluates groups of products already in widespread or established use in the NHS. The recommendations for this topic have been written in line with NICE's late-stage assessment interim process and methods statement and other LSA pilot topics. Evidence generation plans are created for early value assessments where there are new groups of technologies that have the potential to meet an unmet need in the NHS. Here, further data collection or evidence generation is needed before they can be recommended for routine use in the NHS. Technologies considered by LSA are already in widespread use in the NHS and the aim of LSA is to support procurement and commissioning decisions. This is because

			harmonise processes and methods for healthtech, please can NICE explain why this inconsistency is justified?	products within a category may have undergone continuous improvement or incremental innovation, leading to price variation.
5	Consultee 3 Coloplast	Not specified	NICE has asked for comments on whether the draft recommendations are sound. We would argue and have done in Comment 97 on the EAG report that the entire LSA process is not sound for evaluating highly personalised products such as colostomy bags. Therefore, the recommendations resulting from this process also cannot be considered sound. The methodological approach to the evidence base used in the analysis simply cannot be used to inform decision-making, and we ask NICE to reconsider our previous comment on this matter.	Thank you for your comment. The assessment was done in line with NICE's late-stage assessment interim process and methods statement, including topic selection. In relation to the recommendations, please see the response to comment 4.
6	Consultee 3 Coloplast	1.1 1 Recommendations	The sentence ".... available for prescription in the NHS..." should be reworded to ".... listed on Part IX of the Drug Tariff..." to clarify the meaning of 'available for prescription...'	Thank you for your comment. The recommendation wording aligns with other LSA pilot topics and so no change has been made. NICE acknowledges that whilst most prescriptions for one-piece closed bags are done through Part IX of the Drug Tariff, procurement of these products can also be done through NHS Supply Chain.

7	Consultee 3 Coloplast	1.3 1 Recommendations	The recommendation to “try the least expensive bag first” if multiple clinically appropriate options exist devalues SCN expertise and should be removed. Stoma bags are not interchangeable, and prescribing should be based on individual clinical needs, not cost. This undermines Stoma Care Nurses and their clinical judgement This recommendation contradicts the NMC Code, which mandates that nurses must prioritise patient needs and use clinical judgement rather than financial considerations to guide decisions. The RCN’s guidelines on patient choice in stoma care also emphasise that appliance selection should be based on quality, comfort, and clinical suitability, not price. Clinical nurse specialists (CNS) in stoma care undergo specialist training to assess peristomal skin integrity, leakage risks, and appliance suitability. The draft guidance disregards their role, despite NICE’s own acknowledgment (Section 3.4) of the need for standardised care pathways led by stoma nurses.	Thank you for your comment. The wording and order of the recommendations have been amended to make it clear that only if more than 1 type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. Additional detail has been added to section 3.4 to reflect the committee’s discussion on the importance of having access to clinical nurse specialists (CNS) in stoma care.
8	Consultee 3 Coloplast	1.3 1 Recommendations	To more accurately and clearly summarise the committee’s considerations and conclusions in sections 3.18 to 3.22, section 1.3 should be reworded to read: “More information is needed to determine the cost-effectiveness of the presence of one or more innovative features, and to determine	Thank you for your comment. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for people with a colostomy and that if more than one type of bag is clinically appropriate and meets the

			the relationship between acquisition price and product value. Until more evidence is available, and has been assessed, the bag chosen should: -be clinically appropriate; and -meet the preferences and needs of the person with a colostomy (including preventing leakage, seepage and peristomal skin complications as well as reducing number of other complications such as ballooning and pancaking); -take into account the need for supporting products”	needs and preferences of the person with a colostomy, the least expensive option should be used. The recommendations have been reordered and amended to reflect the committee’s discussion and to align with other LSA pilot topics.
9	Consultee 3 Coloplast	1.3 1 Recommendations	As written this recommendation may be interpreted as a ‘do not use’ recommendation, that is to not use a more expensive bag, or to switch from a more expensive bag to a cheaper one. Additional text should be added to clarify that this is not the intention. We suggest using this wording which is based on text used in other NICE guidance: “These recommendations are not intended to affect established bag choice, where clinically appropriate and working well, that was started in the NHS before this guidance was published."	Thank you for your comment. The wording and order of the recommendations have been amended. The guidance prioritises the person’s needs and preferences and emphasises the importance of clinical appropriateness when choosing a one-piece closed bag via shared decision-making. Additional detail has also been added to the ‘what this means in practice (considerations for healthcare professionals)’ section to clarify that the recommendations are not intended to impact existing choice where people with a colostomy are happy with their one-piece closed bag.

10	Consultee 3 Coloplast	1.3 1 Recommendations	We agree that it is clear from the EAG's report that there is currently not enough evidence to determine whether price variations resulting from individual product features are justified. We disagree with the Committee's decision to use this lack of evidence as a justification for a recommendation on costs. An absence of evidence is not evidence of absence. This remains the biggest limitation in this draft guidance. Recommendation 1.3 is inconsistent with the committee's conclusions summarised in section 3.18, including the conclusion that bags with features that are shown to improve outcomes may be worth paying more for. The impact of this recommendation does not sit in isolation and will not always be considered in the full context of these documents. It will lead to decisions not intended by the committee and may bring about a negative impact on patient care, not least if it causes inappropriate bag switching. We therefore advocate for the removal of recommendation 1.3 or the replacement of it with a recommendation which addresses the need for more evidence without making practice recommendations that are not supported by the evidence.	Thank you for your comment. Please see the response to comment 9. The guidance states that more evidence is needed to determine whether price variation can be justified between one-piece closed bags for adults with a colostomy. NICE encourages further evidence generation, and more detail can be found in section 1 and sections 3.21 to 3.23 of the guidance.
11	Consultee 3 Coloplast	3.18 Justification for price variation	We agree with this statement but it is invalid to develop a recommendation to try the 'least expensive' bag (section 1.3) from it.	Thank you for your comment. Please see the response to comment 9.

12	Consultee 4 Individual	1.3 Considerations for people with a colostomy	It is not appropriate to 'experiment' by offering sub quality products. This can have a severe detrimental impact on their quality of life, especially new Ostomists who are going through the grieving process and are extremely vulnerable.	Thank you for your comment. Please see the response to comment 9.
13	Consultee 4 Individual	3.3 Impact of having a stoma	This is why good quality products need to be offered. Enforcing lower cost/standard products will probably increase the need for supplementary products therefore increasing the cost.	Thank you for your comment. Please see the response to comment 9.
14	Consultee 4 Individual	3.8 Equality considerations	It is vital to ensure a wide range of products is available as 'one does not fit all'. For instance I applied 4 different pouches on a client with sensitive skin- the only reaction they had was to the one that was non allergenic.	Thank you for your comment. Section 1.2 states that stoma care services should have access to a broad 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.
15	Consultee 4 Individual	3.16 Results of the economic evaluation	I appreciate the NHS needs to reduce costings however there are several aspects to consider and not by offering the cheapest pouch. I do feel that streamlining prices may be better.	Thank you for your comment. Please see the response to comment 9.
16	Consultee 5 Colostomy UK	1.1 1 Recommendations	Supportive of this recommendation and of course they do have access to all closed bags via the drug tarrif however it's not realistic for them to stock all products, and the current model means that sponsored nurses will generally favour the products from their sponsored company. This is an aspirational recommendation, but something that should be aimed for.	Thank you for your comment. The recommendation has been amended to reflect that services should have access to a broad range of one-piece closed bags. Additional detail has also been added to the 'what this means in practice (considerations for people with a colostomy)' section to make sure people with a colostomy are aware that there is a range of one-piece closed bags (from a number of companies) available for prescription in the NHS, but that not all will be appropriate for them, and that they should be given information about those that are.

17	Consultee 6 Individual	1.2 1 Recommendations	Absolutely - as a patient I appreciate the NHS needs to save money where it can. I don't need the most expensive bag, if a cheaper one can do the same job	Thank you for your comment.
18	Consultee 7 Salts Healthcare	Not specified	We agree with recommendations points 1.1 and 1.2 however we disagree with Point 1.3: which recommends the practice of “trying” the cheapest bag first. The role of the specialist stoma nurse is not to employ trial and error with regards to colostomy bags that could possibly be used for the rest of the patient’s life. The initial period following a colostomy formation is highly critical in the success of a patient coping mentally with the significant life change and attempts to use the cheapest possible bag first can result in severe negative consequences. The stoma nurse is a specialist nurse and it is their job to identify the most clinically appropriate product with the patients input. This recommendation has the potential to undermine the specialist role of a stoma care nurse and to question the specialism as a whole as well as damaging patients trust if this recommendation is taken forward. It has been established that there is insignificant evidence to assess the difference in products. It is therefore not appropriate in our opinion that figures that have no statical significance following the assessment be used to highlight potential price differences of different features. We can therefore not accept any figures generated from the study to be used in any guidance going forward.	Thank you for your comment. Please see the response to comment 7. In relation to the incremental economically justifiable prices (eJPs) listed in the ‘what this means in practice (considerations for procurement and commissioning)’ section of the guidance, additional detail has been added to clarify the uncertainty behind the economic analysis.

19	Consultee 8 British Healthcare Trades Association	Not specified	We agree that a full range of one piece closed bags are available to ensure that the most clinically appropriate product can be used to suit the patients personal needs. Shared decision making is key in this area of health as every patient will have different requirements and needs to be able to exercise choice The committee have stated there is not enough evidence to make a robust view so we do not believe that point 1.3 should be included in the draft guidance. As stated previously we do not believe that the guidance should be taken forward due to the lack of evidence and that a working group of relevant stakeholders should be set up to look at the future requirements for evidence.	Thank you for your comment. Please see the response to comment 8.
20	Consultee 10 Eakin Healthcare	1.3 1 Recommendations	This guidance is vague and fails to account for diverse patient needs, potentially leading to oversimplified product recommendations.	Thank you for your comment. The aim of LSA is to assess if the value added by incremental innovation justifies the price variation of a group of products. The committee concluded that here is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSC may be worth paying more for. Additional detail has been added to the recommendations to clarify that a person's needs and preferences can change over time.

				The user preference assessment was done to capture the criteria that are importance to users (both CNS in stoma care and people with knowledge of or lived experience of a colostomy) when choosing a one-piece closed bag. The user preference assessment highlighted that the degree of importance of each criterion varies from person to person depending on their needs and preferences, but that they should all be considered important. Section 3.8 of the guidance also recognises that the needs of people with a colostomy vary from person to person, and access to a wide range of bags is required. NICE encourages further evidence generation, including the collection of evidence in various different groups of people with a colostomy who have complex needs. Section 3.6 of the guidance highlights the need for shared decision making and acknowledges that the needs and preferences of a person with a colostomy will change over time, which is also reiterated in the user preference report and the external assessment report.
21	Consultee 10 Eakin Healthcare	1.3 Considerations for procurement and commissioning	There is insufficient evidence to drawn any conclusion about cost-based recommendations. The figures of "£1.22 for regular leakage (4 times per month) and £2.39 for peristomal skin complications" aren't based on any specific studies and are misguided.	Thank you for your comment. NICE has presented the results from the external assessment group's (EAG) economic analysis in the guidance but has stated the maximum extra cost per one-piece closed bag to completely or partially prevent complications, rather than making recommendations on the appropriate costs

			The approach to pin numbers to this lacks a validated method to justify price variations.	for one-piece closed bags with potentially innovative features, due to the lack of available evidence. Additional detail has been added to the 'what this means in practice (considerations for procurement and commissioning)' section of the guidance to emphasise the uncertainty behind the economic analysis. More detail about the limitations of the economic analysis is in section 3.18 of the guidance and the external assessment report.
22	Consultee 13 Convatec	1.3 Considerations for healthcare professionals	There may be several bags that are clinically appropriate and meet the needs of the ostomate. Therefore consideration should be given to putting safeguards in place to ensure they are getting an un-biased offering from their Stoma Specialist nurse? Patients often report that they were never offered an alternative pouch to try and often this is connected to the sponsored manufacturer. i.e. the existence of nurse sponsorship arrangements funded by manufacturers in >80% of NHS Trusts in England with a stoma care service. The absence of evidence does not mean that attributes are not valuable to that particular individual. The HCPs should not be experimenting with patient outcomes, therefore the recommendation to 'try the cheapest pouch first and work your way up' is not a way of providing good care to this patient group. The psychological impact of an ineffective pouch can have a long lasting effect on the ostomate. Anxiety depression and social isolation can be the result of a series of failed products	Thank you for your comment. The 'what this means in practice (considerations for healthcare professionals)' section of the guidance states that choosing a one-piece closed bag should be free from sponsorship influence. Additional detail has been added to the 'what this means in practice (considerations for people with a colostomy)' section to clarify that a range of bags are available from different companies, and that people should be given information about those that are suitable for them. In relation to the wording of the recommendations, please see the response to comment 9.

23	Consultee 14 Ostique Limited	Not specified	3.2 Addressing the “Least Expensive First” Approach NICE’s draft guidance suggests that patients should try the least expensive clinically appropriate bag first. We caution against a one-size-fits-all approach for the following reasons: - The cheapest option may not be the best for all patients, particularly those with sensitive skin, complex stoma profiles, or high levels of leakage. - Patients who experience poor outcomes with low-cost bags may require frequent switching, leading to additional consultations and increased NHS costs. - Psychosocial benefits, such as reduced noise and improved comfort, are not sufficiently accounted for in current cost-effectiveness assessments but play a major role in patient quality of life. We recommend that clinician discretion and patient choice be prioritised over cost alone, ensuring that patient well-being remains central to decision-making. 5. Conclusion & Recommendations In light of the above, we respectfully recommend that NICE: - Consider new clinical and patient-reported evidence on the benefits of innovative colostomy bag features, particularly in reducing leakage, skin complications, and anxiety. - Recognise the long-term cost savings	Thank you for your comment. Please see the response to comment 9. The committee’s considerations about equality are in section 3.8 of the guidance, and considerations about the clinical evidence are in sections 3.9 to 3.13 of the guidance.

			associated with products that improve adherence and reduce complication-related NHS spending. - Adjust the recommendation that the least expensive bag be used first, emphasising a more patient-centred approach. - Ensure that equality and accessibility concerns (including disability access, colour representation, and psychological well-being) are factored into final guidance.	
24	Consultee 15 CliniMed Ltd	Not specified	Regarding the question "are the recommendations sound and a suitable basis for guidance to the NHS", our serious concern is that they are not. The LSA has identified that there is a lack of evidence at the required level to effectively compare products and their attributes. Our concern is that guidance is being provided on price/cost reduction based upon statistics, models and evidence that is acknowledged in the guidance as requiring caution in interpretation. We are supportive of guidance that supports the gathering of more robust evidence to inform meaningful recommendations.	Thank you for your comment. The aim of LSA is to assess if the value added by incremental innovation justifies the price variation of a group of products. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSC may be worth paying more for. The wording and order of the recommendations have been amended to make it clear that only if more than one type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. NICE encourages further evidence generation, and more detail can be found in section 1 and sections 3.21 to 3.23 of the guidance.

25	Consultee 16 ASCN UK	2 RIA Report	Lack of choice of stoma appliances for patients is clinically limiting to address the varied and complex needs of individuals; one size does not fit all. The variables taken into consideration when assessing for a suitable stoma appliance includes skin type, ethnicity, underlying co morbidities, impact of treatment variables on patients, body shape and habitus, rising obesity levels and potential poor nutrition levels affecting quality of surgical formation of a stoma and resulting stoma management complications. A poor-quality stoma appliance inevitably leads to an increase in cost as more products are used if the cheaper alternative is unsuitable and not relevant to an individual's requirements. This can also result in further costs for NHS, as the patient who has been using an inappropriate poor-quality appliance invariably will experience appliance leakages resulting in sore skin, which to resolve will require visits to SSCN clinic or a home visits as well as additional products such as powder or seals to resolve the sore peristomal skin.	Thank you for your comment. NICE recommends that stoma care services have access to a broad range of one-piece closed bags. Sections 3.1 and 3.8 of the guidance acknowledge the reasons for needing a colostomy and recognise that the needs of people with a colostomy vary from person to person, so access to a wide range of bags is required. Section 3.6 of the guidance highlights the need for shared decision making and acknowledges that the needs and preferences of a person with a colostomy will change over time. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSC may be worth paying more for.
Economic model				
26	Consultee 2 Hollister Ltd	1.3 Considerations for procurement and commissioning	It seems strange to make considerations for procurement pertaining to cost per bag and complications, given the same paragraph goes on to state "....values are uncertain and do not consider an overlap of complication resolution." This surely means any considerations are at best very speculative.	Thank you for your comment. Please see the response to comment 21.
27	Consultee 2 Hollister Ltd	1.3 Why the committee made these recommendations	The document states that "The cost effective price is highly uncertain..." This therefore would indicate that any conclusions/recommendations relating to	Thank you for your comment. Please see the response to comment 21.

			price would be highly flawed and not applicable.	
28	Consultee 2 Hollister Ltd	3.17 Model limitations	A number of model limitations are apparent and acknowledged by the EAG. 3.17 specifically states that ...."the results from the economic evaluation should be interpreted with caution." This same section concludes that "...caution should be taken when interpreting the model results because of uncertainty in model parameters" Speculative results, methodology uncertainty and lack of evidence are consistent themes throughout the document and indeed the whole process - this indicates that no truly meaningful conclusions and recommendations can be drawn.	Thank you for your comment. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSC may be worth paying more for. In relation to the uncertainty of the economic analysis, please see the response to comment 21.
29	Consultee 3 Coloplast	Not specified	While we thank the EAG for amending the health economic model as a result of some of the factual accuracy comments, we still see large issues with the model. The largest one is model assumptions being drawn based on the opinion of 1-2 CNSs, instead of using published evidence. Critically, the model assumes that the stoma related complications had a 100% resolution rate after 2-3 consultations with a stoma care nurse and no incorporated recurrence of complications. This does not reflect the reality where most people living with a stoma still struggle with recurrent leakages and Peristomal Skin Complications over many years – therefore requiring multiple nurse visits as their body type/stoma changes.	Thank you for your comment. The EAG rechecked the information found in the literature review and conducted a rapid, targeted search to identify any new literature. This found 1 additional paper (Brady 2025), which supplied some data on the quality of life impacts of PSC and leakage using the EQ-5D in a UK population (88% of participants having an ileostomy). No other data was identified, and no additional data was provided during consultation. The committee's discussion related to the additional evidence has been added to section 3.17 of the guidance.

			Therefore, the eJPs do not reflect real value of solving stoma-related complications.	Given the 1-year time horizon of the model (relating to an average year for a person with a colostomy), the EAG considered that the leakage health states, the leakage costs sources, and the number of PSC events per year already take into account the recurrence of complications. The model population considered people who had adjusted to their colostomy (1 year or more after surgery). In section 7.2.6 of the external assessment report, the EAG acknowledged that people with a new stoma (up to 1 year after surgery) are likely to have higher rates of complications and may need to try several different types of bags to find one that suits their needs. A change to body type or changes related to a person's stoma requiring a new type of bag can be reflected in the model as a model restart with the new bag. In relation to PSC, the model used data from Colwell (2018), which indicated that the number of PSC was 2.41 per year. Regarding leakage, the health states defined in the model capture the impact of multiple leakage events per year (with the most severe category assuming 4 events per month [with data available]). So, the EAG considered that the results reflect the value of stoma-related complications to the best possible extent given the limited data available.

				In relation to expert input, 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 HealthTech guidance outputs.
30	Consultee 3 Coloplast	Not specified	In response to Comment 27 on the economic model where we highlighted that GP visits had not been included in the PSC pathway, NICE stated 'None of the GPs consulted by the EAG had ever had contact with a patient in regard to stoma complications. They indicated that stoma care nurses and DACs were the primary places where contact would be made.' We would suggest that more information should have been gathered from a variety of GPs as we find this difficult to believe. We would have expected GPs to have come across issues related to dehydration, obstruction, pain at minimum. Could the Committee please clarify how many GPs were contacted?	Thank you for your comment. The EAG consulted with 3 GPs prior to production of the draft assessment report. They agreed that people with stoma-related complications would typically go to either CNS in stoma care or dispensing appliance contractors (DAC) in the first instance if experiencing complications. They also noted that people may present to the GP with acute problems, such as infection or bleeding, but stated that it is very rare to see these issues in practice. These discussions are reflected in the assessment report that states: "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)." This also aligned with input received from CNS in stoma care who did not consider that GPs were typically

				involved in the treatment of stoma-related complications.
31	Consultee 3 Coloplast	1.3 Considerations for procurement and commissioning	When consulting table 28 of the EAG Report, it is reported that solving leakage events happening twice a year is worth an incremental eJP per year of £1.58, whereas solving leakage events happening 4 times per month is worth only £1.22. In other words, it seems the EAG have concluded that the higher the incidence of a complication, the lower the cost to the NHS. Although this assumption was noted by NICE (in response to Comment 30 on the economic model) to be based on some clinical expert opinion, this exposes the weakness of the base assumptions which are the foundations of the model and the resultant recommendations. The eJPs should therefore be removed from the guidance because the underlying analysis is too uncertain.	Thank you for your comment. The eJPs for different frequencies of leakage events consider the total cost and the total QALY gains. In the mild leakage health state (leakage twice yearly), it is assumed that patients will not seek support from healthcare professionals due to the infrequent leaks, resulting in a yearly disutility for that health state. In the severe leakage health state (4 times per month), it is assumed that people initially experience high disutility, but then seek support from healthcare professionals, which resolves the complication. This allows them to progress to the "no leak" health state and achieve higher utilities after the complication is resolved. These assumptions resulted in a higher eJP for the mild leakage health state compared with the severe leakage health state. The EAG explored the impact of assuming that patients do not seek support for 4 leaks per month in scenario analysis in an addendum to the assessment report to understand the impact of uncertainty around support seeking behaviour. This did not change the committee's considerations.

32	Consultee 3 Coloplast	1.3 Considerations for procurement and commissioning	This section sets out the incremental economically justifiable price (eJP) to prevent complications as calculated by the EAG. It is positioned in the guidance so that it effectively forms part of the overall committee recommendations. However, the underlying EAG conclusions and committee considerations on its quality and reliability do not justify its inclusion in this section. In the executive summary of its report, the EAG acknowledged the limitations of the modelling used and stated (p12) that: "Overall, the analysis indicated that many current bag prices cannot be explained based on HRQoL and resource use impacts alone." The committee concluded in section 3.16 that: "further evidence is needed to evaluate the cost-effectiveness of bags with potentially innovative features." Thus, including these illustrative analyses with such significant uncertainty in the recommendations risks inappropriate and unsafe use by decision-makers.	Thank you for your comment. Please see the response to comment 21.
33	Consultee 3 Coloplast	1.3 Considerations for procurement and commissioning	We thank the EAG for their response to Comment 53 on the EAR. We accept that the model was made to inform the eJP, and bag prices should be the same before and after SCN intervention. We agree that the recurrence of PSCs was considered, however, the estimated recurrence of 2.4 per year is an underestimation (as noted in Comment 36 on the Economic Model) Finally, regarding the recurrence of leaks, we agree that the costs related to bags and	Thank you for your comment. No additional evidence was submitted during consultation to reflect that the estimated recurrence of 2.4 per year was an underestimation. The comment on the assessment report referred to the Martins (2012) and Meisner (2012) papers, which estimated 7.5 episodes per year. But, this estimate was not based on evidence. In relation leakage, please see the response to comment 29.

			accessories/supporting products, are modeled for the full model length. However (as stated in Comment 38 on the Economic Model), the model assumes that a single intervention is enough to fix the leakage indefinitely. This results in no further HCP costs being modeled, and no additional disutilities. We believe this is an underestimation of the complexity of stoma related complications. The Rolls 2022 TTO estimated an experienced disutility of 0.1140 for people experiencing 4 leakages per month. This should be used as the incremental utility in the eJP calculations, as there is no evidence suggesting leakages issues can be solved through a single treatment. Due to the uncertainty of the analysis, the eJPs should be removed from the guidance.	

34	Consultee 3 Coloplast	3.15 Model structure and parameters	As stated in Comment 32 on the EAR and Comment 31 on the economic model, this is not an appropriate reflection of the clinical reality. The Opus NaturFit makes up an insignificant share of the colostomy bag market as it is rarely prescribed. The comparator product used in the analysis should instead be chosen on the basis of features combined with a meaningful level of use in representative patient groups. The committee should consider removing reference to its pricing here as it encourages stakeholders to consider as their baseline price for a standard of care bag a product which does not represent typical NHS practice. The use of Opus NaturFit as a comparator is also contrary to the LSA interim process and methods statement which in section 4.14, states the objectives of the economic evaluation are to "when feasible and appropriate, develop an economic evaluation that represents current practice, based on national guidance and policy, real-world experience and recent data."	Thank you for your comment. During the assessment, the EAG was aware that the Opus NaturFit bag had a low market share. The EAG consulted with CNS in stoma care to see if a 'basic' bag could be defined to use as a comparator for the assessment. But, clinical experts agreed that no bag was considered 'basic' or would be classed as standard care. Section 3.15 of the guidance has been amended to reflect this. In response to consultation comments, the EAG presented a scenario in an addendum to the assessment report which used the cheapest bag with at least a 5% market share as an alternative comparator to the Opus NaturFit bag (in line with proposals for updating Part IX of the Drug Tariff consultation definition). The committee's discussion related to the scenario is summarised in section 3.16 and 3.17 of the guidance.
35	Consultee 3 Coloplast	3.16 Results of the economic evaluation	The economic evaluation fails to fully consider the long-term costs of complications caused by suboptimal pouch selection, such as increased nurse visits and additional prescriptions for treating skin breakdown. We would expect the cost of managing peristomal skin complications, infections, and emergency medical interventions to outweigh the initial savings from prescribing cheaper bags. We do not feel that all the available evidence has been considered, including:	Thank you for your comment. The economic evaluation considered 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 evidence to suggest the impact of complications would change over time (time dependency) outside of the initial post-surgical period. The evaluation included increased CNS in stoma care visits and additional prescriptions associated with

			o NHS England's 2020 Stoma Care Report found that poorly managed peristomal skin complications increase overall NHS expenditure by requiring additional treatments. o Clinical studies consistently demonstrate that prevention is more cost-effective than treatment.	treating PSCs (see Table 20 of the assessment report for further detail about the assumptions made). The eJP for a bag which prevents PSCs (£4.24 for flat and £4.69 for non-flat) was higher than the price of any of the bags available on the Drug Tariff at the time of the assessment, indicating the high level of value that would be placed on a bag that fully prevents these types of complications for people with a colostomy. Thank you for your comment. The EAG's assessment report refers to the delivering excellence in stoma care: a guide to implementation commissioning report. It highlights a number of issues with stoma management which were discussed in the assessment report including: • 62% of patients had not seen a CNS in stoma care about their stoma in over 2 years • 21% of stoma prescribing costs were for accessories that were not contributing to improved outcomes • 35% of people reported sore skin • 62% of people reported leakage • sponsored CNS in stoma care posts in acute trusts • limited GP familiarity with products and DACs ordering on behalf of people with a stoma. The report notes that, based on pilots, they estimate a 20% reduction in overall spend, releasing annual savings of £56 million, could be achieved if better practices were adopted

				in the selection, ordering and supply of stoma care products, and recommended formulary choices and prescribing quantities were implemented in addition to improved quality of care. The report does not provide any estimates of the resources currently used for the management of complications which could have been used to inform the economic analysis. The EAG conducted a review of economic literature to inform this assessment which found 13 relevant articles. The most relevant was Berger (2018), but this assessed 2-piece closed bags and made a number of assumptions which were not supported with clear evidence. The Martins (2012) study was the only other economic analysis that evaluated the use of a stoma bag. This study looked at a mixed population (including people with colostomy and ileostomy), evaluated mixed variations of the SenSura bag (both 1- and 2-piece closed and open bags), and compared outcomes with a mixed comparator. This made results difficult to interpret in the context of this assessment. The EAG did take the learnings from all 13 of the studies identified and applied them to the analyses as far as was feasible with the available data (see Section 7.1 of the assessment report for further detail).

36	Consultee 3 Coloplast	3.16 Results of the economic evaluation	The eJPs included in this guidance could be mis-interpreted as the 'acceptable' price range in practice, which would be incorrect as these results are based on a model with fundamental issues, specifically the lack of evidence available to inform it, with some assumptions that made the results too theoretical to be useful to inform decision making. Please see our comments on the model under Section C pg 155-166 The limitations have been acknowledged by the EAG on page 19.' 'The model has a number of limitations and results from the economic evaluation should be interpreted with caution.' We urge the committee to clearly outline the many limitations of the modelling in the guidance and reconsider the inclusion of these highly uncertain eJPs.	Thank you for your comment. In relation to the eJPs and uncertainty of the economic analysis, please see the response to comment 21. NICE has presented the results from the EAG's economic analysis in the guidance but has stated the maximum extra cost per one-piece closed bag to completely or partially prevent complications, rather than making recommendations on the appropriate costs for one-piece closed bags with potentially innovative features, due to the lack of available evidence. The EAG notes that the number of assumptions required in the economic analysis is due to the lack of evidence available to address the decision problem. The EAG does not consider the issues noted on pages 155/156 of section C to be enough to invalidate the analysis. The specific issues raised on these pages relate to: • Presentation of results for features which may fully address a particular complication alongside results which look at features which may fully or partially address all complications. Given the lack of data to inform alternative analyses the EAG considers this to be a reasonable approach and has detailed the issues involved with considering the impact of multiple complications additively and how this analysis should be interpreted in the assessment report.

				• The use of data from the only published source available for the impact of stoma resiting on quality of life. No alternative data has been suggested during consultation and the impact on the eJP is approximately £0.05. • Perceived internal inconsistency in the utility decrements associated with the presence of bleeding due to a PSC and the likelihood of switching bags. The EAG noted that 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. • The use of data from sources with a mixed population to populate certain model parameters. The EAG clearly described the limitations of using data from mixed populations and from studies with people with an ileostomy and adjusted data based upon expert input where possible. This evidence was used due to a lack of evidence for people with a colostomy.

37	Consultee 3 Coloplast	3.17 Model limitations	The limitations should clearly state the degree to which the model was informed by assumptions and limited expert opinion. As noted in Comment 44 on the EAR and its subsequent response, key assumptions around the impact of complications were driven by the expert opinion of two clinical nurse specialists. This is again seen in our feedback in Comment 21 of the economic model, where a single nurse specialist was used to inform assumptions on treatment time, and again in Comment 30 of the economic model, where an assumption was made on the basis of expert feedback that 4 leakage events per month was less impactful on HRQoL than 2 events per year. The Committee has concluded that caution should be taken when interpreting the model results. In light of the highly uncertain assumptions which underpin the model, we suggest that no recommendation on cost beyond highlighting the need for more evidence is warranted, that eJPs should be removed from the guidance, and that this limitation be more clearly described in section 3.17	Thank you for your comment In relation to the eJPs and uncertainty of the economic analysis, please see the response to comment 21. The EAG used clinical expert input to inform certain model parameters in the economic analysis due to the lack of evidence available to address the decision problem. To clarify, the EAG did not assume that 4 leakage events per month was less impactful on quality of life than 2 events per year. The EAG used the data from the Rolls (2022) study, which has a disutility of 0.114 for 4 events per month compared with 0.022 for 2 events per year. The EAG assumed that people experiencing 2 events per year were less likely to seek support and have their complications resolved, based on input from CNS in stoma care. This resulted in a larger eJP being predicted for twice yearly leaks compared with monthly leaks, as the reduced cost from not seeking support outweighed the impact on quality of life. The EAG explored the impact of assuming that patients do not seek support for 4 leaks per month in scenario analysis in an addendum to the assessment report to understand the impact of uncertainty around support seeking behaviour. This did not change the committee's considerations.

38	Consultee 3 Coloplast	3.17 Model limitations	It should be clearly stated in the limitations that the resolution rate of all other stoma-related complications except PSCs was assumed to be 100% as a result of a single treatment course (see Comment 19 on the economic model). This model assumption was made based on an SCN statement, which likely has led to an underestimation of the costs related to these complications. This statement stipulates that “for most people they can resolve issues within 2-3 consultations, and they wait 2 weeks between consultations”. The impact of this is that for the comparator engine, these complications only occur once for the model duration and are then assumed resolved. However, the research on stoma-related complications conducted by the EAG clearly states that they are still highly prevalent today, and a recurrent issue. Therefore, the modeled stoma-related complication costs are underestimated, leading to an eJP not reflecting the true value of resolving the complications. The committee should not include in the guidance incremental eJPs that are derived from such a limited model as they are highly uncertain and will likely not be understood in their full context.	Thank you for your comment. To clarify, the model assumed that the resolution rate was 100% after a set number of weeks per complication, with the number of weeks informed by the number of visits expected to be required to try different solutions to resolve the complications (for example, different bags, supporting products, medications [where appropriate] and other management suggestions from CNS in stoma care). The EAG explored scenarios around longer time to resolution for these complications to explore the model’s sensitivity to this. To note, resolution was defined in the assessment report as ‘resolution to an acceptable level’ (see page 107 of the report). In relation to the eJPs and uncertainty of the economic analysis, please see the response to comment 21.
39	Consultee 3 Coloplast	3.17 Model limitations	Could the Committee please include more information on the limitations inherent to the use of Structured Expert Elicitation, as discussed in Comment 127 on the EAR?	Thank you for your comment. The EAG provided a full description of the structured expert elicitation (SEE) exercise conducted in Section 7.2.5 of the assessment report. The limitations and uncertainty of the economic analysis are also discussed in section 1 and section 3.18 of the guidance. Known limitations of SEE are:

				• Subjectivity and bias: experts may be influenced by their own experiences, cognitive biases (for example, overconfidence, anchoring), or group dynamics if elicitation is conducted in a panel setting. The EAG conducted training and provided an evidence brief to reduce the chance of such biases impacting results and conducted individual elicitation exercises to eliminate the possibility of group dynamics impacting the results. • Expert selection issues: the validity of SEE depends on selecting a representative and knowledgeable panel. The EAG received 7 responses from CNS in stoma care who were selected by NICE to participate in this process due to their topic expertise. This is above the minimum of 5 recommended in the medical research council protocol. The experts involved had a mean of 11.5 years of experience working with people with stomas. The experts provided good coverage of the different settings of care and a reasonable coverage of different geographies. • Difficulties in quantifying uncertainty: experts may struggle to provide accurate probability distributions, especially for highly uncertain or unfamiliar topics. The EAG provided training to experts to aid in understanding and checked the wording of questions with the experts to ensure these were understood. In

				addition to the steps planned within the protocol, a call was organised with the clinical experts to agree the estimates to provide greater certainty in outputs. • Cognitive load and fatigue: providing structured probabilistic estimates can be cognitively demanding, leading to potential inaccuracies if experts become fatigued or disengaged. The EAG kept the number of questions to the minimum required to populate key gaps in the economic analysis. • Ethical and conflict of interest concerns: experts may have personal or professional interests that could bias their judgments, particularly in regulatory or policy-related decisions. NICE have recorded all potential conflicts and considered these carefully in specialist committee member selection. The EAG noted that the complications which were most dependent upon input from the SEE (ballooning, pancaking, bad odour, discreetness and preferred appearance) were not considered to be as important in the user preference work as other areas where more robust data was available (leakages and PSC).

40	Consultee 3 Coloplast	3.17 Model limitations	As noted in Comment 22 on the Economic Model: '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' This further reinforces that the basis for the eJPs is not strong enough for inclusion in this guidance and that they should be removed.	Thank you for your comment. No data was available at the time of the assessment to inform how different features or bags might reduce the impact of complications differentially. So, this functionality was not included in the model. No further evidence has been supplied during consultation. With the evidence available, the EAG presented the eJP associated with fully or partially addressing individual complications as well as scenarios associated with addressing multiple complications alongside the limitations associated with these scenarios. In relation to the eJPs and uncertainty of the economic analysis in the guidance, please see the response to comment 21.
41	Consultee 4 Individual	3.15 Model structure and parameters	I appreciate the Opus Naturfit is cheaper but we performed a local audit and the outcome was very low patient satisfaction.	Thank you for your comment. Please see the response to comment 34.
42	Consultee 12 Individual	Not specified	It may be worth separating the pricing of bags depending on whether they are flat or convex, or mini, as a flat baseplate is usually cheaper than a convex, or mini bag. Additionally, it is worth mentioning that the only companies offering bags cheaper than the average of £2.9 for flat or £3.3 for convex are the following 3 brands - Protea (£2.46), Marlen (£2) and Opus (£1.86). May be worth looking at their products to better understand why there is such a drastic difference, as all other 15 brands provide their bags and similar prices. Currently, those 3 brands do not provide products for more than 1% of all	Thank you for your comment. Bag pricing for the assessment was separated into flat and non-flat bags. In response to cheaper bags having a lower market share, please see the response to comment 34.

			colostomy patients, therefore, it would be interesting to seek opinions from these patients and see how were they introduced to these brands and why and what their opinions were.	
43	Consultee 13 Convatec	Not specified	The guidance offers no clear recommendation and as such is unlikely to alter the current practice today. The findings state that pouches cannot be said to fully prevent complications. This is an invalidated claim and experience from DACs can demonstrate that a well fitted pouch with the correct formulation can ensure that ostomates do not experience leaks, which is the main contributor of Peristomal Skin complications.	Thank you for your comment. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for people with a colostomy and that if more than one type of bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. The wording 'fully preventing complications is unlikely' has also been removed from the guidance.
44	Consultee 13 Convatec	1.3 Considerations for procurement and commissioning	The reader will need reference to baseline cost if this paragraph is to remain as guidance. Also this baseline cost will become quickly dated (possibly prior to publication)	Thank you for your comment. NICE has presented the results from the EAG's economic analysis in the guidance but has stated the maximum extra cost per one-piece closed bag to completely or partially

				prevent complications rather than making recommendations on the appropriate costs for one-piece closed bags with potentially innovative features, due to the lack of available evidence. Information about the baseline bag prices used in the economic analysis are in section 3.15 of the guidance.
45	Consultee 13 Convatec	1.3 Considerations for procurement and commissioning	How can a limitation be applied when a complication such as leakage is ranked as high importance to the user? There is no data to support that 4 times per month is the average or maximum occasions that leakage occurs and as this is a primary driver within user preference, then no limitation should be stated.	Thank you for your comment. The health state of 4 leakages per month was chosen as it aligned with data on quality of life presented in Rolls (2022) and Scheffel (2023). It should not be interpreted as either the average or maximum occasions that leakage occurs. The Rolls (2022) paper notes that the number of leaks asked about in the vignettes was based upon: • current knowledge regarding patient experiences with leakage events (referenced to the ostomy skin tool 2.0) and • workshop discussions with health economic and medical experts.
46	Consultee 13 Convatec	1.3 Considerations for procurement and commissioning	As values are so uncertain, should this be included within the guidance?	Thank you for your comment. Please see the response to comment 21.
47	Consultee 13 Convatec	3.14 Regression analysis	Subjective opinion rather than validated fact	Thank you for your comment. The wording around the results of the EAG's regression analysis has been amended in the 'what this means in practice (considerations for procurement and commissioning)' section of the guidance to improve clarity.

48	Consultee 13 Convatec	3.14 Model structure and parameters	Finding the correct pouch that eliminated leakage, pancaking, skin complications would in itself save on costs. The cost of interactions with HCPS the cost of products used including accessories and the impact on the patient. it could mean the difference between staying at home or going back to work. It's not really about the cost of the bag itself it is more about ensuring that patient pathways allow for the opportunity for the correct product to be used in the first place; This is where the cost savings will happen.	Thank you for your comment. The cost of interactions with healthcare professionals and products, including supporting products, are included in the economic analysis. Costs associated with productivity and return to employment were not included as costs were considered from an NHS and Personal Social Services perspective only, as detailed in the final scope. NICE recommends bag selection to be based on clinical appropriateness and meeting the needs and preferences of the person with a colostomy first and then choosing the least expensive bag is more than one option is suitable.
49	Consultee 13 Convatec	3.15 Model structure and parameters	For consistency, model should reflect that being used for DT evaluation purposes (eg min 5% market share)	Thank you for your comment. Please see the response to comment 34.
50	Consultee 13 Convatec	3.15 Model structure and parameters	As previously stated that this product used as the baseline is an outlier, the low market share of this brand would indicate that a product with minimum 5% market share would be a better fit as baseline comparator - as per draft guidelines for DT evaluation matrix.	Thank you for your comment. Please see the response to comment 34.
51	Consultee 13 Convatec	3.16 Results of the economic evaluation	Whilst the price positions being included help with the understanding, it will create misleading guidance as the price points incrementally change as per DT current price review mechanism. Even by time this guidance is published, we could potentially see an increase to base price being used.	Thank you for your comment. Please see the response to comment 44.

52	Consultee 13 Convatec	3.16 Results of the economic evaluation	this should include healthcare costs of support that sit with manufacturers and upon which a high % of stoma patients rely.	Thank you for your comment. Section 7.4 of the assessment report acknowledges published information and information provided by companies on sponsorship. It was outside the remit of the assessment to quantify the impact of sponsorship or its removal.
53	Consultee 13 Convatec	3.17 Model limitations	This is at odds with DT reform mechanism being applied; therefore inconsistency of approach between two aligned processes!	Thank you for your comment. Please see the response to comment 34.
54	Consultee 13 Convatec	3.17 Model limitations	Therefore we would propose to remove eJP from guidance altogether and focus on shared decision making	Thank you for your comment. The guidance prioritises the person's needs and preferences and emphasises the importance of clinical appropriateness when choosing a one-piece closed bag via shared decision-making. In relation to the eJP, please see the response to comment 21.
55	Consultee 15 CliniMed Ltd	1.3 Considerations for procurement and commissioning	We are concerned that the considerations presented regarding price differentials are misleading given that the analysis has been presented elsewhere in the document as having "a number of limitations and the results of the economic evaluation should be interpreted with caution". Our concern is that they may not be interpreted with caution when presented as a snapshot of the analysis. The variability in pricing associated with the EAG's eJP clearly show the subjectivity and complexity in focusing purely on price and then trying to establish a suitable uplift per complication. Feedback from the patient associations shows the prevalence of complications clearly	Thank you for your comment. Please see the response to comment 21.

			demonstrating one product is not suitable for all.	
Equality considerations				
56	Consultee 6 Individual	3.22 Evidence needed to demonstrate additional value	You also need to take into account differing skin tones. Most stoma bags are neutral / pink in colour. Not all stoma patients have neutral / pink skin tone which means those patients have an added level of potential difficulty coping with their supplies - both practical (stoma item colour stands out under clothing) and emotionally. It's hard enough adjusting to life with a bag, but one that is of a different colour can cause some people added problems	Thank you for your comment. Section 3.8 states that 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. Section 3.23 encourages evidence to be collected across different groups of people with a colostomy, to reflect their varying needs.
57	Consultee 14 Ostique Limited	Not specified	4. Equality & Accessibility Considerations 4.1 Meeting the Needs of Diverse Patient Populations NICE's consultation highlights the need to ensure equal access to suitable colostomy bags for all patients, including those with protected characteristics under the Equality Act (2010). Ostique's products address several key gaps: - Accessibility for People with Disabilities: Our conformable baseplate is particularly beneficial for individuals with limited dexterity or mobility impairments, making application and removal easier. - Support for Psychological Well-being: The noise-reducing technology in our bags specifically benefits individuals who experience heightened anxiety or sensory sensitivities (e.g., autistic individuals or those with PTSD).	Thank you for your comment. Section 3.8 of the guidance discusses equality considerations including that 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. The recommendations in section 1 state that a broad range of bags should be available and bags people with a colostomy should be offered a bag that meets their needs and preferences.

			We urge NICE to incorporate these considerations into the final guidance, ensuring that the NHS supports patient-centred, inclusive, and equitable colostomy care.	
Implementation				
58	Consultee 3 Coloplast	1	As we noted in our response to the key stakeholder survey on the committee's initial findings, the current recommendations could come into conflict with each other if presented as standalone items. Each recommendation should be implemented in the order presented during the decision-making process, meaning that first stoma services must have access to a full range of products, then HCPs and patients engage in SDM, and finally, once they've narrowed the selection down to those that meet the needs and preferences of patients, costs may be considered. As it stands, a budget holder may use recommendation 1.3 in isolation to limit access to products – running contrary to the intentions of recommendation 1.1 and 1.2. We ask that NICE make this priority designation clearer in the final guidance. Note: although there is reference to recommendation 1.3 here, we disagree that the evidence and real-world experience supports this conclusion (see references to section 1.3)	Thank you for your comment. The wording and order of the recommendations have been amended to make it clear that only if more than 1 type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used.

59	Consultee 3 Coloplast	1.1 1 Recommendations	As we stated in our response to the key stakeholder survey of the committee's initial findings: '[the committee] should add clarity to this statement by recommending that local payers not restrict access to any stoma bags listed on Part IX of the Drug Tariff via formularies, and that the stoma care nurse should have the flexibility to choose any listed bag that meets the clinical and lifestyle needs of patients. Any attempt made by local payers to implement a formulary could amount to a post code lottery of care, where more effective or preferential products are restricted from a shared decision making (SDM) process. Additionally, although we agree services should have access to the full range of products, there are many factors that are not addressed in this guidance which stand as obstacles to this aim. It is clear that there is already a significant variation in the type of stoma care received across the UK, amounting to a post-code lottery (Bowles, 2022).'	Thank you for your comment. Section 1 of the guidance states that stoma care services should have access to a broad 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. The wording and order of the recommendations have been amended to make it clear that only if more than 1 type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. Section 3.4 of the guidance highlights the need for a standardised care pathway for people with a colostomy and has been amended to include reference to the standardised mandatory stoma care pathway that is currently being developed by the Association for Stoma Care Nurses UK.
60	Consultee 3 Coloplast	1.3 1 Recommendations	As we stated in our response to the key stakeholder survey on the committee's initial findings, 'Overall, [this] whole recommendation will be interpreted by the job role that reads the guidance. In the hands of budget holders with limited knowledge in the field of stoma care, the entire guidance will be eclipsed by the word 'cheapest' (note: this has been changed to 'least expensive' in the draft guidance for consultation), and choice at the clinician and patient level may be limited to those deemed by local budget holders to	Thank you for your comment. Please see the response to comment 58.

			be the cheapest of 'equivalent' products. This will compromise patient choice as cheaper and lower quality products may be produced by some manufacturers and favoured by budget holders, leading to increased anxiety and a lack of confidence in products for patients as well as potentially worse clinical outcomes in terms of peristomal skin infections.'	
61	Consultee 3 Coloplast	1.3 1 Recommendations	By recommending the use of the cheapest bag wherever possible, NICE risks driving manufacturers to discontinue higher-quality products. Limiting choices based on cost alone threatens innovation in stoma care, potentially leading to a narrower range of products, forcing patients into suboptimal choices. This potential loss of choice directly contradicts NICE's commitment to patient-centered care.	Thank you for your comment. Please see the response to comment 58.
62	Consultee 3 Coloplast	1.3 Considerations for healthcare professionals	These LSAs set out to: 'address a need' and assess 'clinical and cost effectiveness.' In this case, the EAG has not been able to prove or disprove either of these things. The committee should therefore exercise caution in formulating recommendations based on this absence of evidence. The use of the phrase 'least expensive' may unintentionally become a tool used to limit product selection in this highly personalised therapy area. This wording encourages the use of local low-cost formularies, whereby bags that are deemed too expensive will not be listed, thereby preventing the SDM	Thank you for your comment. The aim of LSA is to assess if the value added by incremental innovation justifies the price variation of a group of products. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSC may be worth paying more for. The wording and order of the recommendations have been amended to

			process encouraged in recommendation 1.2 (please see also our related comment 49 on the EAG report). The use of such formularies will limit patient choice and preferences based on an absence of evidence and will therefore contravene the mission of the LSA programme. This guidance encourages a race to the bottom on price, it does not look to reward innovation or recognise the complexities in stoma care. It has taken a black and white approach to a grey area – deeply personalised healthcare.	make it clear that only if more than 1 type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. The recommendations have been written in line with the late-stage assessment interim process and methods statement and other LSA pilot topics.
63	Consultee 5 Colostomy UK	1.3 Considerations for people with a colostomy	Can a document be produced for circulation to all stoma care departments which has to be given to patients and explains this in similar wording so people understand. Can they be signposted to third sector organisations for support with this if needed?	Thank you for your comment. NICE has included the 'what this means in practice (considerations for people with a colostomy)' section in the guidance to provide additional information to people with a colostomy related to choosing a one-piece closed bags, the findings of this assessment and when to seek help from a healthcare professional. An information for public page will also be created alongside the guidance for when the guidance publishes. This will provide information in simpler language to help people with a colostomy understand the guidance. NICE encourages stoma care services to use this information to help support their service users.

64	Consultee 5 Colostomy UK	3.5 Variation in care pathway	have the impact of the likelihood of the recommendations being carried out in practise been considered based on the sponsorship agreements in place.	Thank you for your comment. The aim of LSA is to provide help 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 committee were informed that sponsorship could influence the choice of bag, as stated in section 3.5 of the guidance. The 'what this means in practice (considerations for healthcare professionals)' section of the guidance encourages the decision of which bag to choose to be made based on clinical appropriateness and the needs and preferences of the person with a colostomy, free from sponsorship influence.
65	Consultee 6 Individual	1.1 1 Recommendations	The NHS should have one overarching formulary for all approved stoma related items: the formulary should be fair for the patients but also potential savings for the NHS are huge with a standard formulary	Thank you for your comment. The aim of LSA is to provide help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.
66	Consultee 6 Individual	1.3 Considerations for procurement and commissioning	Back to the one agreed formulary - stop the postcode lottery in supplies available	Thank you for your comment. Please see the response to comment 65.
67	Consultee 6 Individual	3.17 Justification for price variation	I feel there are currently enough options available to patients to patients for their stoma. We need to streamline this number of options (taking into consideration the outlying patients with added complications: cancer, chemo etc) and remove the expensive products from the Drug Tariff that are found to be no better than the less expensive ones.	Thank you for your comment. Please see the response to comment 65.

68	Consultee 10 Eakin Healthcare	1.3 Considerations for healthcare professionals	How will NICE / NHS ensure that choice will be free from the influencer of sponsorship? The guidance here will be totally ineffective on how this will be achieved / enforced.	Thank you for your comment. Please see the response to comment 64.
69	Consultee 15 CliniMed Ltd	1.3 1 Recommendations	We are concerned regarding how the recommendation may be implemented. The idea that the lowest price product should be the starting point potentially removes clinical appropriateness or patient preference from the decision making process. We believe that the references to a price should be removed. The work of the LSA has identified that there was weak evidence to the required level of the review regarding value, but this does not mean that price variation isn't justified. The report recommends that more evidence is needed to show if certain bags are more effective than others. Implementing a recommendation that promotes prescribing to the lowest price does not feel appropriate in this context. We have concerns that the recommendation may be used to reduce cost at the expense of user preferences and appropriateness with associated negative impacts on the person with a colostomy. Focussing purely on lowest cost may restrict / remove patient choice from any discussions on the most appropriate product. Undue pressure, even if unintentional, could be brought to bear on users, with the acceptance of a poorer performing product and a concomitant reduction in their quality of life.	Thank you for your comment. The wording and order of the recommendations have been amended to make it clear that only if more than 1 type of one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, the least expensive option should be used. In relation to the incremental eJPs included in section 1 of the guidance, please see the response to comment 21.
Levels of evidence and further research				

70	Consultee 1 Individual	1.3 What information is needed	The paucity and poor quality of existing information/evidence is recognised many times throughout these documents. The committee recommends more extensive surveys and polling of patients, etc. However it is glaring that there seems to be no NHS technical or scientific standards/specifications for stoma bags? My personal bag choice was reached eventually via trial and error. My selections relied on manufacturer advertising and user experiences shared on private Facebook groups. There was was no independent information available to compare bags in an objective way. There is no reason why bag size, volume, filter effectiveness/ballooning ratio, pancaking susceptibility, baseplate breathability,outer material noisiness, etc. could not all be lab measured/tested and presented in standard scientific units to allow bag comparisons. Even leakage susceptibility should be able to be measured if medical engineering scientists applied their expertise to this particularly distressing problem.	Thank you for your comment. The guidance acknowledges that a range of bags should be available to meet the needs of everyone with a colostomy, understanding that each person has different clinical requirements and preferences. NICE conducted this independent assessment and found that there was limited clinical evidence to differentiate between one-piece closed bags and their potentially innovative features. NICE has recommended further evidence collection to encourage companies to prove that these features could improve clinical outcomes.
71	Consultee 1 Individual	3.19 Evidence needed to demonstrate additional value	Although laboratory evaluations were excluded as being inappropriate for this assessment, I would suggest that the committee adds a recommendation for the setting up of an NHS scientific panel to devise technical standards for stoma bags. A minimum performance specification should be published. Manufacturers would then strive to exceed this standard. Innovation would then be	Thank you for your comment. This assessment excluded technical studies of bags or their features that were done in a laboratory. This was because they did not provide clinical outcomes that were relevant to the assessment and would not be meaningful to understand the potential benefits of one-piece closed bags for people with a colostomy. NICE has recommended further evidence collection to encourage

			objectively measurable and rewarded via a higher bag cost.	companies to prove that these features could improve clinical outcomes across different groups of people.
72	Consultee 2 Hollister Ltd	Not specified	NICE level evidence has never been required either for Reimbursement purposes or Regulatory purposes for this product category. It therefore seems counter intuitive for NICE to expect it to exist and be measurable in the LSA process. Should such information be required in the future then NICE need to set out future expectations with clarity and importantly be cognizant of the fact that a considerable period of time will be required to gather such evidence. None of this appears to have been taken into account in the current LSA process relating to Colostomies.	Thank you for your comment. The aim of LSA is to assess if the value added by incremental innovation justifies the price variation of a group of products and the EAG conducted an evidence review for the available evidence evaluating one-piece closed bags for people with a colostomy. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSCs may be worth paying more for. 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.

73	Consultee 2 Hollister Ltd	1.3 1 Recommendations	Stating there is not enough evidence to justify price variations is not the same as saying price variations are not actually justified - as per general comments, it should have come as no surprise to NICE that evidence was not available because it has never been required historically for either reimbursement or regulatory approvals. It therefore seems an erroneous conclusion to then link this lack of evidence to choosing the cheapest product.	Thank you for your comment. Please see the responses to comments 9 and 72.
74	Consultee 2 Hollister Ltd	1.3 Considerations for procurement and commissioning	Again, reference is made to lack of evidence to justify price variation - this is because NICE level evidence has never been required for either Reimbursement or Regulatory requirements for these products. This does not mean price variation is not actually justified.	Thank you for your comment. Please see the response to comment 72.
75	Consultee 3 Coloplast	Not specified	Please can NICE add text to the guidance document to explain what process will be used to monitor evidence generation and to review and update the guidance when further information is available. This is also important because the reform of Part IX of the Drug Tariff, which is proceeding in parallel with late-stage assessment, may result in changed NHS categorisation and/or prices of the products under evaluation.	Thank you for your comment. LSA has a different purpose in the lifecycle approach compared with early value assessment (EVA). Evidence generation plans are created for EVAs where there are new groups of technologies that have the potential to meet an unmet need in the NHS. Here, further data collection or evidence generation is needed before they can be recommended for routine use in the NHS. Technologies considered by LSA are expected to be evidence based as they are already in widespread use in the NHS and the aim of LSA is to support procurement and commissioning decisions. This is because products within a category may have undergone continuous improvement or incremental innovation, leading to price variation. However, part of the committee's

				considerations for LSAs is a gap analysis of the existing evidence base as detailed in the 'What information is needed' section of the guidance. This can be used by industry to strengthen the evidence base and prove that these potentially innovative features improve clinical outcomes.
76	Consultee 3 Coloplast	1.3 What information is needed	For the key outcomes and information that should be captured NICE should provide guidance on how this information should be collected and measured to ensure that there is no variance in data collected.	Thank you for your comment. Section 3.22 of the guidance acknowledges that a core outcome set is needed and highlights that outcomes are not reported or measured consistently across studies. It also suggests that psychometrically validated patient-reported outcome measures to measure bag-related quality of life should be developed.
77	Consultee 3 Coloplast	3.10 Clinical evidence included in the assessment	The features of the stoma products that are the object of this investigation are almost identical across the 1pc and 2pc product ranges. This is true for the people who use the products, who, apart from specific use needs, are facing identical challenges in their lives with a stoma regardless of the time a baseplate is worn. Concerns for generalisability of the evidence must therefore have outweighed the benefit the extended evidence base would have provided. In the light of the quality and quantity of the already included literature, we believe that all related evidence would have been an improvement to the evidence base. The EAG, however, has excluded this opportunity without any further argumentation than a feeling that data "may not be generalisable" and then subsequently	Thank you for your comment. Given the lack of evidence, the EAG sought CNS in stoma care opinion during the assessment to determine whether evidence from people with an ileostomy and for 2-piece bags in people with a colostomy should be considered. There was no consensus that the evidence on ileostomy was generalisable and so it was not included in the clinical evidence review. But, there was some transferability of the evidence for 2-piece bags. The scope was broader for the economic model which did consider evidence from ileostomy studies. Details of the decision making and additional evidence considered were presented in appendix E and J in the assessment report. The choice to restrict the evidence considered was due to the issues related to

			concluding on the same feeling. This is insufficient justification to not assess potentially relevant evidence, especially when - as the EAG noted in its report, it was also restricted by the amount of work possible in the time allowed	the transferability of the data and not time restrictions.
78	Consultee 3 Coloplast	3.11 Evidence on potentially innovative features	Re-iterating “absence of evidence is not evidence of absence” seems appropriate here. We suggest rephrasing this sentence to ‘The committee concluded that there is insufficient evidence to determine 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’	Thank you for your comment. The committee considered the alternative wording and decided not to make a change to the guidance. This is because there is not enough evidence to show that one bag or feature is better than another.
79	Consultee 3 Coloplast	3.12 Outcomes and populations	We agree that it would be interesting to involve people with damaged skin in studies on our products, but as majority of (and all closed) stoma bags are, for the purposes of regulatory approval, categorised as class one products, there are limitations to who we are allowed to involve in our studies. Class 1 stoma bags are not to be used on broken skin and, therefore, studies are often limited to mild PSCs, which does not give a representative reflection of people living with a stoma. Further research before market launch in people with broken skin would require upclassification which seems neither likely nor viable, or post-market studies where it is difficult to engage clinical researchers.	Thank you for your comment. The ‘What information is needed’ section of the guidance states what evidence should be collected based on the evidence gaps identified during the assessment to support future procurement decisions and shared decision making by healthcare professionals and people with a colostomy. NICE cannot provide advice on regulatory matters but advice could be sought from appropriate regulatory bodies around research outside of product regulatory classification or changing regulatory classification.

80	Consultee 3 Coloplast	3.12 Outcomes and populations	Not all of the relevant evidence has been considered because this conclusion is a direct consequence of the extremely narrow decision problem where only colostomy bags are in focus. Apart from excluding a significant part of the colostomy population that uses open bags, this decision excludes an extensive pool of research that includes outcomes such as leakage, PSCs and HRQoL. It is therefore not only a question about a lack of evidence, but to a high degree a matter of an initial research question that is too narrow to make sense in a real-life- and clinical setting. Additionally, the EAG did not consistently apply the narrowed focus on colostomy and included some sources which included other stoma or bag types when it suited, which further calls the methodology into question. We have raised this concern from the very beginning of the process (see Comment 105 on the EAG report) and maintain that not all of the relevant evidence has been considered.	Thank you for your comment. Please see the response to comment 77.
81	Consultee 3 Coloplast	3.14 Regression analysis	As noted in Comments 97 on the EAR, colostomy bags should be evaluated based on the combined features of a bag, their interplay and how they work together to deliver optimal care rather than the incremental impacts of individual features. Manufacturers rarely investigate the impact of a single feature but include a large range of improvement to each range of products. This is in part also due to the huge number of individual products needed for each range.	Thank you for your comment. The regression analysis aimed to determine the relationship between the price of one-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 these features. The regression analysis did not look at the impact of features on outcomes. This analysis was 1 part of the

				EAG's 3-part analyses. The other 2 parts (calculating an eJP for bags preventing or reducing complications and an exploratory analysis looking at whether the difference in bag price was explained by the difference in outcomes where head-to-head comparisons existed) are more appropriate to look at the impact of combinations of features on outcomes.
82	Consultee 3 Coloplast	3.20 Evidence needed to demonstrate additional value	Coloplast believes that this is the central finding of this LSA, and that it undermines recommendation 1.3. NICE should replace recommendation 1.3 with an acknowledgement that further evidence is needed. As we have said repeatedly, the absence of evidence is not the evidence of absence, and as it stands this guidance promotes practices that would not be supported by the evidence.	Thank you for your comment. Please see the responses to comments 9 and 10.
83	Consultee 3 Coloplast	3.20 Evidence needed to demonstrate additional value	We support the committee's conclusions on the challenges of evidence generation in stoma care. These were identified during scoping and yet the evaluation proceeded, holding the evidence to a standard already known to be unachievable. This section should be amended to reflect the context of regulatory and policy requirements for evidence on colostomy bags, in order to avoid unrealistic expectations in healthcare decision-makers. We agree that a new agenda for evidence generation is needed in our industry and wish to work alongside NICE to generate the highest possible quality of evidence to show value for money for the NHS and its patients. However, this transition will not happen overnight and will require a roadmap that industry can reasonably adhere	Thank you for your comment. Please see the responses to comments 72 and 79.

			to. We have previously highlighted the challenges in evidence generation in Comment 97 on the EAG report, and we ask that our comments be reconsidered.	
84	Consultee 3 Coloplast	3.21 Evidence needed to demonstrate additional value	We ask that NICE add some context or recommendations on how to proceed with this work, which stakeholders should be involved, and on what timescale evidence should be expected.	Thank you for your comment. Part of the committee's considerations for LSAs is a gap analysis of the existing evidence base as detailed in 'what information is needed' and section 3.21 to 3.23 of the guidance. The aim of the further evidence recommendations is to guide what research is needed to strengthen the evidence base for companies to prove that these potentially innovative features improve clinical outcomes and to aid future procurement and commissioning decisions.
85	Consultee 3 Coloplast	3.22 Evidence needed to demonstrate additional value	We agree with this sentiment and thank NICE for it. However, it should be caveated by the challenges of collecting evidence in certain patient groups. For example, stoma bags are not to be used on broken skin, and therefore, studies are often limited to mild PSCs, which does not give a representative reflection of people living with a stoma. However, as an industry we are limited by the product classification and regulations.	Thank you for your comment. Please see the response to comment 79.
86	Consultee 4 Individual	3.11 Evidence on potentially innovative features	I agree that more research is required to validate our principle that cheap is not necessarily cost effective.	Thank you for your comment.
87	Consultee 5 Colostomy UK	1.3 What information is needed	who would collate and analyse the information?	Thank you for your comment. Section 3.21 of the guidance suggests what research should be collected and

				recommends independently run research (which could be company funded).
88	Consultee 6 Individual	3.9 Clinical evidence included in the assessment	Studies should not be sponsored by manufacturers / suppliers. They should be independent but I appreciate that involves more money which is in short supply	Thank you for your comment. Section 3.21 of the guidance suggests that that independently run company funded studies would be an appropriate solution for further research.
89	Consultee 9 B. Braun Medical	Not specified	The draft guidance suggests that a core outcomes set should be developed to support consistency in future studies. B. Braun agrees with this in principle, but NICE does not elaborate who should develop this core outcomes set. We strongly suggest that its development is led by a patient advocacy group, such as Colostomy UK, to reduce undue influence by manufacturers. As a patient advocacy group, they are also best placed to create a core outcomes set in collaboration with ostomates with lived experience. If a recommendation of this kind was made to Colostomy UK or other patient groups by NICE itself, it would carry more weight than if industry were to make this suggestion.	Thank you for your comment. NICE has suggested what research should be done but it is not in the remit of this assessment to suggest who should do it.
90	Consultee 10 Eakin Healthcare	1.3 Why the committee made these recommendations	Whilst this document calls for more evidence, there are no clear timelines for this and its vague on how these gaps will be closed.	Thank you for your comment. Please see the response to comment 84.
91	Consultee 11 Peak Medical Ltd	Not specified	As an overarching comment. We would argue that this process is somewhat flawed. Looking backwards and attempting to assess products within a process that requires certain evidence, of which none was required to launch the product within the UK, is setting the process up to fail.	Thank you for your comment. Please see the response to comment 72.

92	Consultee 11 Peak Medical Ltd	1.3 Why the committee made these recommendations	To state 'not enough evidence' whilst we can appreciate its direction, is unfair as products assessed had no requirement to provide this type of evidence upon launch. If this statement is to be published publicly, a full explanantion of why should be made.	Thank you for your comment. Please see the response to comment 72.
93	Consultee 13 Convatec	Not specified	As the evidence was so sparse, the only conclusion was that there is no way to determine clinical and cost effectiveness. Therefore it is misleading to include reference to potentially cost effective product attributes that cannot currently be validated.	Thank you for your comment. The EAG's economic analysis found that resolving leakage and PSC had the largest impact on cost on quality of life. The user preference assessment also found that preventing leakage, seepage and PSC were the most important things to users when choosing a one-piece closed bag to use. So, the committee agreed that bags with features that are shown to improve outcomes important to users may be worth paying more for.
94	Consultee 13 Convatec	3.20 Evidence needed to demonstrate additional value	Consideration also needs to be given as to how such studies could be conducted without bias, unless NHS is willing to independently fund them?	Thank you for your comment. Part of the committee's considerations for LSAs is a gap analysis of the existing evidence base as detailed in 'what information is needed' and section 3.21 to 3.23 of the guidance. The aim of the further evidence recommendations is to guide what research is needed and suggests that that independently run company funded studies would be an appropriate solution for further research.
95	Consultee 13 Convatec	3.21 Evidence needed to demonstrate additional value	Convatec would support and welcome this development by EAG and independent (not sponsored) stoma nurse specialists. Given that Scotland and other northern European countries do not support sponsorship, a	Thank you for your comment.

			strong group of clinical experts could be formed.	
96	Consultee 13 Convatec	3.21 Evidence needed to demonstrate additional value	Again another area that could be independently developed to create a standard EQ-5D model for Ostomates!	Thank you for your comment. Section 3.22 recommends the development of a core outcome set and psychometrically validated patient-reported outcome measures to measure bag-related quality of life.
97	Consultee 14 Ostique Limited	Not specified	Response to NICE Consultation on One-Piece Closed Colostomy Bags Submitted by: Ostique Ltd. Date:28/02/25 Consultation Reference: GID-HTE10045 1. Introduction Ostique welcomes the opportunity to contribute to NICE's consultation on one-piece closed colostomy bags. As an innovator in ostomy care, we support efforts to ensure that NHS procurement decisions maximise both clinical effectiveness and value for money. Our response focuses on three key areas: - The inclusion of all relevant evidence, particularly regarding innovative features and patient outcomes. - The interpretation of clinical and cost-effectiveness data, especially in relation to preventing leakage, skin complications, and improving psychological well-being. - Considerations related to equality, accessibility, and patient choice. We provide evidence and arguments to	Thank you for your comment. As Ostique's products were not available on the Drug Tariff at the time of the evaluation, they were not considered as part of the assessment. However, the guidance recommendations and the evidence standards are still applicable to these products going forward.

			demonstrate that premium colostomy bags, such as those offered by Ostique, can deliver meaningful benefits that justify a higher price point, reducing NHS costs in the long term through improved patient outcomes and reduced complications. 2. Consideration of Relevant Evidence 2.1 Clinical Effectiveness & User Outcomes We note that NICE's draft guidance indicates that there is insufficient clinical evidence to justify price variations among colostomy bags. We would like to submit additional data highlighting the benefits of Ostique's products: - Leak Prevention & Skin Protection: - Our colostomy bags feature an advanced conformable baseplate that improves adhesion and prevents leakage and seepage. - Studies have shown that leakage is one of the leading causes of peristomal skin complications, which require additional NHS resources (e.g., nurse visits, barrier creams, and additional prescriptions). - Psychological & Social Benefits: - Ostique's colostomy bags are the first truly silent ostomy bags, addressing a key quality-of-life issue frequently raised by patients: the distress caused by rustling, noisy materials. - Our research indicates that reducing social anxiety and embarrassment can lead to better mental health outcomes and improved socio-economic rehabilitation. - Patient Feedback & Real-World Evidence: - We have gathered qualitative and	

			quantitative data from users demonstrating a preference for our products due to enhanced comfort, security, and discretion. - Our products have shown to reduce the frequency of bag changes (especially after showing, bathing or swimming), leading to lower long-term usage costs. We strongly encourage NICE to incorporate patient-reported outcomes into the final evaluation, as these are critical indicators of real-world effectiveness. 3. Interpretation of Cost-Effectiveness 3.1 Long-Term Cost Savings to the NHS Our products are positioned at a higher price point than many standard colostomy bags (albeit not the most expensive), the additional cost is offset by: - Fewer required bag changes (improving durability and reducing prescription volume). - Reduction in peristomal skin complications, leading to fewer nurse consultations and lower spending on barrier creams and treatments. - Increased patient confidence and adherence, reducing waste and trialing of multiple products. Ostique is happy to provide further evidence, data, and testimonials in support of these recommendations. We appreciate NICE's consideration and remain committed to advancing patient-centred innovations in ostomy care.	
Resource impact assessment				

98	Consultee 2 Hollister Ltd	3.19 Resource impact of reducing price variation	The Resource Impact Assessment appears to be based on a purely hypothetical scenario with arbitrary assumptions. Given this, it would seem impossible to draw any relevant or meaningful inferences at all in relation to sponsorship. One specific point to highlight is that Table 3 assumes one CNS per Trust. The vast majority of Trusts have more than one CNS.	Thank you for your comment. The cost saving analysis was for illustrative purposes only. As the total number of CNS in stoma care in England could not be determined, 1 per trust was given as an example. Other potential resource savings or additional costs (such as supporting products or more frequent bag changes), other aspects of stoma care funded through sponsorship, and any impact on clinical outcomes were not considered in the resource impact assessment (RIA). This is because the RIA looked at a simplistic scenario of resource savings as a result of a reduction in average one-piece closed bag prices based on 2023 prescription data. Any potential savings and staffing levels would depend on local practice and would be assessed at that level. Section of 3.20 of the guidance has been amended to remove reference to sponsorship and keep the example about potential CNS funding based on a hypothetical 10% reduction in bag pricing. Additional wording was also added to acknowledge that this is a simplistic scenario and that any cost savings may be used in other parts of the NHS.
99	Consultee 3 Coloplast	3.19 Resource impact of reducing price variation	We have just received the Resource Impact Assessment (RIA), which is the basis of this section, on 5th March, one day before the consultation deadline. While we appreciate the extension to review the RIA and this section, ourselves and all respondents must reserve the right to comment on any section in this guidance which we feel is impacted or	Thank you for your comment. NICE allowed an extension to comment on the RIA report and the section in the guidance that references the RIA report.

			influenced by the RIA in the extended submission.	
100	Consultee 13 Convatec	3.19 Resource impact of reducing price variation	Not all companies offer sponsorship and so this calculation is misleading and should and could be more reflective of current practice if it modelled only those brands where sponsorship is apparent and not against average mean price.	Thank you for your comment. The cost saving analysis was for illustrative purposes only. NICE acknowledge that not all companies offer sponsorship. Section 3.20 of the guidance has been amended to remove reference to sponsorship and keep the example about potential CNS funding based on a hypothetical 10% reduction in one-piece closed bag pricing.
101	Consultee 16 ASCN UK	1 RIA Report	Whilst potential savings made in reducing the price of closed stoma pouches can theoretically be used to fund more Specialist Stoma Care Nurse (SSCN) posts, this is an issue which we view with a great deal of scepticism. It is widely understood that the NHS is currently in a state of flux and change with financial difficulties. The likely scenario is that any savings are not guaranteed to be directly utilised to fund SSCN posts and will be swallowed up in cost pressure savings. This will not only reduce the choice of pouches available which would usually ensure first class, gold standard care for ostomy patients, but result in further clinical issues with increased incidence of skin issues, leaking pouches, an increase in stoma out-patient appointments/home visits all increasing costs and placing further strain	Thank you for your comment. Please see the response to comment 98.

			on existing low staffing resources to address patients' needs.	
102	Consultee 16 ASCN UK	1 RIA Report	We are pleased however, to note that SSCN posts are recognised as Band 6 and Band 7, representing the view that SSCN posts are highly specialised in nursing and a valuable resource for stoma patients.	Thank you for your comment.
103	Consultee 16 ASCN UK	1 RIA Report	It is unclear how many SSCN posts are currently funded by the NHS and the private sector/industry and the variety of pathways of care that exist nationally. As such, it is difficult to know whether a reduction in the cost of appliances will have a knock-on effect due to a potential, subsequent lack of funding for investment into innovation and research and provision of SSCN services funded outside of the NHS.	Thank you for your comment. Please see the response to comment 98.
104	Consultee 16 ASCN UK	2 RIA Report	Lack of access to SSCN services already exists, whereby not all patients have open access to SSCN services, meaning care is not equitable. This is currently being addressed by ASCN UK with the Advancing Stoma Care Services project aligned with the GIRFT principles of care. Blanket provision of poor quality services and products will continue to negatively impact patients who are already coping with a long term condition which can affect all aspects of their lives. Greater product choice allows SCNs to provide efficient, tailored clinical services to stoma patients, reducing overall costs to the NHS as problems are prevented or quickly addressed. Prompt intervention from the SCN	Thank you for your comment. Please see the response to comment 98. Section 3.4 of the guidance acknowledges variation in access to CNS in stoma care. Additional wording has also been added to acknowledge that the Association for Stoma Care Nurses UK are developing a standardised mandatory stoma care pathway to ensure consistent quality of care.

			can avoid readmission to hospital, with the inevitable and subsequent impact to emergency services and delays to bed flow in hospitals.	
105	Consultee 16 ASCN UK	3 RIA Report	Quality of life (QOL) is paramount for stoma patients; any issues affecting QOL such as the use of a poor quality product which leaks and causes skin issues can affect an individual's psychological adaption to the stoma, poor body image and self esteem and a resulting impact on the individual's ability to return to their full potential, contributing to society in a meaningful way and maintaining personal relationships. The impact for the individual's mental health and wellness results in the need for more NHS resources to address these issues.	Thank you for your comment. Section 3.6 of the guidance acknowledges the impact bag choice can have on long-term physical and psychological wellbeing.
106	Consultee 3 Coloplast	Guidance Document 21 RIA Report	The information in this paragraph, which presents a summary of analyses by the EAG and by the NICE Resource Impact team, of the potential savings released by the mean bag price by 10% is presented without important context and is therefore open to misinterpretation. The NHS price of products in Part IX of the Drug Tariff, from which the EAG sourced price data, is regulated by NHS Business Services Authority on behalf of the Department of Health and Social Care. Any assumptions on price change are therefore subject to change in the current arrangements, which are being reformed and are subject to wholly separate consultation exercises. The EAG has also not modelled the negative impact of price reduction, even if the above mechanism were to enable them, on the	Thank you for your comment. Please see the response to comment 98.

			added value support provided by bag manufacturers, which is provided at no added cost to the NHS or to patients, as highlighted in section 7.4 of the EAG report. Finally, the specialist nurse workforce shortage means that, even if the funding released was equivalent to the cost of 141 additional stoma care specialists, it is very unlikely that these could be recruited across the NHS. We therefore recommend deleting this comparison, as it might give decision-makers and HCPs the wrong impressions of the direct impact of such a price cut. Paragraph 3.19 is therefore speculative, misleads decision-makers and health care professionals, and is presented out of context. It should be removed from the guidance. For more information, please see our detailed comments on the 'Resource impact assessment at MTAC 1' report, which was released on 5 March 2025 (the day before the draft guidance consultation closed).	
107	Consultee 3 Coloplast	General RIA Report	We note that this document was available to the Committee from 19 September 2024. Please can NICE explain why it was not part of the main consultation on the draft guidance, rather than this potentially confusing post-hoc addition?	Thank you for your comment. This is a pilot process. The RIA work was presented in the closed part of the committee meeting and so not shared in the published slides. In response to feedback, NICE created a public version of the information and shared it with stakeholders. NICE extended the consultation to allow comments on whether the summary of the RIA report was reasonable and had been appropriately taken into account in the section in the guidance that references the RIA report i.

108	Consultee 3 Coloplast	General RIA Report	For the reasons explained in our detailed comments, we are very concerned that the RIA's background, assumptions, analysis and conclusions have been developed with a highly incomplete understanding of the stoma care market and care pathway. For example, in discussing the impact of a hypothetical price reduction, NHS-commissioned services provided to secondary care providers are confused with added-value services provided to community-based patients and health care professionals at no added cost to the NHS or patients. The RIA work in its current form should therefore be completely revised, taking into account feedback from stakeholders, and subject to further work with meaningful company involvement. In addition, please can NICE explain what resource impact processes and methods are being applied to this late-stage assessment topic, because we cannot reconcile this work with the (outdated) references to medical technology guidance in the published 'Assessing resource impact manual' (https://www.nice.org.uk/Media/Default/About/what-we-do/Into-practice/Assessing-resource-impact- process-manual.docx) ?	Thank you for your comment. Please see the response to comment 98. The RIA was developed in line with the LSA interim process and methods statement.
109	Consultee 3 Coloplast	General RIA Report	The RIA assumes that cost savings will be immediate, but the real-world logistics of potentially transitioning to new products introduce additional costs and risks that are not accounted for.	Thank you for your comment. Please see the response to comment 98.
110	Consultee 3 Coloplast	General RIA Report	This LSA is about one piece closed colostomy bags for adults, yet this RIA appears to be an incredibly generalised document on stoma care. If NICE were to follow their own guidelines on what is in and	Thank you for your comment. Please see the response to comment 98.

			out of scope and what is permissible evidence, this RIA would be dismissed.	
111	Consultee 3 Coloplast	1 RIA Report	The document states that the Resource Impact Assessment team 'presented…a hypothetical scenario' for potential cost savings. This document is therefore based on a hypothetical scenario meaning it has no place in any evidence-based discussion that is put in the public domain. There are dozens of other hypothetical scenarios are more relevant that could be posed and published such as: • the link of cost of stoma bags and Research and Development spend • the link of the cost of stoma bags and supply chain resilience	Thank you for your comment. Please see the response to comment 98.
112	Consultee 3 Coloplast	1 RIA Report	The statement 'savings could be used to fund clinical nurse specialists in stoma care in the NHS' is speculative and does not hold up to scrutiny. The arguments set out in our response show no link to sponsorship and price. The premise of a hypothetical world where savings can be made to spend on more Stoma nurses is flawed. Stoma care has been underfunded and neglected as a specialty over decades by the NHS, which now means nearly all stoma training for nurses is done by commercial companies. This leads to a situation where it would be almost impossible for the NHS to recruit and train the nurse numbers (141) modelled even if money was available.	Thank you for your comment. Please see the response to comment 98.

113	Consultee 3 Coloplast	1 RIA Report	The Resource Impact Assessment for one-piece closed stoma bags aims to evaluate potential cost savings from a 10% price reduction and explores how these savings could be used to fund Clinical Nurse Specialists (CNS) in stoma care within the NHS. However, the analysis makes several flawed assumptions, including oversimplified cost calculations, lack of clinical outcome consideration, and an unrealistic understanding of NHS workforce constraints. Throughout this document, which very much ties into our response to the main body of the consultation, we have challenged the RIA's assumptions, demonstrating how cost-cutting on stoma products could lead to increased NHS expenditure, worsened patient outcomes, and unintended consequences for workforce development.	Thank you for your comment. Please see the response to comment 98.

114	Consultee 3 Coloplast	1 RIA Report	It is assumed that the price of one-piece closed bags includes a sponsorship element (i.e., funding for CNS roles, training, or IT). The RIA mentions sponsorship but lacks transparency on its value • The RIA acknowledges that manufacturers provide sponsorship for NHS stoma services, including: o Training for nurses and healthcare staff. o Funding for Clinical Nurse Specialists (CNS). o Provision of IT and digital infrastructure. • However, the RIA fails to quantify the value of these contributions, meaning it cannot accurately assess the financial impact of potentially losing sponsorship funding. The RIA's financial analysis is incomplete because it fails to account for the financial value of manufacturer- sponsored training, education, and resources. If sponsorship is reduced due to pricing pressures, the NHS will face additional hidden and indirect costs for both patients and the system.	Thank you for your comment. Please see the response to comment 98.
115	Consultee 3 Coloplast	11 RIA Report	The RIA assumes that a 10% reduction in the mean price of one-piece closed bags is a reasonable scenario. There is no justification for why 10% was chosen, this could be arbitrary and may not reflect real-world pricing behaviour. These suggestions create and uncertain and hostile environment, with the potential to for companies to divest in the UK market.	Thank you for your comment. The 10% reduction in mean price of one-piece closed bags was for illustrative purposes only. Please also see the response to comment 98.
116	Consultee 3 Coloplast	2 RIA Report	The analysis assumes that the NHS would purchase the same number of bags in 2024 as in 2023. This does not account for potential changes in demand, procurement	Thank you for your comment. Please see the response to comment 98.

			strategies, or new product introductions that could alter purchasing volumes.	
117	Consultee 3 Coloplast	2 RIA Report	Does this document in terms of nurse numbers and costs account for the market in any future years in terms of patient population increasing?	Thank you for your comment. Please see the response to comment 98.
118	Consultee 3 Coloplast	General RIA Report	Failure to account for patient adherence and compliance issues The RIA ignores the impact of potential product changes on patient outcomes that may result as part of the Part IX reform or impact of LSAs and some companies needing / deciding to leave the market / withdraw products. • Switching to lower-cost stoma bags could result in lower patient satisfaction, leading to non- compliance with prescribed usage patterns. • A poorly fitting or less effective bag may require more frequent changes, increasing product usage and negating any cost savings per unit. • Patients struggling with unsuitable products may require more frequent healthcare interventions, including: o More GP and specialist nurse consultations to address leakage, discomfort, and skin irritation. o Increased prescription requests for additional accessories and barrier creams. o Higher risks of psychological distress, potentially increasing referrals to mental health support services. The RIA assumes that patient behaviour remains unchanged despite product	Thank you for your comment. Please see the response to comment 98. RIA reports consider budget impact only and not clinical outcomes. Clinical outcomes are considered as part of the economic analysis.

			differences. However, real- world experience suggests that poor-quality stoma products lead to higher consumption rates and increased healthcare utilisation, which could ultimately outweigh any projected savings.	
119	Consultee 3 Coloplast	General RIA Report	Lack of consideration for stoma patients with complex needs The RIA treats all stoma patients as a homogeneous group Aside from the fact this LSA is meant to only be about 1 piece closed Colostomy Bags - the assessment seems to include all stoma, not just colostomy and it then does not distinguish between different patient populations, such as: o Patients with high-output stomas who require specialised products. o Patients with skin sensitivities or pre-existing skin conditions who are more prone to PSCs. o Elderly or disabled patients who may struggle with inferior adhesive performance or bag changes. o Post-surgical patients, where a secure and high-performing product is critical to wound healing and recovery.	Thank you for your comment. Please see the response to comment 98. The potential cost savings from the hypothetical scenario was based on 2023 prescription for one-piece closed bags only, in line with the final scope. NICE acknowledges that there are a wide range of people that use one-piece closed bags, but this was not the focus of the RIA which looked at resources only.

120	Consultee 3 Coloplast	Not specified	The assumption that price reduction will lead to direct cost savings fails to consider market dynamics and procurement practices. -The RIA assumes that a 10% price reduction on stoma products will be directly translated into cost savings for the NHS. However, price negotiations, supplier responses, and procurement frameworks could significantly alter the expected financial impact. -Supplier reactions to forced price reductions could include: • Reducing product quality to meet new price points. • Pulling out of the NHS market, leading to reduced supplier competition and potential future price increases due to monopoly effects. • Offsetting price cuts with higher costs in other areas, such as reducing sponsorships, training, or service support. Healthcare procurement does not work as a simple price-cutting exercise, supplier contracts, market competition, and NHS purchasing strategies all influence whether a price reduction results in long-term financial benefits.	Thank you for your comment. Please see the responses to comments 98.

121	Consultee 3 Coloplast	General RIA Report	Ignoring the role of stoma care nurses in product selection Issue: The RIA fails to consider clinical decision-making in stoma product use • Stoma care nurses (SCNs) play a critical role in advising patients on the most appropriate products for their individual needs. • The RIA assumes that cost-cutting will not impact product selection, but in reality: o Cheaper products could be pushed onto SCNs as a default option, even if they are not clinically appropriate. o SCNs may face restrictions in their ability to prescribe higher-quality alternatives, leading to poorer patient outcomes and increased workload for nurses managing avoidable complications. o If product choice becomes driven by price instead of clinical need, SCNs may experience ethical dilemmas in their practice. The RIA overlooks the clinical role of SCNs in product selection and patient education, failing to account for how restrictive cost-cutting measures could compromise patient care and professional decision-making.	Thank you for your comment. Please see the response to comment 98. The RIA considered a scenario where all product prices are reduced by 10% rather than suggesting using cheaper products. In this hypothetical scenario this would therefore not impact choice.

122	Consultee 3 Coloplast	2 - 3 RIA Report	Funding allocation for CNS roles The assessment assumes that all cost savings would be allocated to hiring Clinical Nurse Specialists (CNS). It does not explore alternative uses of savings, such as improving patient care, investing in better equipment, or funding additional services. The calculation assumes 1 CNS per NHS trust in England (141 trusts), but it does not consider variations in demand for CNS roles across different regions. The funding mix only includes either Band 6 or Band 7 CNS but does not account for blended staffing models.	Thank you for your comment. Please see the response to comment 98.
123	Consultee 3 Coloplast	3 RIA Report	Addressing Nursing Workforce Assumptions The RIA makes several assumptions regarding the funding and provision of Clinical Nurse Specialists (CNS) in stoma care. However, when considered against the broader realities of the UK nursing workforce crisis, these assumptions lack a grounded understanding of the systemic challenges facing CNS recruitment, training, and retention. 1 - The fundamental oversight: Severe nursing shortages The RIA assumes that potential cost savings from a price reduction in one-piece closed stoma bags could be directly translated into funding for additional CNS roles within the NHS. However, this assumption fails to acknowledge the fundamental issue: there is a massive shortage of not just specialist nurses, but nurses in general across the NHS. •Latest workforce data (Dec 2024) from NHS England reports 106,432 vacancies in	Thank you for your comment. Please see the response to comment 98. Section 3.5 of the guidance and the RIA acknowledge that sponsorship can also fund training. Funding CNS salary was used as a hypothetical scenario of where potential cost savings could be spent.

			secondary care, with 27,452 of these in nursing roles. •One in three hospital shifts are running without adequate nursing staff, directly impacting patient safety. •The RCN and NHS leaders warn that retention rates are declining, with early-career nurses leaving at an alarming rate. •One in four nurses currently employed in the NHS was recruited from overseas, highlighting the growing reliance on international recruitment. Thus, while the RIA assumes that the only barrier to hiring CNSs is financial, the reality is that there are not enough trained nurses available to fill these roles, even if funding were allocated. 2 - Training a CNS is not a simple funding equation A Clinical Nurse Specialist (CNS) in stoma care is an advanced practice role requiring significant post- registration education and clinical experience. The RIA assumes that NHS trusts could immediately recruit 120–141 new CNSs if funding were available. This is a fundamental misunderstanding of the resource and training constraints within the NHS workforce. •To become a CNS, a registered nurse must complete a BSc or MSc-level qualification in Advanced Clinical Practice, which can take 2 to 5 years. •Even if funding is available, the NHS lacks the necessary workforce capacity to release existing nurses for specialist training without further exacerbating staff shortages. •Due to financial and staffing pressures, the	

			NHS does not provide sufficient structured pathways for CNS training, a gap often filled by medical device and pharmaceutical companies, who offer this education free of charge to the NHS. In essence, the RIA assumes that money alone solves the problem, when in reality, there is neither the workforce capacity nor the structured NHS training pathways to rapidly expand the CNS workforce. 3. The unacknowledged role of industry-supported training The RIA does not account for the fact that many CNS' in stoma care are trained through industry-sponsored education programs, rather than NHS-funded initiatives. While the document acknowledges that manufacturers provide sponsorship to hospitals, it fails to quantify or recognise the critical role these sponsorships play in CNS training and professional development. •Many stoma product manufacturers offer specialist training programs free of charge to support nurses in developing expertise in stoma care. •These industry-led initiatives fill a major gap in NHS workforce planning, as the NHS does not have the capacity to provide sufficient in-house training. •The RIA does not address whether a reduction in stoma bag prices would reduce manufacturer- sponsored education and training programs, an oversight that could lead to unintended consequences. By assuming that NHS trusts could simply hire trained CNS', the RIA ignores the reality	

			that much of this training is externally funded and that any factor that could negatively impact this training support could hinder workforce development rather than improve it.	
124	Consultee 3 Coloplast	3 RIA Report	A flawed approach based on incomplete assumptions: The RIA fails to engage with the fundamental workforce realities in the NHS. While the document presents a theoretical model of cost savings and workforce expansion, it does not acknowledge: 1. The widespread shortage of nurses, making recruitment of CNS' extremely difficult, even with available funding. 2. The lengthy and resource-intensive process required to train CNS', which is not adequately resourced within the NHS. 3. The critical role of industry-sponsored training, which may be jeopardised by cost-cutting measures on stoma products. The result is an analysis that is not reflective of the practical challenges facing NHS workforce development. Any proposed policy changes regarding cost reductions for stoma care products must consider not just financial implications, but also the long-term impact on workforce education and training provision. Without a comprehensive, evidence-based strategy to address the systemic barriers to CNS recruitment and training, the assumptions made in this report are misleading at best and potentially detrimental to patient care at worst. The overlooked impact of product quality on NHS costs	Thank you for your comment. Please see the responses to comments 98, 121 and 123. The cost analysis was for illustrative purposes only to demonstrate how many CNS could be funded across the country by a 10% drop in the average unit price of a stoma bag. RIA stated that that the analysis did not consider potential clinical differences between the bags.

			The RIA fails to acknowledge the critical differences in product quality and their implications for both patient outcomes and NHS spending. The assumption that all one-piece stoma products are interchangeable based solely on price is a misleading oversimplification that can lead to increased long-term costs and compromised patient care. 1. Not all one-piece stoma products are equal Stoma products vary significantly in terms of adhesive strength, skin protection, flexibility, durability, and overall patient comfort. Cheaper, lower-quality products are more likely to lead to peristomal skin complications (PSCs), quality can come at a cost. The potential for products no longer being available or being altered to reduce manufacturing costs could have major issues for ostomy patients that can result in: •Pain, discomfort, and reduced quality of life •Increased NHS resource use (GP visits, specialist nurse consultations, wound care) •Higher prescription costs (additional appliances, barrier creams, dressings) •Potential hospital admissions for severe cases By failing to factor in the potential rise in PSC cases due to lower-quality stoma products, lack of access to certain products or alteration to products the RIA significantly underestimates the true economic impact of cost-cutting measures in this area. •Frontier Economics (2023) Counting the cost of peristomal skin complications. Available at: https://peristomalskinhealth.com/media/34jdtgtg/frontier-costs-of-peristomal-skin-	

			complications- launch-01-05-24.pdf (Accessed: 5 March 2025). •The Clinical Services Journal (2023) Peristomal skin complications cost England's economy £28.1m. Available at: https://www.clinicalservicesjournal.com/story/46270/peristomal-skin- complications-cost-englands-economy-28-1m (Accessed: 5 March 2025). •Rolls, N., Cottam, J., and Prentice, J. (2023) 'Healthcare resource use and associated costs for patients with an ileostomy experiencing peristomal skin complications', Journal of Wound Care, 32(3), pp. 132-139. Available at: https://pubmed.ncbi.nlm.nih.gov/37020423/ (Accessed: 5 March 2025).	

125	Consultee 3 Coloplast	Not specified	Conclusion: A flawed assumption with potentially costly consequences The RIA's approach to cost savings is fundamentally flawed as it assumes that all one-piece closed stoma bags deliver the same clinical outcomes. This ignores well-documented evidence that lower-quality products increase complications, require more healthcare intervention, and ultimately cost the NHS more in the long run. Rather than focusing solely on price reduction, a more effective cost-saving strategy would involve evaluating products based on their long-term impact on patient outcomes and healthcare resource utilisation. Any policy decision regarding procurement and cost-cutting must be informed by a holistic economic evaluation, rather than simplistic price-based calculations. A GIRFT evidenced-based pathway is the way forward to save money and improve patient outcomes.	Thank you for your comment. Please see the response to comment 98. RIA reports consider budget impact only and not clinical outcomes. Clinical outcomes are considered as part of the economic analysis.
126	Consultee 8 British Healthcare Trades Association	1 RIA Report	My understanding was that sponsorship was out of scope of the one piece closed bag LSA, so I do not understand why this RIA was produced?	Thank you for your comment. Please see the response to comment 98.
127	Consultee 8 British Healthcare Trades Association	1 RIA Report	Aas you state not all companies sponsor so I do not agree with the rationale that all suppliers would be included in any analysis. As stated above, I do not agree that the Hypothetical scenario should be published at all	Thank you for your comment. Please see the response to comment 98.
128	Consultee 8 British Healthcare	1 RIA Report	As a point of clarity sponsorship contracts do not have clauses in them around product use or price and the NHS are issuing the tenders.	Thank you for your comment. Please see the response to comment 98.

	Trades Association		Any solution should be proposed by NHSE not NICE	
129	Consultee 8 British Healthcare Trades Association	2 RIA Report	The assumptions are flawed regarding the average FTE per trust by a very large margin.	Thank you for your comment. Please see the response to comment 98.
130	Consultee 7 Salts Healthcare	3 RIA Report	We agree in principle that this proposal may offer a credible alternative to the sponsorship model currently being requested by NHS organisations. However, to ensure a level playing field within the market any such arrangement would need to cover all potential conflicts of interest currently in use include the placement of company nurses and prescribing services that are run by commercial organisations. This is a complex area and any alternatives to the current model should be robust and considered with no reduction in service and outcomes for patients. To ensure this is the case we would suggest before any changes are made to the current model the body tasked with formulating the program should seek the input of all stakeholders including industry. It is also worth noting that there would need to be mechanisms put in place to ensure any savings made from a reduction in the DT price of stoma products was made available to the stoma services in that locality to ensure services for patients are maintained.	Thank you for your comment. Please see the response to comment 98.

131	Consultee 11 Peak Medical Ltd	1 RIA Report	A question: Why & how did sponsorship become part of the LSA scope? As a supplier who does not sponsor, and wishes to see the practise of sponsorship removed, I would like clarity on where this suggestion came from, please.	Thank you for your comment. Please see the response to comment 98.
132	Consultee 11 Peak Medical Ltd	1 RIA Report	We would suggest the monetary value of sponsorship is known. Each contract is awarded via tender process, and each trust has this value per annum within their annual accounts and budget. Our current estimate is that sponsorship costs in England & Wales are around £20-25M per annum.	Thank you for your comment. Please see the response to comment 98.

133	Consultee 11 Peak Medical Ltd	2 RIA Report	The suggestion of a 10% reduction to fund nursing staff costs in replacement for sponsorship is seriously flawed. It does not consider that not every company sponsors nurse posts within England & Wales. To reduce costs on all products by 10% would punish those brands who have never participated in sponsorship and have therefore never benefited from the increased use of their products that sponsorship brings. This suggestion is also too simplistic to work in the way intended. Without legislation to outlaw sponsorship, to reduce prices by 10% would in fact drive more sponsorship to happen, brands will look to recoup this lost revenue by way of either acquiring more sponsored posts or driving use of their product within current sponsored trust to even higher levels than is seen today. It should also be noted that some of the higher cost products in your table are from those brands who do not participate in the marketing strategy which is sponsorship. Our cost prices are higher, leading to higher selling prices as you have highlighted. A significant cause of this is lack of volume available, as sponsorship is an unethical barrier to entry for those brands who choose not to participate, either out of choice, or because sponsorship costs are prohibitive for an SME such as ourselves.	Thank you for your comment. Please see the response to comment 98.
134	Consultee 11 Peak Medical Ltd	2 RIA Report	This suggestion estimates to generate costs for between 120-141 CNS. Assuming 1 CNS within each trust. Today there are 600 CNS within stoma care, and trust have multiple numbers per trust. This suggestion does not	Thank you for your comment. Please see the response to comment 98.

			seem to consider the reality of these numbers.	
135	Consultee 11 Peak Medical Ltd	3 RIA Report	The conclusion contains the above flawed assumptions, and re states how the model could work. We would suggest that it would be unhelpful, at best, to publish this model at this point. The removal of sponsorship needs to be carefully and thoughtfully considered, to ensure that it benefits CNS, Ostomy patients and the wider NHS system, and as we have highlighted may lead to unintended consequences as we have highlighted. To restate, would removal of sponsorship be a god thing? Yes undoubtedly, but it must be achieved with legislation that is constructed to ensure value for the NHS and fairness and equality for all suppliers.	Thank you for your comment. Please see the response to comment 98.
136	Consultee 13 Convatec	1 RIA Report	Convatec does not support or have any sponsorship agreements in England or Wales and is in favour of the abolition of sponsorships in their entirely. The mechanism of funding through top slicing of product prices as per NICE's proposal is therefore flawed as it penalises organisations such as us and SMEs who have lower market share due to sponsorship. It also calculated the mean average across all spend instead of the spend attributed to suppliers who offer sponsorship. This information is readily available allowing for more accurate calculation of impact. For these reasons, the funding mechanism proposed is not something Convatec supports unless it was to be refined to address spend only affected suppliers.	Thank you for your comment. Please see the response to comment 100.

137	Consultee 13 Convatec	2 RIA Report	ConvacTec Ltd: 3.5% share , quantity bags prescribed 1,076,028, total spend of £3,122,429, mean average price of £2.90. This data supports the above statement and feedback in comment 1. Convatec product sit below mean average quoted price of £3.02	Thank you for your comment. Please see the response to comment 100.
138	Consultee 13 Convatec	Not specified	Flawed calculation overestimating the potential savings for reasons cited above	Thank you for your comment. Please see the response to comment 100.
139	Consultee 13 Convatec	Not specified	This demonstrates the need for more detailed and thorough investigation of the topic. The documented level of sponsorship from those suppliers who participated is estimated to equate to £20-£22M per annum via NHS Provider organisation held contracts. Details of which could be collated through transparency by contract holders within NHS and analysis.	Thank you for your comment. Please see the responses to comments 98 and 100.
140	Consultee 15 CliniMed Ltd	45717 RIA Report	We are concerned that the resource impact assessment introduces the out of scope subject of sponsorship of Stoma Care Nurses and connects this to theoretical savings from application of the proposed NICE guidance recommendations. Further, that the resource impact assessment makes significant theoretical assumptions in a number of areas including : - The price charged for a stoma bag could include a cost of sponsorship element - Assuming a 10% reduction in price with no consideration of differential clinical outcomes between bags The assessment is unclear on sponsorship impact, has no clinical outcome consideration and has introduced a suggestion for the use	Thank you for your comment. Please see the response to comment 98.

			of potential savings that is outside of the remit of LSA.	
141	Consultee 15 CliniMed Ltd	3 RIA Report	We would question whether savings in community/prescription costs would filter back to hospitals to meet the theoretical coverage of Stoma Care Nurse salaries	Thank you for your comment. Please see the response to comment 98.
Shared decision making				
142	Consultee 11 Peak Medical Ltd	1.3 Considerations for people with a colostomy	We do not believe advice to try least expensive product first is consistent with shared decsion making, and may lead to suboptimal outcomes for the patient, leading to the increased use of NHS resource to address this.	Thank you for your comment. Please see the response to comment 9.
143	Consultee 1 Individual	1.2 1 Recommendations	Does this recommendation not remove some agency from patients? My experience in the months following my surgery was to try out various bags as supplied by manufacturers via their free samples system. My stoma nurse supported me throughout this but the choice of bags was entirely mine. Not all patients will be able to undertake this of course but for myself it was important to take some control of my situation during those difficult early months. I understand that the final choice will depend on cost vs. clinical need and that decision will ultimately be made by a professional but I think the wording of this recommendation could be improved.	Thank you for your comment. Please see the responses to comments 9 and 16.

144	Consultee 3 Coloplast	3.5 Shared decision making	NICE's own Shared Decision-Making Guideline (NG197) states that patients must have autonomy in choosing treatments that affect their quality of life. However, the draft guidance contradicts this principle. While the document claims that bag selection should be a shared decision, it may allow local decision-makers to use cost to limit patient choice. Recommending that patients to use the "least expensive" option first limits their autonomy and forces unnecessary product trials, leading to potential distress, complications, and reduced quality of life. A GIRFT approach needs to be taken in stoma care. Shared decision-making should be based on patient need, not financial constraints. Supporting evidence: -NHS England's Delivering Excellence in Stoma Care Report (2020) highlights the significant impact of poor bag selection on physical and mental health. -RCN Stoma Care Standards stress that leakage management is a primary concern and that the wrong bag can lead to severe dermatological issues	Thank you for your comment. Please see the response to comment 9.
145	Consultee 3 Coloplast	3.6 Shared decision making	As previously stated in our responses to the EAG report we fully support the principles of Shared Decision Making (SDM). However, there are equality issues that need special consideration that are not considered in the	Thank you for your comment. Additional wording has been added to section 3.6 to acknowledge the potential barriers to shared decision making.

			draft guidance when it comes to implementing SDM in stoma care. In an ideal world people with a stoma would already be involved in SDM with access to the full range of one-piece closed bags. However, we know that for a variety of reasons, including patient education, health literacy, reluctance to talk about stoma care, lack of understanding of SDM, and NHS resource, that this is not the case for all patients. It is clear that patients are only able to engage with SDM when they are both activated and informed. We would recommend DHSC, NHSE, ASCN, and stoma charities look to the Patient's Association guides on SDM, and the questions they suggest patients should familiarize themselves with: Shared decision making | The Patients Association (https://www.patients-association.org.uk/shared-decision-making#Three). The Patients Association also has a call line that stoma patients should know about: 0800 345 7115.	
146	Consultee 3 Coloplast	3.6 Shared decision making	SDM must consider more than just the bags which are addressed by this guidance. Stoma patients require a variety of supporting products to manage their condition, and it is unclear how these products fit into SDM as outlined in this guidance. Again, this is something on which Coloplast supports the NHS using nurse sponsorship as well as direct patient services.	Thank you for your comment. Shared decision making in relation to supporting products is outside of the remit of this assessment.

147	Consultee 3 Coloplast	3.6 Shared decision making	Stoma care is deeply nuanced and often decisions are not intuitive. There are three major peristomal body profiles of inward, outward, and regular, there are 216 individual body profiles, and when adding output types, there are 648 different variations. Add to this the thousands of available bags and supporting products and it is easy to see how difficult it is for patients to engage in SDM, especially in the overwhelming post-operative period. This is why we advocate for continuous patient education throughout the care pathway, something which we deliver through our Charter service. i.e., guides on travel, diet, clothing, daily routine, or exercise. The other principal barrier to SDM is clinician time. Multiple challenges exist for people living with a stoma, many of which are related to the functioning of their stoma appliance (leakage, ballooning, PSCs, sleep, etc.) while others are psychological (anxiety over malfunction, social avoidance, sexual problems, depression, etc.). Patients need ample nurse time to make SDM a reality to include all these factors. We ask that section 3.6 be amended to add this context to help non-experts better understand the complexities that are obstacles to SDM.	Thank you for your comment. Additional wording has been added to section 3.6 to acknowledge the potential barriers to shared decision making.

148	Consultee 3 Coloplast	3.6 Shared decision making	We are concerned that SDM has been taken lightly here – it is complex and there are barriers to successful, widespread implementation. We recommend that if this was to be a recommendation it cannot be implemented until SDM in stoma care has been thoroughly reviewed, understood, and intentionally designed -- including overcoming barriers like language, learning, digital etc. In combination with this, organisations will also need to signpost at the earliest opportunity to their stoma patients / people with a stoma the NHS Constitution on Rights. This will then be one of the missing pieces of the jigsaw in truly meeting what is clinically appropriate for a patient, as they or their carers will then be able to have powerful conversations, back by law in accessing what is right for them	Thank you for your comment. An information for public page will be created alongside the guidance for when the guidance publishes. This will provide information in simpler language to help people with a colostomy understand the guidance.
149	Consultee 3 Coloplast	3.6 Shared decision making	It is also important to note that SDM is a continuous process which develops over the patient's care journey. As a reminder, someone with a stoma will be in and out of various stoma services throughout their life, yearly at a minimum. Each time their body or lifestyle may have changed slightly or significantly. Even a patient who has a robust SDM process at the beginning of their stoma care may experience changes to their body that requires a change in product. This is why Appliance Use Reviews (AURs) are so key to stoma care, and why it is unfortunate that they are so underutilised. Without consistent and comprehensive follow-up over time, patients may begin to normalise issues with their products, such as minor leakage –	Thank you for your comment. Additional wording has been added to section 3.6 to acknowledge that shared decision making is an ongoing process. Recommendation 1.3 (previously 1.2) and the 'what this means in practice (considerations for people with a colostomy)' section have also been amended to include that needs and preferences change over time. This is also reiterated in section 3.6 and 3.8 of the guidance.

			which may lead to expensive peristomal skin complications (PSC) or more waste of products. Coloplast is committed to delivering comprehensive clinical consultations as part of our AURs that ensure that patients are kept on the best products for them over the course of their lives. We ask that the committee amend section 3.6 to include the need for a continuous SDM process that addresses the changing body and lifestyle needs of the patient over their lifetime. We also ask that this requirement is reflected in section 1.2	
150	Consultee 4 Individual	3.6 Shared decision making	There are several options available for Ostomists to gain knowledge and samples of closed pouches. Online advertising, the 3 associations provide advertising in their booklets or on their website. The manufacturers are happy to provide samples by phone or website.	Thank you for your comment.
151	Consultee 5 Colostomy UK	1.2 1 Recommendations	Supportive of this recommendation however better guidance and information is needed to empower the person with a Colostomy to be part of the shared process	Thank you for your comment. Please see the response to comment 148.
152	Consultee 13 Convatec	1.3 Considerations for healthcare professionals	When it talks about shared decision making there are two points of view. In the immediate post op period patients don't know what they don't know and they rely on the nurse to guide them. Therefore shared care principles are less likely to occur at this juncture, and a chosen product is applied to the abdomen without consultation. If the Hospital is sponsored (ie. Nurse Sponsorship) then this would typically be the	Thank you for your comment. Section 3.6 of the guidance acknowledges that initial choice is often led by clinical need. Clinical and patient experts stated that, over time, bag choice should also consider the preferences of the person with a colostomy. It also acknowledged that the level of involvement in decision making related to bag choice can vary across between services,

			pouch of the sponsoring manufacturer (in market data supports this). The patient would then go home with this pouch and be unaware of what else was available. This point has been raised by patients on the user preference panel and also through published survey results. As a result ostomates often put up with a pouch that is not working for them as they are unaware of what else is available. It is often not until much further along their pathway that they become aware of other products on the market and reach out to seek either advice or to try something else. At this point is it not reasonable that the ostomate can and should take ownership of their own condition and seek alternatives from other manufacturers?	and that they were not always aware of all the available bags. Section 3.5 also highlights that sponsorship could influence bag choice. Additional wording has been added to recommendation 1.3 (previously 1.2) and the 'what this means in practice (considerations for people with a colostomy)' section to state that their needs and preferences may change over the lifetime of living with a stoma.
153	Consultee 15 CliniMed Ltd	1.3 Considerations for healthcare professionals	A shared Product choice decision requires that the healthcare professional fully informs the person with a colostomy of all relevant products available without the influence of cheapest product first as this may exclude appropriate products.	Thank you for your comment. Please see the response to comment 9. Additional wording has been added to 'what this means in practice (considerations for people with a colostomy) to clarify that a range of one-piece closed bags (from a number of companies) are available for prescription, and that they should be given information about all of the bags that are suitable for them.
Sponsorship				

154	Consultee 3 Coloplast	1.3 Considerations for healthcare professionals	The statements made on sponsorship are out of scope, speculative and do not reflect our experience as a provider of sponsored services. As we stated in our response to the key stakeholder survey on the committee's initial findings, 'our NHS sponsorships (which are put out to tender by NHS Trusts), and our Charter service are established with robust, ethical processes. Rated outstanding by CQC, our clinical services ensure that patients are prescribed the right product to fit their anatomical and lifestyle needs – even if is not one of our own products.'	Thank you for your comment. The committee were informed that sponsorship could influence choice as stated in section 3.5 and so the 'what the means in practice (considerations for healthcare professionals)' section encourages the decision to be made based on clinical appropriateness and the needs and preferences of the person with a colostomy.
155	Consultee 3 Coloplast	1.3 Considerations for healthcare professionals	This is not a reasonable interpretation of the evidence which, in section 3.5, the committee concluded was incomplete and uncertain in terms of judging the influence of sponsorship on bag choice. The sentence in the draft guidance does not accurately reflect this conclusion and should be reworded to: "Healthcare professionals should, as for all clinical decision-making, take into account the possible influence of sponsorship but should be aware that there is insufficient evidence on its impact on choosing a 1-piece closed colostomy bag". Alternatively, all reference to sponsorship should be removed as it is not in scope for this LSA, was not evidenced, so conclusions are invalid.	Thank you for your comment. Please see the response to comment 154.
156	Consultee 3 Coloplast	3.5 Variation in care pathway	Not all of the relevant evidence has been considered. The draft guidance says that there is limited evidence discussing the impact of sponsorship in England. However, in our Request for Information, Coloplast submitted an internal company report showing a beneficial cost impact of our added value Charter service which supports those	Thank you for your comment. NICE acknowledges that a range of sponsorship related information was received. This was summarised narratively in section 7.4 of the EAG assessment report. The EAG did not quantify the cost impact of sponsorship as the focus of the assessment

			living with a stoma by providing early telehealth intervention and finding their optimal product solution. This service prevents additional burden on HCPs, the NHS and improves quality of life. Supporting individuals with optimal product solutions helps prevent inappropriate ordering and wasted products.	was on one-piece closed bags. Wording in section 3.5 of the guidance has been amended to acknowledge that there is limited published evidence discussing the impact of sponsorship in England.
157	Consultee 4 Individual	3.5 Variation in care pathway	Although sponsorship is the main source of funding within England this allows support in the acute and community setting for stoma care. Without their funding there would be minimal financial provision for within the depleted budget of the NHS.	Thank you for your comment. Section 3.5 of the guidance acknowledges that sponsorship agreements include funding for CNS in stoma care posts.
158	Consultee 4 Individual	3.5 Variation in care pathway	Although sponsorship funds Stoma Nurses any Registered Nurse has to abide by the NMC Code of Conduct and the NMC to be ethical at all times.	Thank you for your comment. Please see the response to comment 154.
159	Consultee 5 Colostomy UK	1.3 1 Recommendations	As long as this is a shared decision process. Sponsorship arrangements may also lead to a potential conflict of interest from the stoma nurse	Thank you for your comment. The guidance recommends shared decision making.
160	Consultee 5 Colostomy UK	1.3 Considerations for healthcare professionals	These are great but again aspirational considerations. The current stoma nurse funding model means that products from the sponsoring company are often more available and unconsciously favoured over others. Can recommendations include a review of the current SCN funding model?	Thank you for your comment. Discussion of the CNS in stoma care funding model is outside of remit for this assessment.
161	Consultee 6 Individual	1.2 1 Recommendations	Agreed but you need more stoma-trained healthcare professionals who are NOT supplier/ manufacturer funded.	Thank you for your comment. Please see the responses to comments 154 and 160.
162	Consultee 6 Individual	1.3 Considerations for people with a colostomy	Agreed. Ensure there are enough stoma healthcare professionals for patients to	Thank you for your comment.

			access (these professionals should not be funded by manufacturers and / or suppliers)	
163	Consultee 6 Individual	3.5 Variation in care pathway	Remove sponsorship completely. The no-one has an axe to grind and a product to sell. Money saved can then be spent on training up more nurses, which in turn can assist more patients and save more money. Rolling cycle	Thank you for your comment. Section 3.5 of the guidance discusses sponsorship and the potential impact on bag choice, but it is not in NICE's remit to determine whether sponsorship should remain.
164	Consultee 11 Peak Medical Ltd	1.3 Considerations for healthcare professionals	As an SME who have never entered the practise of sponsorship marketing programs. We would argue that choice of product is not free from sponsorship infleunce. Even if this is a subconcious action on behalf of the clinician. The question should be asked, why do commercial organisations undertake sponsorhip if it doesn't provide influence.	Thank you for your comment. Please see the response to comment 154.
165	Consultee 11 Peak Medical Ltd	3.4 Variation in care pathway	Appliance user reviews conducted by DAC employed nurses is a very flawed structure. This allows vertically intergrated manufacturer DACs to exert further control over the patient, as well as increasing income via the payments generated by these reviews whilst at the same time benefit from significant opportunity to promote their own product.	Thank you for your comment. Section 3.4 of the guidance acknowledges that appliance use reviews are done by pharmacy contractors or a nurse working directly with a DAC, which are often linked with stoma appliance suppliers or manufacturers.
166	Consultee 11 Peak Medical Ltd	3.5 Variation in care pathway	We would agree that further information around the impact of sponsorship is needed. However, we would suggest that clinicans who are sponsored would not be truly subjective around this issue, so careful consideration should be given as to how this information is gathered.	Thank you for your comment.

167	Consultee 11 Peak Medical Ltd	3.14 Regression analysis	In relation to the final statement around pricing being driven by competition rather than innovative features. Whilst we undertand why at certain levels this may appear a logical conclusion. However it should be kept in mind that for an SME who has never participated in sponsorship, this program has an impact upon our pricing. As a barrier to entry for ourselves, it means we struggle to generate sufficent volume which enables us to achieve lower cost prices.	Thank you for your comment. This statement acknowledges that there could be other factors that drive pricing as there is limited association between potentially innovative features and price.
168	Consultee 13 Convatec	1.3 Considerations for healthcare professionals	This statement needs to be more explicit to ensure that it is clear that all brands should be presented and discussed with patients at post surgery. In addition, manufacturers should cease the practice of obligating NHS Trust' stoma units to provide data on the number of stoma procedures and which products and manufacturers were offered to each patient; this is creating expectations on nurses to only use the products of the sponsoring manufacturer.	Thank you for your comment. The recommendation states that stoma care services should have access to a broad range of one-piece closed bags and that decisions should be based on clinical appropriateness and the needs and preferences of the person with a colostomy. The 'what this means in practice (considerations for healthcare professionals)' section encourages the decision to be free from sponsorship influence. Additional wording has been added to 'what this means in practice (considerations for people with a colostomy) to make people aware that a range of one-piece closed bags (from a number of companies) are available for prescription, and that they should be given information about all of the bags that are suitable for them.

169	Consultee 13 Convatec	1.3 Considerations for healthcare professionals	Sponsored nurses have an obligation to their sponsor to report the products used and DAC provided for their patients. This metric is regularly checked by a sponsor relationship manager for compliance, which conflicts with the terminology within the sponsorship contracts between manufacturer and NHS Trust which points out that nurses will not be influenced by the manufacturer on the products to use; in practice, this is exactly what happens and in-market data supports this. For example, where a manufacturer is the main or sole sponsor of nurses in a Trust, in-market data will highlight that the largest market-share of product usage in that Trust will be with that manufacturer. This could be considered as conscious or unconscious bias on the choices made by the sponsored nurse	Thank you for your comment. Section 3.5 of the guidance highlights the StoMap programme baseline report (2019) in which data from the East of England showed that, for 12 out of 13 hospitals with formal sponsorship agreements, the sponsor was the market leader in product use.
170	Consultee 13 Convatec	3.5 Variation in care pathway	Given the importance highlighted by the committee on this matter, below is a list of 23 (former CCG) neighbourhoods that demonstrate a direct correlation between hospital sponsorship and >60% market share in 1 piece colostomy bags for annual data ending November 24: NHS Bristol, North Somerset And South Gloucestershire Ccg Coloplast 79.4% NHS Gloucestershire Ccg Coloplast 74.3% NHS Stafford And Surrounds Ccg Coloplast 74.2% NHS Leicester City Ccg	Thank you for your comment. Section 3.5 of the guidance highlights data from the StoMap programme baseline report (2019) in which correlated formal sponsorship agreements and being the market leader in product use in that hospital. This aligns with the data presented in your comment.

			CliniMed 73.8% NHS Wolverhampton Ccg Coloplast 73.7% NHS Bassetlaw Ccg Coloplast 72.8% NHS Southend Ccg Dansac 72.2% NHS Morecambe Bay Ccg Coloplast 71.5% NHS Hounslow Ccg Coloplast 70.9% NHS Cannock Chase Ccg Coloplast 70.8% NHS Walsall Ccg Coloplast 70.0% NHS Stoke On Trent Ccg Coloplast 69.1% NHS Luton Ccg Dansac 68.3% NHS North Staffordshire Ccg Coloplast 66.3% NHS West Leicestershire Ccg CliniMed 65.2% NHS West Essex Ccg Coloplast 64.9%	

			NHS Castle Point And Rochford Ccg Dansac 63.8% NHS Doncaster Ccg Coloplast 63.6% NHS Hammersmith And Fulham Ccg Coloplast 62.3% NHS Herefordshire and Worcestershire Coloplast 61.2% NHS West London (K&C & Qpp) Ccg Coloplast 61.0% NHS Central London (Westminster) Ccg Coloplast 60.8% NHS Telford And Wrekin Ccg Coloplast 60.6%	
171	Consultee 13 Convatec	3.20 Evidence needed to demonstrate additional value	Consideration needs therefore to be given to finding stoma nurses who are not company sponsored and therefore biased. Given >80% of current positions are funded through direct or indirect sponsorship , this poses a challenge to progression.	Thank you for your comment.
172	Consultee 3 Coloplast	1 RIA Report	The statement ‘the price charged for stoma bag could include a cost of sponsorship element’ is not backed by evidence and undermines the whole premise of this document, so the document should be withdrawn. In addition, the statement shows a misunderstanding of the reimbursement process. Any new product is submitted to Drug Tariff and NHS BSA with evidence and the Drug Tariff set the price.	Thank you for your comment. Please see the response to comment 98.

			The price is based solely on the quality of the product. For sponsorship to influence price you would have to have an infeasible situation where a company is asked by Drug Tariff if they sponsor NHS Trusts – if the answer is yes, then you get a higher price than if you do not sponsor.	
173	Consultee 3 Coloplast	1 RIA Report	Because the cost of sponsorship is not known' 'monetary value of sponsorship is not known'. All sponsorships are 100% initiated by individual NHS Trusts, so these questions should be answerable. The Trusts contract and tender under current procurement regulations. Price is never part of any sponsorship contract, so there is zero connection between an NHS Trust initiated sponsorship and Drug Tariff price setting.	Thank you for your comment. Please see the response to comment 98.

174	Consultee 3 Coloplast	1 RIA Report	Stoma sponsorship delivers proven clinical benefits to the NHS, driving improvements in patient outcomes and experience. It fulfils an essential service for the NHS, patients, and the taxpayer, as requested by the health system itself via tenders. However, the current model for sponsorship in England and Wales is not without issue in the way that it operates and there are concerns regarding conflicts of interest and transparency. In addition, we know that not all sponsorships are equal, with some providing greater quality and value than others. If sponsorship was simply to be stopped, the impact on patient care and the NHS would be unacceptable. Local NHS trusts would not have the capability or resources to plug the gaps. Whatever happens in the future it is imperative that a 'quantum of service' is maintained to avoid any decline in patient care, or reduction in patient and clinical choice.	Thank you for your comment. Please see the response to comment 98.

175	Consultee 3 Coloplast	1 RIA Report	87% of the market in England and Wales is currently sponsored by industry. Sponsorship fulfils a much- needed and requested service by the NHS – one that it may not be able to afford itself. Companies providing sponsorship, such as Coloplast, do so in a manner that is transparent, ethical and offers independent, impartial advice, regardless of profit. Industry support for stoma care services is well integrated with patient care at an acute and community level and, as it has developed over many years, operates smoothly within standard NHS pathways. Currently many of the value adding support services such as IT systems and Educational Programmes have been developed by industry and are not currently available within NHS training and development capacity and capability.	Thank you for your comment. Please see the response to comment 98. Section 3.5 discusses the types of services funded by sponsorship.
176	Consultee 3 Coloplast	1 RIA Report	Guarantees that a quantum of service would be maintained is needed, as seen by this case study on what happened in Scotland: Removal of sponsorship in Scotland: the Scottish Government made the decision to remove stoma sponsorship. The result has been negative for both patients and stoma nurses alike: 46 stoma nurses in 2006 down to 21.4 in 2017, The NHS Scotland workforce survey has not been completed since 2018. A recent 2023 survey by the Scottish Stoma Forum highlights that patient to WTE nurse comparison is 510 patients on average to 1 stoma nurse in Scotland, compared to 330 patients in England. Nurses report that this overburden of patients is causing concerns	Thank you for your comment. Published papers on the impact of ending nurse sponsorship in Scotland are mentioned in section 7.4 of the EAG assessment report.

			over the care available to patients and significant challenges in reviewing patients at least annually. This coincides with patients conveying a strong message about the need for more regular reviews from stoma care nurses. The specialist role of a stoma nurse is being diluted in some boards, with experienced nurses retiring and lower bands being employed, and some nurses are being employed as a colorectal nurse specialist who have stoma care as part of their role.	
Technology features				
177	Consultee 1 Individual	2.2 2 The technology	I have been a user of the Trio Genii closed bag with the silicon baseplate since July 2022. This bag has never leaked, never required any supporting products and the flat standard baseplate moulds easily around my parastomal hernia. I am highlighting this bag because it was a game changer for me and I would consider it to be a next generation technology. Consequently I would ask that baseplate material/composition be added to this innovation list. Hopefully this would give other manufacturers an incentive to develop their own silicone technology bags.	Thank you for your comment. Baseplate additives, shape and adhesive were all considered innovative features. Durability of the baseplate and fit of the baseplate were also criteria identified in the user preference assessment that were ranked of high importance to users when considering which one-piece closed bag to choose.
178	Consultee 4 Individual	Not specified	In my 28 years of Stoma Nursing I have never encountered clients wanting to wear black pouches to match their underwear. They choose the colour for their own skin colour and for aesthetic reasons to improve their body image. This is so important to ensure optimum psychological rehabilitation. Each Ostomists will have different	Thank you for your comment. The guidance recommends choosing a bag that meets the clinical need and the needs and preferences of the person with a colostomy as the first priorities, and encourages shared decision making. If more than one type of one-piece closed bag is

			interpretations of what they need. I understand the economics but when the price is too good to be true then it often is. In my experience the cheaper bags do not provide quality and confidence our clients deserve.	clinically appropriate and meets the needs and preferences of the person with a colostomy, then the recommendations suggest using the least expensive option. Section 3.8 of the guidance states that people may prefer choosing a bag that most closely matches their skin tone, if this is available.
179	Consultee 11 Peak Medical Ltd	2.2 2 The technology	It seemsodd that no mention of Convexity, either soft or standard, shallow or deep varaiants are mentioned within this list of potentially inovative features. It could be argued that convexity is the biggest innovation in stoma care over the last 25 years.	Thank you for your comment. Flat and non-flat bags (including convex bags) were considered as groups with separate cost structures in which there were additional innovative features.
User preference				
180	Consultee 1 Individual	3.7 User preferences	Fully agree that leakage prevention is the most important criteria. Every leakage is devastating for a patient ... physically, mentally and socially. I consider it a complete product failure and there should be a zero tolerance of it. It is not a problem to be managed or partially accepted.	Thank you for your comment.
181	Consultee 3 Coloplast	3.7 User preferences	It should be noted that the User Preference work is limited in its generalisability by the small sample size, as we discussed in detail in Comment 16 and Comment 30 on the User Preferences report. The committee noted that the process was robust, but Section 3.7 should be amended to reflect the level of uncertainty in the resulting evidence.	Thank you for your comment. 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. The report acknowledges that this assessment uses a sample of CNS in stoma care and people with lived experience and may not be fully representative of the wider population.

				The committee considered this comment and decided not to change the guidance wording.
182	Consultee 3 Coloplast	3.7 User preferences	We disagree – patients should have access to bags with features that meet ALL criteria as defined important to the patient to ensure quality of life is not just maintained but is improved. As we noted in Comment 32 on the User Preferences report, though users completed the task of ranking the different criteria, they reiterated the importance of all of the criteria on product selection. The user preferences work done as part of this LSA has demonstrated the importance of patient preferences in the decision-making process. We believe that the highlighted text should be amended to the following: '...meets all or as many as possible of the preferences and needs of the person with a colostomy'	Thank you for your comment. Section 3.7 acknowledges that all criteria are important but that users would prioritise a bag that reduce leakage and seepage and maintain and promote healthy peristomal skin. This is reflective of the outcomes of the user preference assessment and the guidance wording has been reviewed by specialist committee members who were involved in this process.
183	Consultee 4 Individual	3.7 User preferences	This shows a clear indication that good quality products are required to avoid these distressing situations.	Thank you for your comment.
Wording				
184	Consultee 3 Coloplast	1.3 Considerations for healthcare professionals	Please amend to: "Clinical appropriateness, preferences and needs of the person should be prioritised. When taking cost into account, be aware that, although some features may be worth paying more for, more information is needed to demonstrate this.'	Thank you for your comment. Please see the response to comment 9.

			This is because a cost-minimisation recommendation can only be appropriate when there is good evidence of equivalent clinical effectiveness. Neither the EAG nor the committee were able to reach this judgement, but did accept that some evidence showed that some features were associated with increased benefit. In its assessment report (p13), the EAG stated that price variation was not supported “due to an absence of evidence rather than evidence of no benefit associated with the bag features." The committee concluded similarly, as summarised in the first sentence of section 3.18. None of these conclusions support a recommendation to choose the lowest cost product, and the wording places an invidious responsibility on healthcare professionals to choose between “...multiple options which could be suitable” on the basis of price, when the evidence assessment has not provided reliable value signals to help them choose.	
185	Consultee 6 Individual	1.3 Why the committee made these recommendations	Line two - 'low-quality and.....' and what? Missing information here. Agreed that there should be physical evidence that expensive bag A is better for my skin (leaks, lifestyle etc) than cheaper bag B	Thank you for your comment. The committee has considered this comment and no changes to the guidance have been made.
186	Consultee 13 Convatec	1.2 1 Recommendations	Propose enhancing this statement to include .."having been presented with all available information to allow for meaningful selection"	Thank you for your comment. The committee has considered this comment and no changes to the guidance have been made.
187	Consultee 13 Convatec	1.3 1 Recommendations	Propose adding further bullet to this section: * and allows for minimum disruption to daily living.	Thank you for your comment.

				The committee has considered this comment and no changes to the guidance have been made.
188	Consultee 13 Convatec	1.3 Considerations for procurement and commissioning	This statement, having been written from a negative perspective offers little value to the reader. Consider reframing the information be be more informative?	Thank you for your comment. The wording and structure of this section has been amended to improve clarity.
189	Consultee 13 Convatec	1.3 Considerations for procurement and commissioning	With appropriate bag selection, this statement becomes invalidated. Complications occur when inappropriate selection has occurred and the bag does not offer a good fit and seal for that individual body contour. Surveys can demonstrate that there are as many users who experience no leakage as those who do	Thank you for your comment. NICE has added additional wording to section 3.6 to acknowledge that getting the right bag from the beginning of a person's journey can reduce costs linked to bag-related complications. The guidance recommendations aim to encourage the choice of bag that meets the needs and preferences of the person with a colostomy. This would include choosing a bag that does not leak.
190	Consultee 13 Convatec	3.9 Clinical evidence included in the assessment	Is this level of detail required in the guidance?	Thank you for your comment. The committee considered this comment and concluded that an appropriate level of detail was included in this section of the guidance.
General				
191	Consultee 1 Individual	1.1 1 Recommendations	Could this recommendation not be interpreted by some that colostomy patients will be entitled to closed bags only on prescription? Please note that I'm assuming that there is currently no other NICE stoma bag guidance elsewhere. Colostomy patients do also need access to drainable bags. For instance,I sometimes use a drainable bag on social occasions where there are no facilities to change a closed bag. I also rely on drainable bags to cope with instances of diarrhoea/high volume output.	Thank you for your comment. Section 3.6 of the guidance has been amended to acknowledge that some people with a colostomy use two-piece or drainable bags.

192	Consultee 2 Hollister Ltd	Not specified	We would suggest that the whole LSA process is fundamentally unsuited to assessing products of this nature. It is very evident from the work already undertaken by NICE and the EAG that there have been numerous issues with both with the actual process itself, and then the ability to make any robust conclusions. The EAG repeatedly commented on the paucity of evidence and that as a result any finding would at best be highly speculative. It appears a very significant amount of money and time has been spent undertaking this work with no robust and meaningful conclusions possible - should future work be required to assess these products a different methodology could therefore be more appropriate. We would also comment that NICE have repeatedly received consistent feedback from across industry, from the very beginning of the process, as to the lack of appropriateness of the LSAs to this market sector.	Thank you for your comment. The purpose of LSA guidance is to evaluate categories of technologies that are already in widespread use within the NHS to assess whether price variations between technologies in a category are justified by differences in innovation, clinical effectiveness and patient benefits. During the LSA pilots, NICE have been making notes of the lessons learnt and will also consider feedback from after action reviews prior to revising the methods and processes.
193	Consultee 3 Coloplast	Not specified	Coloplast understands that comments on the processes and methods for late-stage assessment (LSA) are outside the scope of this consultation. However, we ask that the committee is made fully aware of stakeholders' significant and ongoing concerns about these. Coloplast has repeatedly asked for live topics to be paused so that a robust approach can be developed as part of NICE's lifecycle approach to evaluation, which we support. Our concerns with the Methods and Processes are addressed in separate comments.	Thank you for your comment. The committee have received and read all consultation comments. The LSA pilots are being done according to the LSA interim process and methods. Following the conclusion of the pilots, the topic challenges and interim methods and process will be considered using feedback from these comments, lessons learnt collected from each pilot and after action reviews prior to revising the methods and process. The LSA pilots are being done in the same way as the early value assessment pilots where topics are done using an interim methods and

				process which is then revised following lessons learnt.
194	Consultee 3 Coloplast	Not specified	Concerns with Methods: No methodological research was commissioned or published (such as from the Decision Support Unit), or any pilot work carried out (such as in NICE's HTA Lab), before the first topic was started, or before the interim process statement was developed. This is in contrast to the approach used routinely for novel medicines, or for other healthtech streams such as early value assessment. In addition, we are not aware of the approaches adopted by NICE being used by any other HTA agency, from which learning could be drawn or shared. NICE's response to this is that late-stage assessment is a minor extension to its healthtech evaluation programmes, building on 15 years of experience, and that the interim statement, alongside the main Health Technology Evaluations manual are sufficient and appropriate. We disagree with this, on the basis that all 8 live topics have, so far, resulted in inconclusive assessments and inconsistent application of the methods. Unresolved issues include: whether the feature/component-focused approach is methodologically appropriate for value	Thank you for your comment. Please see the response to comment 193.

			determination in all product areas chosen; whether the multiple user preference approaches – which vary by topic - are robust and why these are not carried out independently by an External Assessment Group; and how the clinical and economic, and user preference, evidence is integrated in decision-making.	
195	Consultee 3 Coloplast	Not specified	Concerns with Process: The methodological concerns and rush to complete the LSA pilots has resulted in project timelines which are chaotic, with multiple changes, leading to disruption for stakeholders and compromising their ability to prepare and respond to engagement or consultation opportunities. Short project timelines have also required External Assessment Groups to carry out rapid overviews, rather than systematic assessments. NICE's response to this is that LSA is a pilot, test-and-learn initiative. However, the rush to launch 7 live topics over 6 months during 2024 does support this; there has also been little or no evidence of learning between topics.	Thank you for your comment. Please see the response to comment 193.
196	Consultee 3 Coloplast	Not specified	In this evaluation, we have argued that the lived experience of people with ileostomies and urostomies would provide relevant evidence to complement published studies, which NICE declined. We are also stakeholders in the late-stage assessment of antimicrobial dressings for infected leg ulcers,	Thank you for your comment. NICE invited people with a colostomy to take part in this assessment as specialist committee members. As NICE received a large number of applications from people with a colostomy, some of whom also bring

			in which a patient expert has been providing lived experience insights with a surgical site infection (SSI), from a caesarean section, an indication which was outside the scope of the evaluation. We are concerned that there is a lack of consistency between late-stage assessment topics which is resulting in not all the relevant evidence being taken into account.	experience of also having a urostomy, NICE did not need to seek input from people with other types of stoma. From speaking to people with a colostomy and CNS in stoma care, NICE acknowledge that people with a urostomy or ileostomy may have different experiences, needs and preferences due to the differences in stoma type and output, making their input less applicable to this evaluation. In terms of the EAG assessment, the evidence considered was based on the NICE scope for the LSA, which was restricted to people with a colostomy. Given the lack of evidence, the EAG sought CNS in stoma care opinion during the assessment to determine whether evidence from people with an ileostomy and for 2-piece bags in people with a colostomy should be considered. There was no consensus that the evidence on ileostomy was generalisable and so it was not included in the clinical evidence review. But there was some transferability of the evidence for 2-piece bags. The scope was broader for the economic model which did consider evidence from ileostomy studies. Details of the decision making and additional evidence considered were presented in appendix E and J in the assessment report.
197	Consultee 3 Coloplast	3.1 The condition	The Colostomy UK survey is still, to our knowledge, unpublished. As we raised in Comment 14 on the User Preferences report, it is impossible for stakeholders to review this survey and verify the cited information. NICE has indicated in its responses to	Thank you for your comment. The Colostomy UK survey data has been used for contextual purposes as it was done on a relevant population. The final guidance has been amended to provide data from people with a colostomy in England. Quality

			feedback that the Colostomy UK survey was 'used to provide context due to a lack of other appropriate data sources.' There have been numerous data sources, including those that are peer-reviewed; however these were not deemed of high enough quality by the EAG. Please can NICE describe what quality assessment was done on the Colostomy UK survey which justified its use over peer-reviewed published data?	assessment of this information was not required, as it is not used to make clinical or economic decisions. No alternative sources of information have been provided to NICE during stakeholder engagement steps and no published papers were excluded that provided equivalent information.
198	Consultee 4 Individual	3.4 Variation in care pathway	ASCN are leading a project for ensuring a standardised pathway of care across the United Kingdom in the future.	Thank you for your comment. This has been acknowledged in section 3.4 of the guidance.
199	Consultee 5 Colostomy UK	3.4 Variation in care pathway	we agree strongly that a standardised 'best practise' pathway is needed to ensure everyone has access to the same care. Without this people living with a colostomy will continue to face the same stoma management challenges that they do now	Thank you for your comment.
200	Consultee 6 Individual	1.3 Considerations for healthcare professionals	Agreed	Thank you for your comment.
201	Consultee 6 Individual	3.2 Impact of having a stoma	Agreed - this is the same for other ostomy patients	Thank you for your comment.
202	Consultee 6 Individual	3.3 Impact of having a stoma	Patients with ileostomies can suffer more bag related problems than those with a colostomy. Ileostomy waste is more liquid and more acidic and contact with the skin usually more damaging. Please role this work out to include ileostomy bags / patients as they tend to have more complications with leaks and skin damage.	Thank you for your comment. NICE acknowledges that people with ileostomies have more bag related complications than people with a colostomy and that some people would like this process to be repeated in this population.

203	Consultee 11 Peak Medical Ltd	3.3 Impact of having a stoma	If 31% of responders do not have a colostomy, have the responses of these 1,160 respondents been excluded from the results. If not, how is it justified to include.	Thank you for your comment. The survey results have now been updated to response from people with a colostomy in England only.
204	Consultee 13 Convatec	Not specified	This LSA has thrown many challenges and demonstrates immaturity of market readiness for such evidence based review guidance. Given the personal nature of the topic, the 'lived' experience plays such a fundamental part of any choice therefore all guidance should be worded to support this. Some comments included in our feedback that offer an alternative lens and more appropriate worded guidance.	Thank you for your comment.
205	Consultee 13 Convatec	3.4 Variation in care pathway	There is already a model in place to support this practice; the support offered by DAC does not feature within this guidance but in reality contributes to a significant benefit to users	Thank you for your comment. Section 3.4 aims to capture that there is a variation in the care pathway for people with a colostomy, including the use of DACs.
206	Consultee 16 ASCN UK	Not specified	ASCN UK Response to consultation 3/3/2025 1.2 – We feel this should read a Specialist Stoma Care Nurse (SSCN) who has advanced specialist skills and knowledge of the stoma care speciality. A patient MUST have a thorough Clinical Assessment by a SSCN which is why we have raised the issue of the need for a national pathway which currently does NOT exist and may lead to inequity in care delivery for any person with a stoma. (please see attached letter). The prescription for stoma products can be written by any HCP holding a prescribing qualification, however the clinical assessment	Thank you for your comment. The committee considered the suggested wording and decided that CNS in stoma care would be used in the guidance for consistency. Section 3.4 of the guidance discusses the importance of access to CNS in stoma care and the current variation in care between stoma care services. This section also highlights the need for a standardised care pathway for people with a colostomy and has been amended to include reference to the standardised mandatory stoma care pathway that is currently being developed by the Association for Stoma Care Nurses UK.

			must be carried out by an NMC registered SSCN with informed consent and in collaboration with the patient. 1.3 As clinicians our understanding is that within stoma care industry there is mutual respect between manufacturers resulting in no cross comparison of products resulting in evidence from the manufacturer only. Manufacturers are at pains to produce new evidence supporting their new innovation and developments within the speciality. This has been evident in the huge advances in technology and as SSCN we are aware of the issues that arise from using outdated products as we see patients in clinic with leakages and sore skin resulting in increase in costs (time and product) as well as a significant impact on the patient's quality of life. As clinicians, the quality of newer more innovative products is evident to us in our expert practice. Cheaper products lack advanced technology and do not offer adequate wear time, comfort, reassurance for the patient, lack discretion, do not offer adequate skin protection, resulting in leakages, peristomal sore skin resulting in visits to SSCN (if available). Visits to the SSCN are a cost to the NHS and IF stoma care services are not available patients will seek non expert information and potentially order inappropriate products, frequently perpetuating the economic burden even further. This can include additional products (Eg. seals, pastes) that a SSCN after assessment would not deem necessary which leads to an increase in prescription	The aim of LSA is to assess if the value added by incremental innovation justifies the price variation of a group of products and the EAG conducted an evidence review for the available evidence evaluating one-piece closed bags for people with a colostomy. The committee concluded that there is not enough evidence to determine whether price variations are justified between different one-piece closed bags for adults with a colostomy. But, it noted that one-piece closed bags with features that can be proven to improve or prevent leakage, seepage and PSCs may be worth paying more for. The wording and order of the recommendations have been amended. The guidance prioritises the person's needs and preferences and emphasises the importance of clinical appropriateness when choosing a one-piece closed bag via shared decision-making. Additional detail has been added to the 'what this means in practice (considerations for healthcare professionals)' section to clarify that the recommendations are not intended to impact existing choice where people with a colostomy are happy with their one-piece closed bag. Additional wording has also been added to section 3.19 stating that clinical experts noted that some less-expensive bags were of lower quality and led to worse outcomes, but acknowledges that there is a lack of evidence to demonstrate this.

			costs. An equitable pathway of care would provide the patient with on-going education and support for the whole time they are living with a stoma allowing direct access to clinical expertise and advice regarding stoma products and management. This would include appropriate product updates as new innovations enter the stoma care speciality that may enhance quality of life for the patients, equally we support patients who very often choose to remain on a product they have confidence in and are reliant upon. Many SSCN has been witness to patients being “swapped”/or actively encouraged to change product (when they were happy with current product) by non-specialists onto cheaper, inappropriate products resulting in an increase in anxiety for the patient due to poor function of the product and withdrawal from daily life. Reduced self-esteem for the patient, which is difficult to measure profoundly impacts on patient quality of life and their ability to function as a fully contributing member of society which has a further socio-economic impact. Once a clinical assessment has been completed and discussions with the patient regarding the most suitable products determined, it would be unethical to alter the focus of the assessment to cost. Patient clinical need should be PARAMOUNT and the driving determinant to product choice. By reviewing One-piece closed bags for colostomies: late-stage assessment in silo without considering the SSCN service provision nationally is failing to recognise the	In relation to the definition of a colostomy, this has been amended to align with the NHS definition. In relation to appliance use reviews, the wording in section 3.4 has been updated and the link has been removed. In relation to stakeholder engagement, NICE recruited 5 clinical specialist committee members and 4 clinical experts to contribute to this process. 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 and review relevant documents at multiple stages throughout the process.

			cost-efficient nature of SSCN. We, as SSCN ensure right product, right patient, at the right time. SSCN's are advocates for the patients and for the NHS and fulfil an overarching, ethical stewardship of resources for NHS. 3.1 – We feel this definition is still poorly worded. 3.4 – The highlighted ASCNUK link is incorrect and outdated. There is a significant difference between Appliance Use Review (AUR) that can be carried out by pharmacy contractors or a nurse working directly with a DAC, which are often linked with stoma appliance suppliers or manufacturers and an Annual Review that is a clinical review carried out by a SSCN. We feel that you have confused the definitions and thus misrepresented our recommendations. Letter regarding Advancing Stoma Care Services Project We hope this finds you well and that you do not mind us reaching out in this manner. We are the committee of the Association of Stoma Care Nurses (ASCNUK), the only professional organisation to represent stoma care nurse specialists. We advise, support and advocate for specialist nurses in order that they can deliver best practice care to ostomates. We produce guidelines, education and conference events, and devise and deliver projects that we understand to be of value to our members, but ultimately to ensure that ostomates are protected,	

			supported and cared for. It is with one of our projects in mind that we are writing to you. Advancing Stoma Care Services (ASCS) project started in 2019, following the identification of national variation in stoma care service provision resulting in inequalities for ostomates. This variation means that patients undergoing stoma surgery can be at the mercy of, what is often termed, a 'postcode lottery'. There is currently no standardised pathway of care for patients. This is in direct comparison to services for other patients with long term health conditions such as cancer or diabetes. All stoma care nurse specialists strive to deliver best possible care, the variance in commissioning, funding and understanding of services and workforce leads to unwarranted variance for patients. We use the term 'unwarranted variance' very deliberately as it is a term used within the NHSE Getting it Right First Time (GIRFT) lexicon and we are proud to say that the ASCS project is now within the framework of future pathways under the GIRFT team. This is a huge achievement, and we believe this will make a massive difference to the impact and success of the project, enabling us to protect and standardise stoma care services for all ostomates. ASCNUK members, and stoma care nurse specialists (SCNS), have recently participated in the NICE Late Stage assessment into Colostomy bags (LSA) process, as well as the Part IX review. It has resonated with us that understanding of the complexities of the speciality is generally poor and that as an	

			association we owe it to our members, and patients, to speak up and endeavour to educate and inform so that any national NICE Assessment is ultimately effective and fair. The reason we include so much background is because of the said complexities and poor understanding, • there are no standardised pathways for how stoma care is regulated (beyond NMC for those registered practitioners), • there is no funding particular to stoma care, nor within colorectal pathways so funding and commissioning is decided locally, if at all. Services can be based in NHS primary care or secondary care, they can be sponsored, or the workforce may be industry employed. • Stoma prescription management in the UK varies with GP's, agreed prescription services and non-medical prescriber (NMP) stoma care nurse specialists (SCNS) all contributing to this according to agreed local services. There are many misconceptions related to stoma care; some around sponsorship or product use and decision-making, others about provision and expectations. ASCNUK trusts that all NMC registered nurses will make decisions about product use based on clinical need, clinical relevance and in discussion with patients, because our registration matters to us as does getting it right for our patients. This is why the ASCS project is such a vital part of our work at ASCNUK. Not only will it provide standardised, mandated, acknowledged pathways (supported through	

			NHSE GIRFT) but it will provide the oversight of the whole speciality which will raise awareness and understanding and ultimately permit and support ethical practice as well as the ability to challenge poorer practices. Throughout the LSA you have rightly sought the voices of stake holders, but we feel that the questions needing answers have been narrow and have failed to encompass all the nuance that surrounds complex stoma care practice, and it is this nuance that is important. To ensure cost efficiency and best outcomes and experience for patients the wider picture MUST be considered, or the review will create only division, upset and problems and will ultimately fail to deliver on its aims. It may seem a simple 'fix' to advocate use of the least costly product, but costs increase for the following reasons: • patients changing MORE often because they are in a cheap or inappropriate or poorly applied product – the actual fix is that they should see a stoma care nurse specialist. • They leak when in the wrong product, so they order more because they use more, • they 'stockpile'- worrying they will run out of supplies as they are using more, • They have sore skin due to leakage, so they order more or other products, often totally inappropriate and counterproductive, • They are made anxious when press reports imply shortage or stoppage of products and can 'stockpile'. They need review by stoma specialist to treat	

			skin, monitor progress and ensure the correct product is being prescribed. They need access to specialist nurses to reassure, review and prompt appropriate product and ordering routine. Ostomates are subject to marketing, like everyone else in society, they need access to specialist services to discuss whether the desired product is appropriate, useful and safe. Nursing is after all the largest safety critical workforce in the NHS, stoma care is no different, poor care without expert specialist nurses' results in human and fiscal costs elsewhere whether that be admissions, length of stay or outpatient time and medication use. In this sense cost efficiencies are the same as outcomes, money is wasted when patients struggle or have a poor service. This is even more pertinent in stoma care, patients who leak withdraw from others, family friends etc, incidence of depression and mental health issues increase with chronic ill-health and loneliness. This then leads to work/education avoidance which impacts prospects, financial stability and then has an impact on society and the economy. It is understandable that the National Institute looking at Clinical Evidence should look for this evidence in stoma care, we all desire best practice and best products for our patients and understand the need to validate this evidence. However, the complex nature of stoma care means that to simply look at product alone is an oversimplification and will not bring about the improvements in outcomes, experience or efficiencies that are hoped for. We, as a professional Association,	

			ask that you consider the work of our ASCS project, await it's establishment as policy, so that there is the specialist support to ensure that any assessment is safe, effective and will not negatively impact a group of patients who already suffer at the hands of variable service provision and acute condition related stigmatisation which affects their quality of life and outcomes. We would be very happy to give more information about the project and its progress and are grateful for your time in reading this, Warmest regards, ASCN UK Committee	
207	Consultee 17 CEO of Vanilla Blush	Not specified	I appreciate the concerns raised in the document regarding pricing inequalities for colostomy bags on the drug tariff. While my company does not supply colostomy bags, we operate within this field, and I also speak from the perspective of someone who has lived with a stoma for 19 years. One crucial aspect that appears underrepresented in the document is the fundamental importance of patient independence. For many individuals with a stoma, managing their condition is not just a medical necessity but a key aspect of maintaining autonomy and quality of life. The ability to make independent decisions about the products they use should be recognised as a fundamental right. From years of experience both personally and professionally, it is evident that a significant number of people with a stoma live entirely independent of clinician input. These individuals become experts by experience in their own stoma management and are often	Thank you for your comment. NICE promotes shared decision making in the recommendations in this guidance, acknowledging that clinical need and the needs and preferences of the user should be considered together when choosing a one-piece closed bag. NICE has done work on user preferences to highlight the key considerations that can be used when deciding on the type of bag to use. Hopefully this information, the information presented in the guidance and information for public will help people with a colostomy in their decision making. NICE encourages the collection of further evidence, including real world data to demonstrate the additional benefits of potentially innovative features. Section 3.6 of the guidance highlights the need for shared decision making and acknowledges that the

			more likely to seek advice from peers—others with a stoma—before consulting a stoma care nurse. The document focuses heavily on price inequality versus benefit, stoma product switching, and the cost-effectiveness of innovations in bag and baseplate design. While these are valid considerations, they must also be balanced with real-world patient experience. There is no denying that new and innovative products will attract interest, and many individuals enjoy trailing new samples to compare with their current products. However, personal experience has shown that initial preferences may change over time. In some cases, individuals may begin by prioritising aesthetics or convenience but ultimately gravitate toward products that provide greater security and peace of mind. When considering pricing, this shift from "style over substance" can sometimes come at a higher cost. For example, one individual who has lived with a stoma for nearly two decades found that the bag providing the greatest level of security and comfort was more expensive than others with additional features or enhancements. However, the higher cost was balanced by eliminating the need for supplementary products such as sprays or seals. The concern arises when price reductions force manufacturers to withdraw certain products from the market. The potential loss of a trusted and effective product due to financial constraints would be far more detrimental to many independent individuals with a stoma than any perceived cost-saving measures.	needs and preferences of a person with a colostomy will change over time. The recommendations made in the guidance encourage bag choice to be made based on clinical appropriateness and the needs and preferences of a person with a colostomy. If there is more than one bag that meets these criteria, the recommendations then suggest using the least expensive bag. Sections 3.1 and 3.8 of the guidance acknowledges the reasons for needing a colostomy and recognises that the needs of people with a colostomy vary from person to person, and access to a wide range of bags is required. NICE encourages further evidence generation including the collection of evidence in various different groups of people with a colostomy who have complex needs.

			This document appears to take a broad-brush approach to patients requiring stoma appliances but does not fully recognise the diversity of individuals who rely on them. Some distinctions are made—for example, between a cancer patient with a potentially reversible stoma and someone with IBD—but these nuances require deeper exploration. More importantly, the lived experiences of people with a stoma should be central to discussions on product benefit, choice, and cost. Increased patient representation is essential to ensuring that any policy or pricing decisions reflect the realities of those who depend on these medical devices every day.	
208	Consultee 3 Coloplast	Not specified	Increasing pressures on the NHS due to long-term conditions (alongside an aging population, obesity, and dementia) means health and social care are becoming more complex and fragmented. Specialist stoma nurses have been shown to deliver cost efficiency savings, greater service efficiencies, better patient recorded outcomes and bridge gaps in the system leading to a more seamless journey, resulting in improved patient experience [Mockford et al 2018, Hart& Benn 2019]. A stoma community programme which conducted specialist nurse led reviews across the UK between June 2016 and February 2018 resulted in £229 per patient annual cost saving from a reduction in wasted and inappropriate products (Mockford et al 2018).	Thank you for your comment.