NICE National Institute for Health and Care Excellence

NICE guidance

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

Health technology evaluation

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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1 Recommendations

1.1 There is not enough evidence to determine whether price variation is justified between different one-piece closed bags for adults with a colostomy.

1.2 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.

1.3 A healthcare professional and the person with a colostomy should decide together which one-piece closed bag to use. Decisions should take into account clinical appropriateness and the person with a colostomy's needs and preferences (including preventing leakage, seepage and peristomal skin complications [PSC]), which may change over time.

1.4 If more than 1 one-piece closed bag is clinically appropriate and meets the needs and preferences of the person with a colostomy, use the least expensive option.

What information is needed

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

- leakage and seepage
- PSCs
- impact on psychological and social outcomes
- health-related quality of life
- healthcare resource use, particularly the number of appointments with clinical nurse specialists in stoma care
- the specific bag used

- how long a person uses 1 range or brand of bag before switching to another
- supporting products used.

  A core outcome set and validated patient-reported outcomes should also be developed to help consistency in outcome reporting across studies. Evidence should be generated across different groups of adults with a colostomy, including those who have complex needs (such as stoma or skin complications, or other conditions that could affect outcomes).

  This information could be collected through real-world evidence generation or formal research studies. For more detail, see sections 3.21 to 3.23.

What this means in practice

Considerations for procurement and commissioning

- Between April 2023 and March 2024, one-piece closed bags prescribed in primary care cost the NHS almost £92 million. There is a large difference in price between the least and most expensive bags available on the Drug Tariff (£1.85 to £3.84; April 2024 pricing).
- Current price variation cannot be justified by the presence of potentially innovative features because the external assessment group's (EAG) regression analysis shows limited correlation between the current price of bags and whether they have potentially innovative features.
- There is uncertainty in how much the NHS should pay for one-piece closed bags that prevent complications. The EAG's analysis calculated the maximum extra cost per one-piece closed bag to completely or partially (a 50% reduction) prevent complications. To completely prevent regular leakage (4 times per month) the estimated extra cost per bag is £1.22 and for PSCs it is £2.39. For partial prevention, the extra cost is £0.59 for regular leakage and £1.15 for PSCs. But these values are uncertain because of limited evidence and do not consider an overlap of complications.
- It may be worth paying more for one-piece closed bags with features that are proven to improve or prevent leakage, seepage, PSCs and related psychological and social outcomes.

Considerations for healthcare professionals

- Choosing a one-piece closed bag should be free from sponsorship influence.
- Decide together with the person with a colostomy which one-piece closed bag to use, and follow the principles of NICE's guidance on shared decision making.
- Consider the quality of the clinical evidence when prescribing new bags with claimed innovations.
- When choosing a bag, clinical appropriateness and the needs and preferences of

the person with a colostomy should be prioritised. But if more than 1 bag is suitable, the least expensive option should be used. This is because there is no evidence to justify variations in price.

- These recommendations are not intended to affect existing bag use if the choice is clinically appropriate and meets the needs and preferences of the person with a colostomy. These recommendations should be considered when people with a colostomy are switching bags.

Considerations for people with a colostomy

- You and your healthcare professional should decide together which one-piece closed bag to use. The bag you choose should be clinically appropriate and meet your needs and preferences. There is a range of one-piece closed bags (from a number of companies) available for prescription in the NHS. But not all one-piece closed bags will be appropriate for you. You should be given information about those that are.
- If more than 1 bag is clinically appropriate and meets your needs and preferences, your healthcare professional will offer you the least expensive one. This is because this assessment found no evidence to show why one bag should cost more than another.
- Your needs and preferences may change over time. Seek support from a healthcare professional if the one-piece closed bag you use causes complications, such as leakage or skin irritation, to see if changing the bag type (or supporting products) helps.

Why the committee made these recommendations

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

The cost-effective price for a bag is highly uncertain because of the lack of good-quality evidence. There is also not enough evidence to show whether differences between bags or features of bags justify the differences in costs. But the economic evaluation found that bags or features that can prevent PSCs and leakage may have the biggest impact on costs and quality of life.

More evidence is needed on outcomes that are important to people with a colostomy, and that allow clinical and cost benefits to be assessed. This evidence should be collected across different groups of people.

2 The technology

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

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

- baseplate additives
- baseplate shape
- baseplate adhesive
- bag shape
- filters
- bag material
- flushable disposal
- inspection window.

3 Committee discussion

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

The condition

3.1 A colostomy is where part of your large bowel (colon) is brought out through an opening made in your tummy. The opening is called a stoma. A colostomy may be needed during the treatment of conditions including, but not limited to:

- anal cancer
- colorectal cancer
- vaginal or cervical cancer
- ovarian cancer
- diverticular disease
- inflammatory bowel disease
- endometriosis
- Hirschsprung's disease
- birth defects
- nerve damage
- faecal incontinence

- trauma.

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

Impact of having a stoma

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

3.3 Some people with a colostomy will experience complications related to their one-piece closed bag. Interim results from a Colostomy UK survey with 2,101 responses from people with a colostomy (in England) found that 34% of people believed their physical and mental health had worsened since their surgery. The survey found that several factors contributing to this were linked with stoma-related complications, including leakage, skin irritation and pancaking (when poo collects around stoma instead of moving to the bottom of the bag). Another patient and carer organisation highlighted that using the right bag is vital for properly managing the physical and psychological effects of a stoma and related complications. Clinical and patient experts highlighted that some people experiencing complications may not seek support, including to change bag type, and will have ongoing issues. They stated that the proportion of these people, often referred to as 'lost ostomates', is unknown and they should be identified by their GP for annual reviews. Patient experts explained that maintaining skin health is key to quality of life. The committee acknowledged the large potential impact of complications. It also highlighted the need for further information about 'lost ostomates', to ensure that everyone with a colostomy can maintain their quality of

life.

Current management

Variation in the care pathway

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

3.5 Over 80% of hospitals in England have a formal sponsorship agreement (awarded by an NHS tender process) with stoma appliance suppliers or manufacturers (see the StoMap programme baseline report 2019). These agreements may include funding for clinical nurse specialists in stoma care, training, IT equipment and admin support. There is limited published evidence discussing the impact of sponsorship in England with mixed opinions on its advantages and

disadvantages. NHS England's commissioned report Delivering Excellence in Stoma Care (2020; PDF only) highlights that clinical nurse specialists in stoma care operate independently of the sponsoring company and may recommend competitor products. But, it also notes that they may receive training on sponsored products and be most familiar with bags from the sponsoring company. This can result in people who use colostomy bags being given sponsored products on discharge and continuing to use these products in the community, potentially impacting user choice. In the East of England it was reported that, for 12 out of 13 hospitals with formal sponsorship agreements, the sponsor was the market leader in product use (see the StoMap programme baseline report 2019). The committee concluded that more information is needed to understand the true impact of sponsorship on one-piece closed bag choice in England.

Shared decision making

3.6 Choosing a bag should be a shared decision between a healthcare professional and the person with a colostomy. After surgery, initial bag choice can be based on multiple factors. These include the person's:

- body shape
- skin type
- skin integrity
- stoma construction
- stoma position on the abdomen
- stoma output
- manual dexterity (Bowles et al. 2022).

Clinical experts explained that this 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. They stated that getting the right bag from the beginning of a person's journey can reduce the

long-term physical and psychological impact and reduce costs linked to bag-related complications. Patient experts stated that the level of involvement in bag choice can vary between services, and that they were not always aware of all the available bags. Stakeholders noted that the main barriers to shared decision making include lack of patient education and healthcare professional time. Patient and carer organisations and stakeholders highlighted that a person's bag needs may change over time, for example because of changes in skin condition, stoma output, body shape or lifestyle. They stated that shared decision making is an ongoing process. They also highlighted the importance of being aware of, and having equal access to, the variety of bags available to ensure a good quality of life. The committee acknowledged that, although this guidance is for people with a colostomy who use one-piece closed bags, some people with a colostomy may prefer to use 2-piece or drainable bags. NICE's guideline on shared decision making highlights that people have the right to make informed decisions about their care and should understand the choices available to them. The committee concluded that choosing a one-piece closed bag should be a shared decision between a healthcare professional and the person with a colostomy. The decision should consider the individual needs and preferences of the person, as well as clinical appropriateness.

User preferences

3.7 A user-preference assessment was done and included people with lived experience or knowledge of using one-piece closed bags, and clinical nurse specialists in stoma care (or people previously in this role with ongoing knowledge in the area). Users value bags with features that can reduce leakage and seepage, and maintain and promote healthy peristomal skin. The users identified and ranked a total of 16 criteria considered important to them when choosing a one-piece bag. Although users reiterated the importance of all 16 criteria, the top 3 criteria related to reducing leakage and seepage and maintaining and promoting healthy peristomal skin. The top 3 criteria had a combined weighting of importance of over 50%. Patient experts agreed that leakage, seepage and peristomal skin complications (PSC) have the largest physical and psychological impact on people with a colostomy. A patient expert

also highlighted that leakages have a wider impact on daily life including on what a person can wear, their confidence to do everyday activities, and the cost of washing and replacing bedding and clothes. Clinical and patient experts agreed that all criteria are important. They noted that the user-preference assessment was a robust process that captured the experiences of the users involved, and the population more widely. Interim results from a Colostomy UK survey (including 2,101 people in England with a colostomy) found that 52% of responders reported that they were impacted by leakage and 43% by skin irritation. This reiterates the need for bags that reduce leakage and seepage and maintain peristomal skin health. The committee concluded that people with a colostomy should have access to bags with features that meet most criteria identified as important, to ensure quality of life is maintained. There should be a particular focus on bags that prevent or reduce leakage, seepage and PSC.

Equality considerations

3.8 The needs of people with a colostomy vary from person to person, and access to a wide range of bags is needed. People with a colostomy having cancer treatment, such as chemotherapy, may experience changes in skin condition or output as a result of this treatment. This may impact the type of bag that is needed. Some people may need additional support or may struggle to use certain bags because of a visual or cognitive impairment, reduced manual dexterity or a learning disability. Autistic people or people with sensory processing difficulties may also find certain bags unsuitable or may need additional support. People who are unable to read or understand health-related information (including people who do not have English as a first language) may need additional support to understand the options available to them. Wheelchair users, people who sit for long periods of time, or people who experience excessive sweating, may struggle with the durability and security of certain bags. Changes in body shape or skin condition, such as because of pregnancy, aging or hormonal changes may also impact the type of bag that is needed. One-piece closed bags are mostly offered in beige, grey or clear colours. A small number of bags are offered in black. People may prefer choosing a bag that most closely matches their skin tone, if this is available. A patient and carer organisation submission highlighted the importance of having access to, and a choice of, a range of stoma bags with different features. This is to allow people with a colostomy to benefit from bags

that meet their needs. The committee understood that people with a colostomy are individuals with needs that change over time. It stated the importance of maintaining a wide range of choice for people with a colostomy.

Clinical effectiveness

Clinical evidence included in the assessment

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

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

Clinical experts noted that, in clinical practice, people would typically be followed up for 6 months to 1 year to assess improvement in outcomes. They reiterated that short follow-up times may not be appropriate for key outcomes such as PSC. The committee acknowledged that the directly available evidence was limited and of poor quality. It stated that higher-quality evidence with validated outcomes and longer follow up would be needed to accurately assess certain key outcomes.

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

Evidence on potentially innovative features

3.11 The clinical evidence base included bags with potentially innovative features that could impact outcomes for people with a colostomy. But the EAG stated that these findings were from low-quality studies and not conclusive because of the limitations highlighted in section 3.9. The results from the directly relevant published evidence showed improvements in some outcomes related to filter function, such as ballooning. But other outcomes related to filter function, such as pancaking and odour control, did not show differences between the bags being evaluated. Other differences such as bag security, adhesion, ease of removal and comfort were not measured using validated scales, so the EAG considered them to be difficult to interpret and unreliable. No difference was reported in PSC or leakage in the published evidence base. Clinical and patient experts noted that the studies covered a small number of bags currently available for prescription on the NHS, and these were often not the most recent ranges from companies. The committee concluded that there is insufficient evidence to show whether any bags with potentially innovative features offer greater benefit for people with a colostomy compared with other bags or bags without potentially innovative features.

Outcomes and populations

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

Excluded evidence

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

Economic evaluation

Regression analysis

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

Model structure and parameters

3.15 Because of the limited clinical evidence, the EAG could not evaluate the cost effectiveness of features of one-piece closed bags. Instead, the EAG used multiple discrete state-transition models to calculate the economically justifiable price (eJP; maximum cost-effective price) for a bag that can completely prevent complications identified by experts. The complications were:

- PSC
- leakage
- pancaking
- ballooning
- odour
- issues with discreetness, appearance and comfort.

An incremental eJP was added to a baseline bag price for flat and non-flat bags to create a total eJP. Clinical experts agreed that no bag was considered standard care. So, the prices of the least expensive bags and the least expensive bags with a minimum of 5% market share on the Drug Tariff (at the time of the evaluation) were used as the baseline bag price The least expensive bag on the Drug Tariff was the Opus NaturFit range (flat bag £1.85, non-flat bag £2.30). The least expensive bags available with a minimum of 5% market share were the Nova colostomy bag (flat bag, £2.80) and Confidence natural soft convex bag (non-flat bag, £3.26). The EAG used a 1-year time horizon, representing an average year for a person experiencing a complication after they have adjusted to their colostomy.

Results of the economic evaluation

3.16 Bags with features that can improve PSC and leakage have the biggest impact on cost and quality of life. The incremental eJP per bag to completely prevent a single complication ranged from £0.37 for odour to £2.39 for PSC. When this is added to the cost of the least expensive bag, the total eJP for flat bags ranged from £2.66 for odour to £4.24 for PSC. For non-flat bags it was £2.66 for odour to £4.69 for PSC. When this was added to the least expensive bag with at least 5% market share, the total eJP for flat bags ranged from £3.17 for odour to £5.19 for PSC. For non-flat bags it was £3.63 for odour and £5.65 for PSC. The average mean bag price for all bags available on the Drug Tariff in 2023 to 2024 was £3.02, which sits within the range of these total eJPs. The EAG highlighted that a 100% reduction in these complications is unlikely and explored scenarios with lower reductions in complications. Although decreasing the proportion of complications resolved decreases in the incremental eJP, the change in the incremental eJP is not linear because some costs are unavoidable. The economic evaluation reported that improving PSC had the largest impact on costs and quality of life, followed by leakage, pancaking, ballooning, discreetness, appearance and comfort, and odour.

3.17 The EAG looked at several scenarios. It found that scenarios that substantially reduce the total eJP included lower costs for resource use, more bags used per day for people with no complications, and less time to resolution for complications. Increasing the impact of complications on utilities, increasing the

time to resolution for complications and assuming support is not sought with more frequent leakage events increased the eJP. An alternative source of utility data for leakage and PSC (Brady et al. 2025) found that the results were relatively insensitive to the new data. Key model drivers were the unit cost, frequency of healthcare professional interactions, cost of supporting products and expected improvements in quality of life. The committee concluded that further evidence is needed to evaluate the cost effectiveness of bags with potentially innovative features. Bags with features that can improve PSC and leakage may have the biggest impact on costs and quality of life for people with a colostomy.

Model limitations

3.18 The model has a number of limitations and the results from the economic evaluation should be interpreted with caution. The EAG highlighted that the lack of evidence directly related to the assessment and uncertainty around the accuracy of model parameters is a key limitation. This is because some inputs were from structured expert elicitation or taken from published studies in mixed populations with a high proportion of people with an ileostomy. Some studies also used vignettes, which may be less accurate at capturing quality of life than patient-reported outcomes. The EAG noted that the model used optimistic estimates for the resource-use impact of PSC and leaks. Some of the model assumptions were also based on clinical expert opinion where no relevant evidence was available. The EAG used the following as bag price comparators:

- the least expensive bag on the Drug Tariff, which has less than 1% of the market share, and
- the least expensive bag with at least a 5% market share.

It assumed that these bags are priced appropriately and do not resolve complications. The EAG also stated that the model looks at complications discretely. Although it created a scenario for all complications being additive, it also highlighted that the total eJP for preventing multiple complications is unknown. Patient and clinical experts confirmed that, in reality, the impact of a bag or features on complications will likely overlap. For example, leakage may lead to PSC, which may then impact the fit of the baseplate around the

stoma, leading to more leaks. The EAG stated that the actual incremental eJP is likely between the incremental eJP for the single most impactful complication and the sum of the incremental eJP of all of the complications. The committee concluded that because of uncertainty in model parameters, the model results should be interpreted with caution.

Justification for price variation

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

Resource impact of reducing price variation

3.20 The committee considered a hypothetical scenario that calculated how many clinical nurse specialists could be funded with a 10% reduction in mean bag price (reported as £3.02 from a mean of all bags available on the Drug Tariff in 2023). The scenario did not consider potential clinical differences. It concluded that this overall cost reduction could fund about 1 band-6 clinical nurse specialist in stoma care per trust in England (141 acute NHS trusts). This included residual savings to account for travel and non-pay costs. The scenario did not take into account a mixture of band-6 and band-7 nurses. The committee acknowledged that this is a simplistic scenario and that any cost savings may be used in other parts of the NHS.

Evidence needed to demonstrate additional value

3.21 The committee concluded that further evidence is needed to justify price variation between one-piece closed bags. This research should be done in people with a colostomy (or a subgroup reporting for people with a colostomy) with a clear description of the included population. The committee acknowledged the difficulties of doing large-scale randomised studies. These include funding requirements, time to study completion and possible recruitment difficulties relating to people's reluctance to try new bags if they are happy with their current bag. Clinical experts also noted that data is currently stored across care settings depending on how the service is set up. They highlighted that for the analysis of real-world data, it needs to be collected, clearly coded and stored centrally. The EAG noted that the current published evidence base directly related to the decision problem is sponsored by 1 company and studies often have authors with financial conflicts of interest. It highlighted the need for independence in those doing studies and reporting findings. The committee agreed that independently run company-funded studies would be an appropriate solution and that clinical nurse specialists in stoma care should be encouraged to lead this research. It concluded that both formal research studies and real-world evidence collection may be appropriate to fill evidence gaps related to one-piece closed bags for adults with a colostomy.

3.22 A core outcome set, clear comparator and longer follow up is needed. The EAG explained that there is currently no core set of outcomes for people with a colostomy, and that outcomes are not reported or measured consistently across studies. Clinical experts agreed that developing a core set of outcomes with definitions on how they should be measured would be beneficial and improve consistency in reporting. They also stated the need to develop psychometrically validated patient-reported outcome measures to measure bag-related quality of life. The EAG noted that a small number of stoma-related quality-of-life measures do exist, but these cannot currently be used to generate utilities. Both the EAG and clinical experts also highlighted the need for a more standardised or clearly justified comparator in future evidence generation, as well as longer follow-up times. The EAG noted that the longest follow-up length in the current evidence base is 2 weeks. But clinical experts explained that, in practice, follow up for much longer is needed to evaluate the impact on complications. The committee concluded that further evidence should report on a core set of outcomes that are

important to users, with longer follow up. More work is also needed to identify the appropriate comparator and develop bag-related patient-reported outcome measures.

3.23 Evidence should be generated across different groups of people with a colostomy who have complex needs. Clinical and patient experts reiterated that the needs of people with a colostomy are individual and that not all bags will be suitable for everyone. Patient experts noted that the current published evidence base excludes people with more severe skin complications. They highlighted the need for evidence collection for this group of people because of the large incidence and impact. They also explained that other populations may have different outcomes and should be considered separately. This includes people having chemotherapy or radiotherapy as part of cancer treatment, people who irrigate their stoma, autistic people or people with sensory processing difficulties. The committee concluded that evidence should be collected across different groups of people with a colostomy, to reflect their varying needs.

4 Committee members

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

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

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

Chair

Professor Tom Clutton-Brock
Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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