Late-stage assessment

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

Final scope

1 Introduction

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

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

This scope is limited to publicly available sources of information.

Population

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

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

Current management

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

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

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

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

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

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

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

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

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

The level of involvement for people with a colostomy in the decision-making process related to bag choice may vary across services (Bowles, 2022). NICE's guideline on shared decision-making highlights that people have the right to make informed decisions about their care and should understand the choices available to them.

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

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

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

2 Technologies

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

2.1 Current NHS market for the technologies

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

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

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

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

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

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

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

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

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

Description of the technologies

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

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

2.2 Technology features

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

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

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

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

Basic technology requirements

One-piece closed bags that:

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

Additional features, adaptions, and potential innovations

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

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

2.3 Technology user issues and preferences

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

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

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

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

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

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

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

3 Decision problem

Population	Adults 18 and over with a colostomy that use 1-piece closed bags

Subgroups	If the evidence allows, the following subgroups will be considered:
	• People with more fragile skin that is prone to tearing such as older people or people with an underlying skin disorder
	• People with conditions that may impact self-care (such as issues with manual dexterity, mobility and visibility)
	• People with a non-complex abdominal profile or peristomal anatomy or physiology
	• People with a complex abdominal profile (including but not limited to a stoma close to bony prominences, abdominal dips or creasing and scarring from prior surgery)
	• People with complex peristomal anatomy or physiology including but not limited to people with:
	  ○ parastomal hernia or bulging
	  ○ retracted or sunken stoma
	  ○ prolapsed stoma
	  ○ stomal fistula
	  ○ stomal stricture
	  ○ stoma ischaemia
	  ○ peristomal skin conditions
	  ○ large stoma
	  ○ thick faeces prone to pancaking
	  ○ high output stoma
	  ○ stoma positioned close to a wound, mucous fistula or device (such as a suprapubic catheter)

Intervention	One-piece closed bags (flat and convex or concave) with 1 or more of the following features: • baseplate additives (e.g. alginate, ceramide, manuka honey, vitamin E, silicone, pH buffering system) • modified baseplate shape (e.g. flower shaped, oval shaped, tapered) • modified baseplate adhesive (e.g. to improve adhesion, reduce residue or improve peristomal skin condition) • modified bag shape (e.g. to be more discrete or allow water to drain off more easily) • modified filters (e.g. to improve gas release or reduce odour) • modified material (e.g. to be more discrete, reduce noise, improve absorption, improve comfort, reduce odour or improve water repellence) • flushable disposal

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

	• Cost of supporting products (e.g. adhesive removers, flange extenders, belts or underwear, irrigation appliances, skin fillers and skin protectors)
	• Costs of medicines (e.g. topical steroids or barrier creams)
	• Cost of other resource use including:
	  ○ Health care professional appointments or visits (primary, community and secondary care)
	  ○ Costs associated with managing stoma-related complications, frequency of bag change, waste disposal of excess bags and prescribing and dispensation
	
	User preference will be assessed to identify and understand features of the technologies that influence decision making when selecting which technology to use. This is done alongside the assessment of the clinical and economic evidence.

Economic analysis	A health economic model will be developed, where possible, comprising a cost-comparison or cost utility analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

3.1 Potential equality issues or considerations

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

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

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

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

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

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

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

4 Stakeholders

4.1 Healthcare professional organisations

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

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

4.2 Patient and carer organisations

NICE's Public Involvement Programme have identified the following patient and carer organisations for advice:

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

4.3 Additional non-clinical professional organisations

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

- British Healthcare Trades Association

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Appendix A Related NICE Guidance

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

Appendix B Abbreviations

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