NICE National Institute for Health and Care Excellence

HealthTech Programme

Intermittent urethral catheters for chronic incomplete bladder emptying in adults: Late-stage assessment

Draft guidance comments and responses

Theme 1. Draft recommendations

Comment no.	Consultee	Section no.	Comments	Responses
1.	Consultee 3 Convatec	1.2 1 Recommendations	Convatec propose that NICE should reinforce that sponsorship of nurses in the NHS either on honorary contracts or contract sponsorships should not influence that choice and that more than one companies catheter should be offered.	Thank you for your comment. Section 1.3 of the guidance highlights that choosing which catheters to use should be based on people's needs and preferences as well as clinical appropriateness. It does not specifically refer to sponsorship as this was not highlighted as a key consideration during committee discussions. The 'what this means in practice' section of the guidance states people that use intermittent catheters should be told about the range of catheters available and given a choice of catheters that are suitable for them.
2.	Consultee 3 Convatec	1.2 1 Recommendations	Convatec propose that consideration is given to adding the term 'removal' to ease of comfort of insertion. Evidence to suggest that the removal stage often causes trauma	Thank you for your comment. An amendment to the recommendations has been made, 'ease and comfort of insertion' has

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				been changed to ‘ease and comfort of use’ which includes removal.
3.	Consultee 3 Convatec	1.3 1 Recommendations	Convatec propose that NICE should reinforce that sponsorship of nurses in the NHS either on honorary contracts or contract sponsorships should not influence that choice and that more than one companies catheter should be offered.	Thank you for your comment. Please see response to comment 1.
4.	Consultee 4 ACP	Not specified	1. Recommendations point 1.2 i would add ease of use of the product not just ease of insertion	Thank you for your comment. ‘ease and comfort of insertion’ has been changed to ‘ease and comfort of use’.
5.	Consultee 6 British Healthcare Trade Association	1	We do not agree with recommendation 1.1 in its current form. We would propose you remove the statement 'So, if more than one catheter is available use the least expensive catheter' as you have stated there is no evidence available to back this up. We do agree with the two bullet points in 1.1. We agree with points 1.2 and 1.3.	Thank you for your comment. The wording and order of the draft recommendations have been amended.
6.	Consultee 7 Wellspect Healthcare	1.2 1 Recommendations	We suggest this should state, "ease and comfort of insertion and removal." This better reflects the findings in section 3.4 User experiences, needs and preferences, which states: "Patient experts emphasised the need to adhere to catheterisation to prevent infection, and the importance of comfort during catheterisation from insertion to removal."	Thank you for your comment. Please see response to comment 2.
7.	Consultee 7 Wellspect Healthcare	3.4 User experiences, needs and	Comfort during removal should also be reflected in recommendation 1.2.	Thank you for your comment. Please see response to comment 2.

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		preferences		
8.	Consultee 9 Urology Trade Association	1	The UTA believe that the recommendations fail to provide clinicians and other stakeholders with proper guidance on the provision of intermittent catheters for patients that require their use. The reasons for this are laid out below: 1. The statement that clinicians should use the “least expensive catheter” risks clinicians focusing just on the aspects of price/costs of individual products, causing them to prescribe patients products that may lead to sub-optimal care and create further activity and costs downstream when the patient experiences a crisis or exacerbation of their condition. 2. We also believe that the emphasis on product cost risks that documented innovation will not be sufficiently rewarded. This could be seen as a price penalty instead of an innovation premium and is a concern for suppliers and companies working hard to bring innovation to people living with bladder issues heavily impacting the supply chain of the country. If companies struggle to introduce innovative products, they might decide to exit the UK market and/or not introduce innovative products in the future. This will have a negative effect on patients, the wider healthcare system and the UK economy. 3. We also believe that there is the risk that budget holders will continue to facilitate and/or enable a mindset focusing on prescribing cheaper products as patients move out of a specialist setting rather than focusing on prescribing the most appropriate products for the patients' needs and preferences.	Thank you for your comment. The wording and order of the recommendations has been amended to prioritise considerations about catheters’ clinically appropriateness and people’s preferences. The late-stage assessment interim process and methods statement state it assesses if the value added by incremental innovation justifies the price variation. Innovative products will be recommended if the committee conclude that its benefits have been appropriately evidenced to justify any difference in price.

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9.	Consultee 9 Urology Trade Association	1.2 1 Recommendations	UTA members believe that there are other factors which should be considered by patients, carers and prescribers when deciding which intermittent catheter a patient should use. Focusing simply on ease and comfort of insertion and risk of infection risk omitting other essential aspects, such as the patient's lifestyle, their general health conditions, as well as how the catheter supports the patient in their bladder management while helping them maintaining a good quality of life. Also, the list ignores the top 5 user preferences and instead re-ranks the most important ones differently.	Thank you for your comment. Following the first committee meeting, the 2 factors (ease and comfort of insertion, risk of infection) were included in the draft guidance because they were the most common factors that people considered important across the 3 pieces of user-centred work (a user preference assessment, an online survey and a thematic review of the literature). The committee has considered this comment and decided to amend section 1.2 of the draft guidance. This section has been renumbered as section 1.3 of the final guidance.
10.	Consultee 10 Hollister Ltd	1.1 1 Recommendations	Price variations may well be justified - as per our previous general comment, NICE level evidence has never been required for these products before. Stating there is a lack of evidence is not the same as saying pricing differences are not justifiable. Given the EAR failed to reach any consensus on the basic definitions or importance of features, it seems illogical to be able to make any usage recommendation in 1.1	Thank you for your comment. LSA's purpose is to assess technologies that are in widespread or established use in the NHS to support procurement and commissioning decisions. It does this by assessing whether the value added by incremental innovation justifies the price variation. There is an expectation that these technologies should have evidence to support their proposed benefits to the NHS over existing technologies in order to justify any differences in price.

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				The rationale for the decisions made by the committee is detailed in 'why the committee made these recommendations'. The guidance acknowledges the lack of consensus on the original features categorisation. To explore this area of uncertainty, an alternative feature categorisation and updated CNMA results are in the addendum. The committee has also considered this extra work in their deliberations (see section 3.15 of the final guidance) and decided not to change the recommendation.
11.	Consultee 10 Hollister Ltd	1.2 1 Recommendations	Other factors should be included as well as ease and comfort of insertion and risk of infection. These could for example include user mobility, general health, dexterity etc.	Thank you for your comment. Section 1.2 of the draft guidance has been amended and renumbered as section 1.3 of the final guidance. The recommendation states that the clinical appropriateness and people's needs should be taken into consideration when choosing a catheter. The committee considered that people's mobility, general health and dexterity will be included in this consideration.
12.	Consultee 10 Hollister Ltd	1.3 1 Recommendations	A wide range of intermittent catheters should be available to take into account the wide variety of needs between individual users.	Thank you for your comment. Section 1.3 of the draft guidance has been amended to highlight that catheters that meet

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				people's needs and are clinically appropriate are available. This section has been renumbered as section 1.2 of the final guidance.
13.	Consultee 11 CliniMed Ltd	1.1 1 Recommendations	We are concerned about 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 references to price should be removed. The LSA identified weak evidence regarding value; however, this does not mean that price variation isn't justified. Therefore, implementing a recommendation that promotes prescribing based on the lowest price does not seem appropriate. We also worry that the recommendation might reduce costs at the expense of user preferences and appropriateness, negatively impacting patients. Focusing purely on the lowest cost may restrict or remove patient choice in discussions about the most appropriate product. Even unintentional pressure could lead to users accepting a poorer performing product, reducing their quality of life. The recommendations in the draft guidance are not sound and are not a suitable basis for guidance to the NHS. They fail to provide clinicians and other stakeholders with proper guidelines on the provision of intermittent catheters for patients who need them. The statement that clinicians should use the "least expensive catheter" risks pressuring clinicians to focus solely on price and cost, potentially leading them to prescribe products that might not be clinically appropriate for patients' needs and preferences. We understand that the NHS aims to reduce costs where possible, but clinicians might feel pressured to prescribe cheaper	Thank you for your comment. The committee did not agree it was appropriate to remove the reference to price, however, the wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. Extra wording has been added to 'what this means in practice' ('considerations for healthcare professionals' and 'information for people with chronic incomplete bladder emptying') to highlight more than 1 type of catheter may need to be prescribed, to inform people there is a range of catheters available, and to offer them a choice. The aim is to ensure people have the most suitable catheters to use..

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			products without considering the impact on patient wellbeing and quality of life.	
14.	Consultee 12 Coloplast	1	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 urology and continence services must have access to a full range of products, then HCPs and patients engage in shared decision-making, 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, there is a high risk that a budget holder may use recommendation 1.1 in isolation to reduce costs, thereby limiting access to products contrary to the intentions of recommendation 1.3 and 1.2. We ask that NICE make this priority designation clearer in the final guidance. We also ask that the committee reorder the recommendations to reflect the evidence as well as this priority (more detail in a separate comment). Note: Although there is reference to recommendation 1.1 here, we disagree that the evidence and real-world experience supports this conclusion (see additional comments on section 1.1)	Thank you for your comment. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences.
15.	Consultee 12 Coloplast	1	The order in which the recommendations are presented does not reflect the relative certainty of the committee's considerations and conclusions on the evidence presented on user experience (sections 3.4 and 3.6) or equality issues (section 3.7), compared with that on the clinical and economic evidence (sections 3.15 and 3.24). To more accurately reflect these, the recommendations should be re-ordered so that section 1.3 and 1.1 are swapped, leaving section 1.2 in its current place (i.e. ordered 1.3, 1.2, 1.1).	Thank you for your comment. Please see response to comment 14.

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16.	Consultee 12 Coloplast	1.1 1 Recommendations	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 intermittent catheter care, the entire guidance will be eclipsed by the phrase 'least expensive,' and choice at the clinician and patient level may be limited to those deemed by local budget holders to 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.	Thank you for your comment. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. Extra wording has been added to 'what this means in practice' ('considerations for healthcare professionals' and 'information for people with chronic incomplete bladder emptying') to highlight more than 1 type of catheter may need to be prescribed and to inform people there is a range of catheters available. The aim is to ensure people have the most suitable catheters to use.
17.	Consultee 12 Coloplast	1.1 1 Recommendations	This recommendation may be interpreted as a 'do not use' recommendation, that is to not use a more expensive catheter, or to switch from a more expensive catheter 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 catheter choice, where clinically appropriate and meets the patient's needs and preferences, that was started in the NHS before this guidance was published."	Thank you for your comment. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. The 'what this means in practise' section acknowledges the need for regular review of catheter suitability. Extra wording has been added to 'what this means in practice' ('considerations for healthcare professionals') to address concerns

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				about the recommendations affecting established catheter choice.
18.	Consultee 12 Coloplast	1.1 1 Recommendations	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 catheters that are deemed too expensive will not be listed, thereby preventing the shared decision-making process encouraged in recommendation 1.2. 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 intermittent catheter care. It has taken a black and white approach to a grey area – deeply personalised healthcare.	Thank you for your comment. The late-stage assessment interim process and methods statement state it assesses if the value added by incremental innovation justifies the price variation. Innovation of a product will be recommended where its benefits have been appropriately evidenced to justify any difference in price. Recommendation 1.1 of the guidance states that there is not enough evidence to determine if the price variation is justified between different intermittent catheters for chronic incomplete bladder emptying. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. The rationale for the decisions made by the committee is detailed in 'why the committee made these recommendations', which states that more information is needed to justify price variation.

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				This late-stage assessment was done in line with the late-stage assessment interim process and methods statement, including topic selection.
19.	Consultee 12 Coloplast	1.1 1 Recommendations	Based on the many limitations of the modelling (as listed in the 'General Comments' section), we do not believe that it is a reasonable interpretation of the evidence to recommend that the least expensive catheter that is clinically appropriate and meets the preferences and needs of the patient be used. Recommendation 1.1 should therefore be removed from the guidance.	Thank you for your comment. Please see response to comment 18.
20.	Consultee 12 Coloplast	1.1 1 Recommendations	The wording of this recommendation suggests or would likely be interpreted as meaning that there is good evidence to conclude that different catheters have near-equivalent efficacy. This is not the overall finding of the assessment, as set out in the committee's considerations and conclusions in 3.22, 3.24 and 3.25. Additionally, the impact of this recommendation as written 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 catheter switching. We would suggest that the wording of this recommendation be replaced with the wording used on page 3 to fully reflect the findings of this current assessment, which were an absence of evidence rather than evidence of absence:	Thank you for your comment. Recommendation 1.1 of the guidance states that there is not enough evidence to determine if the price variation is justified between different intermittent catheters for chronic incomplete bladder emptying. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. The rationale for the decisions made by the committee is detailed in 'why the committee made these recommendations', which states that more information is needed to justify price variation.

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			'More information is needed to show if price variation between intermittent urethral catheters can be justified by added clinical or economic value or attributed to any specific feature.'	
21.	Consultee 12 Coloplast	1.1 1 Recommendations	This wording needs changing. There will and always should be more than 'one available,' especially for those adhering to Recommendation 1.3 of the guidance. Leading with this recommendation places emphasis on cost as the primary driver, which is not in keeping with best practices and not reflective of the EAG's findings. Furthermore, as written the recommendation implies that there may be a situation where an HCP only has access or authority to prescribe one catheter, which would negate the shared decision-making process and violate the rights of patients laid out in the NHS Constitution.	Thank you for your comment. The wording and order of the recommendations has been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. Recommendation 1.2 of the guidance states that service provider should provide access to a range of intermittent catheters, so that catheters that meet people's needs and preferences and are clinically appropriate are available for them. Wording has been added to the 'What this means in practice' section of the guidance to state that more than 1 type of catheter may need to be prescribed to suit different settings and situations.
22.	Consultee 12 Coloplast	1.2 1 Recommendations	Can NICE explain why it is only these two considerations are highlighted in recommendation 1.2. for decision making? Based on Table 5 in Appendix A, Page 26 of the User preference report the top 5 considerations from users with lived experience are documented and clearly ranked. We recommend changing the wording to reflect top 5 considerations: Comfortable to Insert; Comfortable to Remove; Full Bladder Drainage; Risk of Infection; Options to suit individual needs. Convenience is referred to a	Thank you for your comment. The committee based its decision about which people's preferences to include in the recommendations on all 3 pieces of user-centred work as detailed in section 3.5 rather than the user preference assessment only.

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			number of times by both HCPs and Users (especially for use outside the home) from the work NICE conducted so the options to suit individual needs should not be underplayed and would be less discriminatory for those with mobility/dexterity issues if acknowledged fully in the recommendations.	The recommendation also states that the clinical appropriateness and people's needs should be taken into consideration when choosing a catheter. The committee considered that people's mobility and dexterity will be included in this consideration.
23.	Consultee 12 Coloplast	1.3 1 Recommendations	The Committee should further clarify this statement by adding that local payers should not restrict access to any intermittent catheters listed on Part IX of the Drug Tariff via formularies, and that the local clinical experts and specialists should have the flexibility to choose a listed catheter 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.	Thank you for your comment. Please see the response to comment 21.. The "what does this mean in practise" section of this guidance outlines how commissioners and healthcare professionals should use the guidance.
24.	Consultee 12 Coloplast	1.3 1 Recommendations	We would suggest that this recommendation be reworded to: 'Urology and continence services should have access to a full range of intermittent urethral catheters listed on Part IX of the Drug Tariff, so that adults with chronic incomplete bladder emptying can have a catheter which is suitable for their individual needs, considering additional needs such as physical disability, poor dexterity or discretion. ' This text clarifies the meaning of 'available for prescription' and ensures that the range of catheters available is not restricted in such a way that they would not be able to meet the needs and preferences of users. As it is currently written a service could offer two catheter options which do not meet the needs of their patients and still have a valid claim to offering 'a range.'	Thank you for your comment. Please see the response to comment 21. The committee considered that people's mobility and dexterity will be included in the clinical appropriateness and people's needs considerations.

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25.	Consultee 12 Coloplast	1.3 What information is needed	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 catheter 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. Shared decision-making should be based on patient need, not financial constraints.	Thank you for your comment. The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinically appropriateness and people's preferences. The 'considerations for healthcare professionals' section of the guidance states that healthcare professionals decide together with the person with chronic incomplete bladder emptying which catheter to use, following the principles of NICE's guidance on shared decision making.
26.	Consultee 12 Coloplast	3.22 Results of the economic model	We agree that the model's results require cautious interpretation. This is why we are puzzled by the decision to issue a recommendation to use the least expensive catheter first, as this would suggest evidence of absence. It should instead be noted that this LSA has uncovered an absence of evidence and a need for better evidence generation in this area of personalised medical technologies, which in our opinion is a more justifiable and valuable conclusion. Please see our comments on Recommendation 1.1 for a detailed response on proposed amendments.	Thank you for your comment. Please see the response to comment 18..
27.	Consultee 12 Coloplast	3.25 Evidence needed to show	Coloplast believes that this is the central finding of this LSA, and that it undermines recommendation 1.1. NICE should replace recommendation 1.1 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	Thank you for your comment. Please see response to comment 26.

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		additional value	guidance promotes practices that would not be supported by the evidence.	

Theme 2. Draft guidance – general comments

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28.	Consultee 1 Multiple Sclerosis Trust	Not specified	I have read the documents pack and have the following comments: - I agree that the evidence collected and the methodology used are appropriate and proportionate for this assessment. - UTIs are a particular risk in Multiple Sclerosis, and IC is a key mitigator of that risk. Without it, we would see increased unplanned hospitalisations and the potential for longer and less effective rehabilitation. The view is that IC keeps people out of hospitals which saves the NHS time and money. - I am pleased to see that the draft guidance puts patient choice and comfort as priorities and recognises the importance of these in adherence to IC. - I am pleased to see guidance that patients should be trained and supported by an experienced health professional to use an intermittent catheter, and that this may need to be an ongoing or repeated process for best outcomes. - I support the view that a single patient may need a variety of different models of catheter in order to live a full life, including IC out of the home, in public conveniences, while travelling etc. With a fluctuating condition like multiple sclerosis, different catheter models may be needed to accommodate symptomatic changes too. - It is good to see concerns around sustainability and recycling	Thank you for your comment.

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			brought to the fore. Many patients would like this information made more available in order to make their choices.	
29.	Consultee 3 Convatec	Not specified	Please note that within page 2 of the committee papers the link to final scope leads the reader to GID-HTE10039 Drug-eluting coronary stents for treating coronary artery disease: late-stage assessment	Thank you for your comment. This link has been fixed.
30.	Consultee 8 BD	Not specified	Has all of the relevant evidence been taken into account? BD believes the economic model and findings should have been republished once the assumption about the incorrect weightings given to different catheter features was identified. This was a factually inaccurate assumption. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? BD does not view the interpretation of the evidence as reasonable for this primarily Class I medical device. Firstly, NICE could have considered that medical device evidence has historically been driven by regulatory approval demands, which have focused on safety outcomes. Therefore, the evidence likely to appear in a late-stage evidence review is also likely to be older and not include the same criteria as pharmaceuticals or newer devices, hence the health-related quality of life evidence gap. There is substantial evidence that an insertion sleeve/grip is an important feature for reducing infections, but no device can ever be "proven" in the same way as an antibiotic can show efficacy. Disregarding mixed catheter evidence ultimately disadvantages	Thank you for your comment. The categorisation approach has been transparent. NICE accepts there are limitations in the categorisation of intermittent catheters features used and that some stakeholders disagree with the categorisation; however, it does not accept that these are factual inaccuracies. To address concerns about the impact of the feature categorisation the EAG used a different categorisation that has been developed independently. The updated feature categorisation and CNMA results are reported in the addendum. There was no justification for rerunning economic analysis because the uncertainty is still very high. The committee considered these results and concluded that it did not change their recommendations. The late-stage assessment interim process and methods statement state it assesses if the value added by incremental innovation justifies the

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			patients who depend on catheters with mixed features. This evidence was created long before NICE set any such requirements for the type of evidence it would consider. We would also propose two changes in the content of the draft guidance. Section Wording Suggested replacement 3.0 The condition Clinical Context 3.0 Chronic incomplete bladder emptying can be caused by neurological or non-neurological conditions. Chronic incomplete bladder emptying is a symptom of a condition / disease state. The condition may have neurological or non-neurological origins. 3.0 People with this condition need to use intermittent catheters for long-term bladder management. People with symptoms of chronic complete bladder emptying may need to use intermittent catheters for long-term bladder management. Are the recommendations sound and a suitable basis for guidance to the NHS? The recommendations could be seen as ambiguous, and the lack of a pricing threshold outcome may lead to unintended consequences. For example, the guidance to choose the “least expensive catheter” might result in generic catheters being the first choice, with more clinically appropriate catheters being second or third choices. Additionally, the guidance is light on infection prevention and does not provide specific guidelines to minimize this risk. Are there any aspects of the recommendations that need	price variation. Evidence to show that the benefits added by an innovative feature justify the incremental cost will support the committee’s decision making. So, the type of evidence required is different to the evidence needed for regulatory purposes. The EAR reported a lack of evidence reporting the clinical and cost-effectiveness of insertion sleeve or grip separately. The guidance and the EAG’s report highlight that the outdated evidence was included, and the committee recognised that some of the evidence was outdated, and this might not reflect current practice. When making the decisions, the committee also noted the lack of evidence and limitations in their deliberations. For the evaluation of combined features, the draft guidance and the EAG’s report acknowledge that there is evidence for catheters with different features. However, this assessment is to determine whether price variation between different intermittent urethral catheters can be justified and attributed to any specific feature, a CNMA was conducted to isolate the effect of individual features. As a result, there is not enough evidence of the effectiveness of individual features separately, or how each feature contributes to the reported

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			particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation? The lack of subgroup analysis, for those with mobility issues is an area that requires further investigation by NICE. As per the user preference report, “it is possible that the importance of preferences associated with this feature among people with limited mobility has not been captured.”	outcomes. So, more information is needed to estimate the effect size of individual features. For the comment relating to the condition, section 3.1, the committee considered these suggestions but decided that the existing wording was appropriate as a brief description of the condition. The wording and order of the draft recommendations have been amended to prioritise the considerations around catheters’ clinical appropriateness and people’s preferences. The rationale for the decisions made by the committee is detailed in ‘why the committee made these recommendations’. Please note this is a guidance but not a guideline to provide details on risk prevention The guidance acknowledges the importance of people’s choice to have the most appropriate catheters to meet their needs and preferences and highlights that the best choice of catheter may change over time. Section 3.7 highlights the needs of people with chronic incomplete bladder emptying vary from person to person. This covers people with mobility issues. Whilst the user preferences report accurately reflects that none of the contributors to that report had mobility issues, the thematic review of the

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				literature includes people with mobility issues caused by, such as spinal cord injury or multiple sclerosis. Extra wording has been added to section 3.7 to ensure different needs can be met.
31.	Consultee 10 Hollister Ltd	2.4 2 The technology	Given there was no consensus on definition or importance of catheter features, it would seem significantly flawed to then try and draw meaningful conclusions based on those features.	Thank you for your comment. The guidance acknowledges the lack of consensus on the original features categorisation. To explore this area of uncertainty, an alternative feature categorisation and updated CNMA results are in the addendum. The committee has also considered this extra work in their deliberations (see section 3.15 of the final guidance) and decided that it did not change their conclusions about the evidence.
32.	Consultee 11 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 late-stage assessment interim process and methods statement state it assesses if the value added by incremental innovation justifies the price variation. The methodology used within this late-stage assessment for data synthesis and economic modelling are in line with sections 3 and 4 of NICE health technology evaluations: the manual (pmg36).

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				The 'why the committee made these recommendations' section and 'committee discussion' sections 3.8 to 3.26 of the guidance highlight the lack of evidence, details the limitations of the assessment, and acknowledges the appropriateness of the methodological approach to analyse the benefits of the components. So, more information is needed.
33.	Consultee 12 Coloplast	Not specified	NICE has asked for comments on whether the draft recommendations are sound. We would argue and have done in Comment 77 on the EAG report that the entire LSA process is not sound for evaluating highly personalised products such as intermittent catheters. 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. This late-stage assessment was done in line with the late-stage assessment interim process and methods statement, including topic selection. In response to the comments about the methodology used and recommendations please see comments 32.
34.	Consultee 12 Coloplast	Not specified	Note on the Equality Impact Assessment: The LSA has not adequately considered the lives of those who are disabled and rely on ISC to meet a basic need of going to the toilet. We refer back to our comments made on the draft scope, although this comment is about single use, it is an example of the needs of disabled people and their use of ISC:	Thank you for your comment. The guidance acknowledges the importance of people's choice to have the most suitable catheters to meet their needs and preferences and highlights that the best choice of catheter may change over time.

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			'Disability organisations and clinical experts from the medical community have raised critical concerns in a united voice to protect human rights for people in need of ISC and their right to access hydrophilic single-use catheters as the best standard of care, unless national/local resources and funding are extremely limited (Krassioukov et al. 2024). Considering the lack of sufficient evidence on the safety and cleaning of reusing as well as the patient voice and rights to the best available evidence-based treatment, the sustainability debate should not jeopardize the health, well-being and lives of individuals who are life-dependent of intermittent catheterisation (Grasdal et al. 2021; Krassioukov et al. 2023, Krassioukov et al. 2024).' Again, we cannot stress enough that many of the decisions about which catheter is best for someone is not a patient preference – it is a need!	The wording and order of the draft recommendations have been amended to prioritise considerations about catheters' clinical appropriateness and people's preferences. Section 3.7 highlights the needs of people with chronic incomplete bladder emptying vary from person to person. This includes people with mobility issues. Whilst the user preferences report accurately reflects that none of the contributors to that report had mobility issues, the thematic review of the literature includes people with mobility issues caused by, such as spinal cord injury or multiple sclerosis. Extra wording has been added to section 3.7 to ensure different needs can be met The use of reusable catheters for bladder drainage is outside the scope of this guidance. Section 3.5 has been amended to recognise sustainability.
35.	Consultee 12 Coloplast	Not specified	As we previously stated in Comment 77 on the EAG Report, the publication of this guidance could deepen health inequalities: 'The disregard of certain vital features of products, which have been specifically designed to meet the needs of particular patient groups, runs in complete opposition to the direction of travel for healthcare in general and the NHS in particular. Indeed, given that many intermittent catheter users are vulnerable or living with	Thank you for your comment. Please see response to comment 34. The assessment included a comprehensive range of catheter features.

Comment no.	Consultee	Section no.	Comments	Responses
			chronic disabilities, were this to become published guidance it could contribute to the post-code lottery of healthcare provision, deepen health inequalities and promote prejudice against people with disability in the UK.'	Recommendation 1.2 of the guidance states that service providers should provide access to a range of intermittent urethral catheters, so that catheters that meet people's needs and preferences and are clinically appropriate are available for them. The committee considered that this guidance ensure that people with chronic incomplete balder emptying are involved in choosing a catheter that meets their needs and is clinically appropriate for them and feel that this guidance will not deepen health inequalities.

Theme 3. Draft guidance rationale

Comment no.	Consultee	Section no.	Comments	Responses
36.	Consultee 10 Hollister Ltd	1.3 Why the committee made these recommendations	This section again references the lack of evidence and consistency of reporting outcomes. In that context it would therefore seem very difficult to make meaningful recommendations.	Thank you for your comment. The late-stage assessment interim process and methods statement state it assesses if the value added by incremental innovation justifies the price variation. The methodology used within this late-stage assessment for data synthesis and economic modelling are in line with sections 3 and 4 of NICE health technology evaluations: the manual.

Comment no.	Consultee	Section no.	Comments	Responses
				The 'why the committee made these recommendations' section and 'committee discussion' sections 3.8 to 3.26 sections of the guidance highlight the lack of evidence and details the limitations of the assessment. So, more information is needed.
37.	Consultee 12 Coloplast	1.3 Why the committee made these recommendations	Recommend changing the wording to "This assessment aimed to determine whether the differences in clinical, economic and non-clinical outcomes could be attributed to specific individual features to justify price variation" This would align to the paragraph below which specifically calls out individual features and so would provide a consistent narrative.	Thank you for your comment. The committee has considered this comment but decided not to change the wording as the suggested text did not provide any additional value.
38.	Consultee 12 Coloplast	1.3 Why the committee made these recommendations	As stated previously in reference to Recommendation 1.2, this statement is not reflective of Table 5 in Appendix A, Page 26 of the User preference report. The top 5 considerations from users with lived experience are documented and clearly ranked. We recommend changing the wording to reflect top 5 considerations: Comfortable to Insert; Comfortable to Remove; Full Bladder Drainage; Risk of Infection; Options to suit individual needs. Ease is not a category on its own in the user preference report, it is described as "easy to remove from packaging and prepare for use" or "Ease of Disposal" not "Ease" on its own and both of these preferences are ranked lower.	Thank you for your comment. This is based on all 3 pieces of user-centred work as detailed in section 3.5 rather than the user preference assessment only. An amendment to the wording has been made. Please see response to comment 2.

Theme 4. Technology and features categories

Comment no.	Consultee	Section no.	Comments	Responses
39.	Consultee 3 Convatec	Not specified	There would appear to be evidence taken into account that has not been referenced within committee papers. Convatec also offer opinion that not all the relevant evidence has been considered as key scientific published evidence has been disregarded without due consideration or full understanding specifically related to innovative lubrication. When introducing innovation in this category, step one is to understand the scientific difference of how catheters are lubricated; Integrated amphiphilic surfactant(IAS) has been recognized scientifically as a true innovation as it has hydrophilic properties without the potential negative effects of PVP (hydrophilic coating). The Independent scientific evidence conducted by Queens University Belfast has showed that IAS reduces micro trauma to the urethra and thus reducing the risk of infection. This supports one of the key recommendations (1.2). The published independent scientific evidence has been previously shared and we appreciate that due to its relative recent introduction to the market, there is the potential need to help the Expert Committee to understand the technology. Convatec (who hold intellectual property for the technology have offered several times through the process to provide clarity on the scientific differences between PVP lubrication (hydrophilic coating) and IAS lubrication (hydrophilic integrated properties). Convatec acknowledge that in 2.4 'enhance lubrication' has now been noted for the first time but with the continued reference to 'enhance coating' or 'coating' (ref: 2.2, 3.13, 3.21,3.23) this causes confusion for healthcare professionals and for patients, who , as advised in the guidance should make an informed choice. Key scientific papers that were excluded from consideration. Burns et al, 2024,	Thank you for your comment. The scope states 'enhanced lubrication or coating' (such as multi-layer coating and hydrophilic integrated amphiphilic surfactant) which covers IAS. The EAG used 'enhanced coating' as an aggregate and covered IAS in the feature definition. The EAG has explored an alternative, independent categorisation of features and their impact on CNMA (see addendum). IAS has also been considered in this alternative categorisation and discussed by the committee (section 3.15 of the guidance). The EAG has considered the papers cited by the consultee: • Burns et al. 2024. The EAG excluded two papers published by Burns in 2024 (see #24,#25 of Appendix C5 in original EAG report); both were excluded due to study design. One was an abstract described an ex vivo porcine model, the other was described an in-vitro biomimetric uretral model using human urothelial cells cultured on customised silicone sheets.

Comment no.	Consultee	Section no.	Comments	Responses
			Sticking, shedding of PVP and cell damage to the urethra causing micro trauma to the sensitive epithelia layer of the urethra leaving it open to bleeding, microtrauma, and increased risk of UTI. IAS catheters cause 30% less damage to human urethral cells than the leading PVP coated hydrophilic catheters including those with 'enhanced coating'. Pollard et al, 2022, Sticking leads to increased force required to remove a catheter, increasing discomfort for the user and so decreased compliance on removal. Quinn et al, 2024, PVP also impacts sperm mobility, so PVP residue in urethra is a risk for males who may want their partners to conceive.	• Pollard et al, 2022. The EAG excluded a paper by Pollard in 2022 (see #185 of Appendix C5 in the original EAG report) due to study design. This study described an agar model where hydrated catheter samples were lowered vertically into agara and withdrawn after 2 minutes. • Quinn et al, 2024. The EAG had not previously reviewed a paper by Quinn, this was not shared by the company within their RFI. The EAG has identified an online poster authored by Quinn from 2024, which also summarises an ex-vivo porcine model; which the EAG would exclude based on study design. The EAG note that sperm mobility was not an outcome listed in the Final Scope, nor was it an outcome prioritised by the sample of users within the User Preference report. There were no comparative human studies identified which included GentleCath or GentleCath Air by convatec which have amphiphilic surfactant used in a population in scope. Therefore, additional comparative evidence would be required to demonstrate the benefit of this type of enhanced lubrication to warrant further analysis.

Comment no.	Consultee	Section no.	Comments	Responses
40.	Consultee 3 Convatec	Not specified	Convatec offer opinion that as full evidence was unconsidered, the draft guidance is not a fair representation of fact. The EAG focused on 18 studies, and has cited that they were 'evaluating intermittent catheters with different features, coatings and lubrication methods. The included evidence covered all intermittent catheter features of interest listed in the NICE Final Scope.' This is factually incorrect as none of the studies included a catheter that had IAS technology for lubrication (FeelClean Technology™). The number of studies used had one sole company as 'funding or support by' and is therefore disproportionate to provide balanced judgement.	Thank you for your comment. Please see response to comment 39. It is unclear what additional comparative evidence was not considered by the EAG. The EAG focused on comparative evidence to enable the evaluation of the effectiveness of one or more innovative features. The EAG has not identified any comparative evidence for Convatec catheters with integrated amphiphilic surfactant in a human population in scope.
41.	Consultee 3 Convatec	Not specified	Convatec offer opinion that the recommendations included in 2.4 additional features to be misleading as some 'additional features' do not have the scientific evidence or clinical evidence to conclusively be included in this category and for IAS to be excluded. Convatec question the weakness in evidence presented regarding: • Enhanced coating specifically referring to Coloplast 'triple action coating' • Micro zone technology referring to Coloplast Luja range Convatec dispute the conclusion that 'triple action coating' is an innovation within the category 'enhanced lubrication' due to insufficient published scientific or clinical evidence that supports this marketing claim. The only published evidence that is supporting the claim for the 'triple action coating' is Stensballe J, Looms D, Nielsen PN, et al. Hydrophilic-coated catheters for intermittent catheterisation reduce urethral micro trauma: a prospective, randomised, participant-blinded, crossover study of three different types of catheters. EurUrol	Thank you for your comment. Please see responses to comments 39 and 40. The EAG has not identified any comparative evidence to demonstrate that the Convatec intermittent catheters are superior, inferior or the same to intermittent catheters by other manufacturers. Regarding the risks of catheter features, intermittent catheters should be used in line with IFU, which is current practice.

Comment no.	Consultee	Section no.	Comments	Responses
			2005;48(6):978–83, n=49. The objective of this study was to compare two hydrophilic-coated and one uncoated, lubricated catheter with regard to withdrawal friction force and urethral micro trauma. The primary endpoint was the friction force when the catheter is withdrawn. The findings in this study indicate that using hydrophilic-coated catheters for intermittent catheterisation reduces urethral micro trauma as determined by the level of haematuria vs an uncoated catheter. Therefore, this study fails to support the claims of 'staying bonded, staying smooth and staying hydrated' as an innovation differentiated from market standard. It is the opinion of Convatec that this statement is an unsubstantiated marketing claim and is therefore inappropriately considered within the guidance. The EAG shared no other data to substantiate these claims, and upon formal written request from Convatec to Coloplast, no further evidence was revealed; Convatec conclude that inclusion of triple action coating is therefore misleading and an unfair representation for supporting informed choice for the NHS patients and clinicians. Convatec offer the perspective that Triple coating of PVP is a PVP coated catheter with all its associated problems and not an innovation. By comparison, the published independent evidence that Convatec have submitted from Queens University Belfast regarding IAS technology (FeelClean Technology™). recognises IAS as a true innovation in lubrication technology. We kindly request again that this is recognised within the guidance to allow for Clinicians to understand the differences in features and attributes. Convatec would also suggest that NICE endorsement of 'micro hole technology' as an innovation without clearly highlighting the risks of this technology is misleading to the NHS. The micro hole technology claims to be suitable for all patients, in its patient facing material and marketing claims however this is contradictory to wording within the	

Comment no.	Consultee	Section no.	Comments	Responses
			IFU. In the IFU there is a 'Caution specifically for healthcare professionals regarding the issue of particles as it may lead to transient urine retention (IFU Luja™ 2024). Convatec therefore offer opinion that the guidance is misleading and offers potential to introduce risk to some patients for whom the micro technology would not be suitable. A significant proportion of ISC users will have sediment or mucus in the urine at any one time and during their cathing life this can come and go due to body changes, infections or drugs including certain antibiotics. Recent poster showed that 22% reported visible sediment in their urine (Skountrianos et al, 2024). In Coloplast's own study it showed 40% of samples with visible sediment remained undrained 8/20 samples with Luja™ vs only 2/20 [10%] with conventional eyelets (Athanasiadou et al.2023). This raising this warning is essential for all patients. The claim of one free flow is not truly accurate, the clinical data showed that in 10% of cases micro holes catheters had flow stops (Landauro et al 2023). The claim being made related to catheters with micro holes highlights a 10% incidence when the urinary flow had stops, therefore the 'One free flow' claim is inaccurate. (evidenced in Landauro et al 2023 paper). The claim of mucosa suction reduction again is based on weak scientific evidence. To visualise the sucking in of bladder mucosa with conventional eyelets, the study used a 50ml syringe to drain urine. Due to the presence of a telescope in the catheter lumen, thus needing a higher suction pressure to achieve the same flow rate as in an unobstructed catheter. (Tentor et al, 2022). In a further study (Stærk et al,2023) to assess bladder mucosa damage, the pig was catheterized 20 time over 2hours, every 6mins which is unrealistic in a clinical setting and the findings irrelevant. Contrary to these claims it has been shown due to the reduced PVP	

Comment no.	Consultee	Section no.	Comments	Responses
			coating (51%) that urethral damage is increased. Analysis of uroepithelium damage after catheterisation (number of cells removed from the monolayer) 30% more damage caused by micro hole technology product on 'insertion' than GentleCath™ with FeelClean Technology™ and 20% more damage caused on 'withdrawal' than GentleCath™ with FeelClean Technology™. (J Burns, et al, 2024) Again, this supports the need to show that Hydrophilic IAS technology (FeelClean Technology™) does offer a benefit to patient and reduces the risk.	
42.	Consultee 3 Convatec	1.3 What information is needed	Average price range, highest price is £3.31 Vapro plus pocket. However quoting prices will quickly outdate the guidance due to price increase mechanism within DT process	Thank you for your comment. The price range reflects the intermittent catheters available to the NHS when preparing the assessment report and issuing the draft guidance. For clarity, extra wording has been added to the guidance to reflect the time of the price quoted.
43.	Consultee 3 Convatec	2.4 2 The technology	Convatec would advise that we believe this should carry the warning/contra-indication which is unique to the technology so it is clear for HCPs and users. Classifying this as an innovation without this warning is increase risk for users.	Thank you for your comment. Intermittent catheters should be used in line with IFU, which is current practice.
44.	Consultee 3 Convatec	2.4 2 The technology	Convatec have requested that 'enhanced coating' should be further defined and IAS should stand alone as an innovation for enhance lubrication.	Thank you for your comment. Please see response to comment 39.
45.	Consultee 3 Convatec	3.9 Key evidence and	This is not factually true as no catheters with IAS (FeelClean) Technology were included. As this is a new innovation , Convatec have provided the scientific evidence to support our positioning.	Thank you for your comment. Please see response to comment 39.

Comment no.	Consultee	Section no.	Comments	Responses
		feature categories		
46.	Consultee 3 Convatec	3.23 Resource impact	Convatec request that this should reference 'enhanced lubrication'	Thank you for your comment. Please see response to comment 39.
47.	Consultee 5 B. Braun Medical	3.10 Key evidence and feature categories	Companies were asked to self-categorise their products and it would appear that this has not been verified by either clinicians or procurement teams; doing so may help NICE address the issue of having no agreement on the categorisation. In addition, while most self-categorisation by manufacturers appears to have been accepted by NICE, B. Braun Medical's position that pre-lubricated catheters should not be categorised as "uncoated", as they are in fact coated with gel lubricant, does not seem to have been accepted and NICE has not given justification for this. There is also a marked difference in the coated/non coated classifications for lubrication in Intermittent catheters within the ongoing Drug Tariff Part IX consultation and the LSA. This is surprising as we would expect alignment across the NHS and NICE.	Thank you for your comment. The EAG used a consistent set of definitions as described in section 3 of the EAR, which were applied across all catheter families to achieve consistency. The EAG note that all catheters by B.Braun were categorised as "uncoated (pre-lubricated)" (as described in Appendix A of the original EAG report) to denote that it did not include a PVP coating, but also to highlight that the catheter families by this manufacturer can be used straight from packaging without additional preparation.
48.	Consultee 9 Urology Trade Association	2.4 2 The technology	UTA members are aware that the researchers of the EAG were unable to come to a consensus on the assignment of product features with the wider industry and other clinical experts, and this raise concerns on the way the features were effectively defined by the EAG. It is important to highlight that during the Committee meeting on 16th January, it was flagged that the definitions of the features were open for interpretation and that they failed to consider patient preference. The UTA feels that the LSA process was too rushed and therefore	Thank you for your comment. The guidance acknowledges the lack of consensus on the original features categorisation. To explore this area of uncertainty, an alternative feature categorisation and updated CNMA results are in the addendum. The committee has also considered this extra work in their

Comment no.	Consultee	Section no.	Comments	Responses
			failed to consider how patient preference could be integrated into the outcomes.	deliberations (see section 3.15 of the final guidance). There was some overlap between the outcomes in the EAG's report and patient preference. The committee considered both aspects in their deliberations.
49.	Consultee 12 Coloplast	2.3 2 The technology	As in our comment on 'What this means in practice,' we recommend changing this wording to: '...and the price per catheter broadly ranged from £0.40 to £3.28, though it should be noted that included in this range are catheters with integrated drainage bags which are understandably associated with higher feature prices' Please see our previous comment for a detailed explanation.	Thank you for your comment. Please see response to comment 42. The source, inclusion and exclusion criteria applied are transparently described in section 3.1 and 3.2 of the EAG's report. The breakdown of price by feature is transparently reported, which highlights the contribution of features using the categorisations.
50.	Consultee 12 Coloplast	3.10 Key evidence and feature categories	The categorisation of features is fundamental to this analysis. If features have been miscategorised, then all results would be called into question. In Comment 61 on the EAG report, we describe the limitations of the EAG's methodology, but the comment did not – because it was not judged to be a factual inaccuracy - receive a substantive response. We maintain that the method would be improved by additional stakeholder engagement. Indeed, at the MTAC meeting on 17 January, the EAG – when questioned on what additional work would have been useful – responded that more work on categorisation would have been valuable. We therefore believe, despite the uncertainties having originally being discussed but not	Thank you for your comment. The guidance acknowledges the lack of consensus on the original features categorisation. To explore this area of uncertainty, an alternative feature categorisation and updated CNMA results are in the addendum. The committee has also considered this extra work in their deliberations (see section 3.15 of the final guidance). No justification for rerunning

Comment no.	Consultee	Section no.	Comments	Responses
			resolved at the scoping workshop on 21 August, that the LSA process has not allowed for a fair or sufficient engagement to determine a robust categorisation method. Given that feature assignment is the underpinning of the model, and therefore the basis of the recommendation to choose the least expensive catheter first, we ask that recommendation 1.1 not be included in the final guidance, to be replaced with the previously suggested wording describing the need for more information.	economic analysis because the uncertainty is still very high. The wording and order of the draft recommendations have been amended.
51.	Consultee 12 Coloplast	3.10 Key evidence and feature categories	We also believe that not all the relevant evidence has been made available to stakeholders. Section 3.9 of the EAG report from the updated Committee pack released on 4 March states (p32): "One Specialist Committee Member and members of the University of Southampton Bladder and Bowel management research group shared with the EAG two days before final report submission their independent categorisation of features for all intermittent catheters available on the Prescription Cost Analysis, which was based on information available on company website and physical review of sample catheters (where provided by manufacturers). This work is ongoing has been shared with and utilised by the modernising section IX of the Drug Tariff project. While there was no time to include this within the EAG report, the independent and clinically informed intermittent catheter feature categorisation led by the Specialist Committee Member and their team could be considered in future analysis to determine the impact on regression analysis, CNMA and economic analysis." Please can NICE confirm when this further categorisation will be available to stakeholders and/or used in further assessment work?	Thank you for your comment. Please see response to comment 50.

Theme 5. Condition and current practice

Comment no.	Consultee	Section no.	Comments	Responses
52.	Consultee 2 Guernsey Health and Social Care	1.3 Why the committee made these recommendations	Intermittent Catheters are also used for the instillation of intravesical medications	Thank you for your comment. This guidance focuses on the use of intermittent catheters for bladder drainage. The recommendation highlights clinical appropriateness which includes the use of intermittent catheters for the installation of intravesical medications and other purposes.
53.	Consultee 2 Guernsey Health and Social Care	1.3 Why the committee made these recommendations	Intermittent Catheters are also used for the instillation of intravesical medications	Thank you for your comment. Please see response to comment 52.
54.	Consultee 2 Guernsey Health and Social Care	2.1 2 The technology	used for the instillation of intravesical medication	Thank you for your comment. Please see response to comment 52.
55.	Consultee 3 Convatec	3.3 Current practice	Convatec support this and the RCN guidelines state the patient should get an annual review, however in practice, once discharged patients do not get reviewed.	Thank you for your comment. The committee heard from people with lived experience, and from specialist committee members, that people's needs can change over time and that a regular review is recommended. The 'what this means in practice' section of the guidance states that people should be offered

Comment no.	Consultee	Section no.	Comments	Responses
				a regular review of the chosen catheter's suitability.

Theme 6. What information is needed

Comment no.	Consultee	Section no.	Comments	Responses
56.	Consultee 3 Convatec	1.3 What information is needed	Convatec would propose that guidance is prepared to include the type of evidence is required. RTC's in this category would limit innovation and exclude SME bringing newer products into the UK market and maintain the monopoly of a few.	Thank you for your comment. As part of the committee considerations, it considers gaps in the existing evidence. The 'what information is needed' section of the guidance states that evidence can be generated through formal research studies or real-world evidence. The evidence should be comparative and include people that use intermittent catheters for chronic incomplete bladder emptying. This can be used by industry to strengthen the evidence base and prove that the potentially innovative features improve clinical outcomes. Currently, it is not within the scope of an LSA to publish an evidence generation plan. Following the completion of the LSAs, there will be a review and update of the methods so this may be subject to change.

Comment no.	Consultee	Section no.	Comments	Responses
57.	Consultee 4 ACP	Not specified	2. Under 'what information is needed - what about patient satisfation?	Thank you for your comment. This outcome has been added to the list of key outcomes.
58.	Consultee 5 B. Braun Medical	1.3 What information is needed	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 body or professional organisation (such as Association of Continence Professionals, Bladder & Bowel UK or Bladder Health UK), to reduce undue influence by manufacturers. If a recommendation of this kind was made to one of these bodies by NICE itself, it would carry more weight than if industry were to make this suggestion.	Thank you for your comment. Please see response to comment 56.
59.	Consultee 6 British Healthcare Trade Association	1.3 What information is needed	We have stressed the need for an evidence generation framework to be put in place developed by a wide range of stakeholders including industry. This should be created alongside the key outcomes you have detailed. The guidance should not be issued until this evidence framework is in place.	Thank you for your comment. Late-stage assessment has a different purpose in the lifecycle approach to early value assessment (EVA). LSA evaluates technologies that are in widespread or established use in the NHS to inform commissioning and procurement decisions. It is expected that technologies in use in the NHS are evidence based. In contrast, EVA evaluates new technologies that have the potential to meet an unmet need in the NHS. Technologies suitable for EVA require further data collection or evidence generation before they can be recommended for routine use in the NHS.

Comment no.	Consultee	Section no.	Comments	Responses
				As part of the committee considerations, it considers gaps in the existing evidence. The 'what information is needed' section of the guidance states that evidence can be generated through formal research studies or real-world evidence. The evidence should be comparative and include people that use intermittent catheters for chronic incomplete bladder emptying. This can be used by industry to strengthen the evidence base and prove that the potentially innovative features improve clinical outcomes. Currently, it is not within the scope of an LSA to publish an evidence generation plan. Following the completion of the LSAs, there will be a review and update of the methods so this may be subject to change.
60.	Consultee 9 Urology Trade Association	1.3 What information is needed	The UTA members also question what type of evidence should be generated, and how it will be collected. We believe that certain types of research studies for example large-scale, double-blinded randomised control trials are not an appropriate research methodology for personal medical devices like intermittent catheters. The evidence collection and methodologies used to analyse the data should be appropriate for the type of product analysed.	Thank you for your comment. Please see response to comment 56.

Comment no.	Consultee	Section no.	Comments	Responses
61.	Consultee 10 Hollister Ltd	1.3 What information is needed	Under considerations for procurement and commissioning there is reference to providing evidence of clinical superiority to show additional value. There should be an explicit definition of what is required. There should also be an acknowledgement of the time it may take to gather such evidence.	Thank you for your comment. Please see the response to comment 56. The point relating to clinical superiority has been removed as the detailed information is covered in 'what information is needed'.
62.	Consultee 10 Hollister Ltd	3.25 Evidence needed to show additional value	It would be helpful if NICE could provide explicit criteria as to evidence requirements moving forward so that companies can ensure they are focusing resource in the right areas.	Thank you for your comment. Please see response to comment 56.
63.	Consultee 12 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 with no obvious links between the two, may result in changed NHS categorisation and/or prices of the products under evaluation.	Thank you for your comment. Please see response to comment 56 and 59. The new categorisation of catheter features used in the addendum of this assessment contributes to the modernising section IX of the Drug Tariff project.
64.	Consultee 12 Coloplast	1.3 What information is needed	Recommend changing this wording to "evidence, which should compare catheter features with each other to show if a specific feature affects outcomes and user preferences, was limited and only available for certain technologies; i.e. MHZT."	Thank you for your comment. The 'what information is needed' section of the guidance aims to explain what information is needed, which includes outlining gaps in the evidence. This section does not comment on the existing evidence

Comment no.	Consultee	Section no.	Comments	Responses
				.

Theme 7. What this means in practice

Comment no.	Consultee	Section no.	Comments	Responses
65.	Consultee 3 Convatec	1.3 What information is needed	Many factors influence which type of catheter is used but there is no mention of market dynamics and distortion in market through sponsored nurses, company nurse running clinics or Prescription Management Services which limit or restrict choice. Also that there is no real follow up of patients once discharged or circumstances change for them to be reviewed.	Thank you for your comment. Please see response to comment 1. Extra wording has been added to 'considerations for healthcare professionals', acknowledging the need for regular review of catheters suitability.
66.	Consultee 3 Convatec	1.3 What information is needed	Convatec propose that NICE expressly state that this should not be choice of one companies catheters but a range of company catheters	Thank you for your comment. Please see response to comment 1.
67.	Consultee 3 Convatec	1.3 What information is needed	Convatec propose that patients should be informed of the risks of PVP coated catheters both with regards to urethral micro trauma, risk to sperm. Those considering micro hole technology should be made aware not only via their HCP but also in any direct to patient facing material or social media advertising.	Thank you for your comment. Please see response to comment 43.
68.	Consultee 12 Coloplast	1.3 What informatio	Recommend changing this to '...and the price per catheter broadly ranged from £0.40 to £3.28, though it should be noted that included in this range are catheters with integrated drainage bags	Thank you for your comment.

Comment no.	Consultee	Section no.	Comments	Responses
		n is needed	which are understandably associated with higher feature prices' It is important to understand what you are paying for when considering a price range of £0.40 - £3.28. To ensure value for money for the NHS it is critical to make the distinction between the price range of catheters alone versus catheters with other integrated equipment. On face value a reader is directed by Recommendation 1.1 to choose catheters at the lower end of this price range. For those patients who require an integrated drainage bag; ie those with mobility/dexterity issues or neurogenic clinical presentations, this price range and the recommendation to choose cheapest first could prejudice their care alongside pushing the price up for the NHS. An example to illustrate this is SpeediCath Compact Male Set (a combined catheter and integrated bag product) which is priced at £2.86 currently for both catheter and bag. Prescribing like-for-like components separately would cost the NHS £4.73 and would not therefore justify value for money. It would be misleading for the NHS to say the price difference could be £2.88 per catheter as there are 2 products in a combined catheter and integrated bag set, not just a single catheter and this is a good example where the LSA could have the opposite effect and push prescribing costs higher alongside the inconvenience caused for patients.	The price range reflects the intermittent catheters available to the NHS when preparing the assessment report and issuing the draft guidance. For clarity, extra wording has been added to the guidance to reflect the time of the price quoted. The source, inclusion and exclusion criteria applied are transparently described in section 3.1 and 3.2 of the EAG's report. The breakdown of price by feature is transparently reported, which highlights the contribution of features using the categorisations. The wording and structure of the draft recommendations have been amended to prioritise considerations about catheters' clinical appropriateness and people's preferences. .
69.	Consultee 12 Coloplast	1.3 What informatio n is needed	This recommendation relates to evidence requirements for new catheters. Additional text is needed to explain that, while the recommendation may be relevant for secondary care procurements, availability for primary care prescribing – which is where the vast majority of intermittent catheter prescribing occurs – is governed by the process for inclusion in Part IX of the Drug	Thank you for your comment. The committee has considered this comment but concluded that this is beyond the scope of this guidance.

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			Tariff which is subject to separate policy development, and not under the control of local or regional commissioner.	
70.	Consultee 12 Coloplast	1.3 What information is needed	This statement assumes clinical superiority is required to deliver value. As suggested by the User Preferences work, this is not the case.	Thank you for your comment. The statement referencing clinical superiority has been removed from the 'what information is needed' section.

Theme 8. User experiences, needs and preferences

Comment no.	Consultee	Section no.	Comments	Responses
71.	Consultee 3 Convatec	3.6 User experiences, needs and preferences	In practice Convatec agree this should be done but reality is that many patients do not get an opportunity for a review. Many patients are not offered compact catheters and some patients who want to change are refused this can be due to practices lack of knowledge or local service.	Thank you for your comment. Extra wording has been added to the 'what does this mean in practice section' which now states that people should be offered a regular review and wording has been added to section 3.6 to state that there can be variation in practice.
72.	Consultee 9 Urology Trade Association	1.3 Why the committee made these recommendations	The UTA question whether clinical and economic benefits and/or attributes should be in the same pool and assessed together. We also feel that the user-centred work done ahead of the publication of this draft guidance for consultation was limited. The user preference assessment only included 10 people between patients and clinicians. This is too small of a cohort to assess	Thank you for your comment. In line with section 6.1 of NICE health technology evaluations: the manual (pmg36) and the 'committee decision making' section of the LSA interim methods and process statement, the committee considered the

Comment no.	Consultee	Section no.	Comments	Responses
			criteria, given that it may have excluded patients with particular characteristics, like having reduced mobility as a wheelchair user, that have not been included in the user assessment report and subsequent conversations and decisions that have led to this draft guidance. A similar comment can be made with respect to the user survey report, where only 73 people responded to the survey and 69 responses could be included and analysed. We believe that a wider range of patients' responses should have been collected, to broaden the data and inform subsequent analysis. UTA members are also aware that during the committee meeting held on 16th January for this LSA, the committee was made aware that no person with mobility issues was involved in the user-centred work, meaning that potentially a wide spectrum of patients with need for bladder drainage intervention has not been taken into consideration while drafting this guidance. This will put certain categories of patients being prescribed products which deliver sub-optimal care and increases the risk of patients requiring more costly interventions further downstream if they go into crisis or their condition worsens. We feel that relevant evidence has not been taken into account when considering patients with different lifestyles, backgrounds and other characteristics, and this should be rectified to avoid any form of discrimination.	assessment of clinical and economic evidence and user-centred work together in their deliberations. The user preference assessment report and the online survey report acknowledge the small sample size. To increase the representation of patients for this topic, there was a second round of lay specialist member recruitment, and the survey was shared with 23 patient and carer organisations (e.g. Spinal Injuries Association). A 73 people responded to the survey and 69 responses were included in the analysis. This included 67 people who used IC for managing their own incomplete bladder emptying and 2 family members or carers. The guidance (section 3.6) also states that the user preference assessment lacked data on the preferences of people with mobility issues and people's needs, preferences and experiences of using intermittent catheters varied. However, the thematic review of the literature includes studies reporting on a broad population which includes people with mobility issues caused by, such as spinal cord injury or multiple sclerosis.

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73.	Consultee 9 Urology Trade Association	3.5 User experiences, needs and preferences	As mentioned above, the UTA feels that the user-centred work lacks enough data and information properly to provide an assessment of the factors and criteria needed to assess intermittent catheters. At the Committee meeting there were only two patients who discussed their experiences, needs and preferences. Again, this does not offer a wider understanding on these topics and more patients should have been involved.	Thank you for your comment. Please see response to comment 72. Two patient experts and 2 lay specialist committee members attended the committee meeting to represent the patient voice and user-centred work (which included a user preference assessment [n=9], an online survey [n=69] and the thematic review of the literature [n=19 articles]). To increase the representation of patients for this topic, there was a second round of lay specialist member recruitment.
74.	Consultee 9 Urology Trade Association	3.7 Equality considerations	We feel that the lack of data on preferences of people with mobility issues should have been rectified before the publication of the draft guidance. Other than mobility issues, there was a lack in data of people that for example needed a carer to use catheters (only 1 person in the survey). With such a narrow scope, there is the risk that the guidance fails to reflect on a number of disabilities and other issues that patients face daily.	Thank you for your comment. Please see response to comment 72.
75.	Consultee 10 Hollister Ltd	3.3 User experiences, needs and preferences	As a general comment to this section it seems that low numbers of users with lived experience were involved - it would have been good to have a much broader sample to make findings applicable to the wider IC population.	Thank you for your comment. Please see response to comment 72.

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76.	Consultee 12 Coloplast	Not specified	Note on the Equality Impact Assessment: As noted in Comment 8 on the User Preferences report, we were alarmed to see that the survey of the people using ISC only contained four people with spinal injuries – and this is because 'mobility issues' do not necessarily cover, or do not clearly enough describe why this population need to access a range of products. For instance, we know that according to the Spinal Injuries Association's annual What Matters report, for three years running – the biggest concerns people have are management of their bladder and bowel – these rank above wheelchairs and pain management, for instance. See: https://www.spinal.co.uk/wp-content/uploads/2024/06/SIA_What_Matters_Report_2024_v3.pdf	Thank you for your comment. Please see response to comment 72. In the thematic review of the literature, 7 studies included people with spinal cord injury only (n=487).
77.	Consultee 12 Coloplast	3.5 User experiences, needs and preferences	While we appreciate the use of alternative methods to supplement the User Preferences work in this LSA, the results suffer from a lack of generalisability. Comment 8 on the User Preferences work highlights the underrepresentation of spinal cord injury patients in the User Survey. Comment 31 describes the impact of the small sample sizes used in the analysis.	Thank you for your comment. Please see response to comments 72 and 76.
78.	Consultee 12 Coloplast	3.6 User experiences, needs and preferences	We do not feel that all the available evidence has been considered. During the fact check process on the user preference reports, we identified evidence which has not been considered. Much of this was rejected by the EAG and we argue is due reconsideration (see Comment 18 on the Thematic Review). Additionally, in Comment 26 on the User Preference Report we argue for the inclusion of a study, which provides important context on the risk of UTIs in the catheterised population, but	Thank you for your comment. Regarding the papers cited by the consultee (comment 18), one was included in the thematic review (van Achterberg 2008 included in Balhi 2021) and the other studies did not meet the inclusion criteria. For the paper relating to user preference (comment 26), the user preference assessment aims to evaluate

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			which was excluded because it was not open access. We would ask that the Committee reconsider including this information.	the criteria that users consider important when deciding which technology to choose but it is not to summarise the literature relating to the context of the UTIs risk.

Theme 9. Equality considerations

Comment no.	Consultee	Section no.	Comments	Responses
79.	Consultee 10 Hollister Ltd	3.7 Equality considerations	Yes, as the committee noted, products with integrated bags are absolutely key, particularly for certain users such as spinally injured people, where they bring very significant benefits.	Thank you for your comment.
80.	Consultee 12 Coloplast	Not specified	Note on Equality Impact Assessment: It has been shown that deprivation has a negative impact on health outcomes. Individuals living in most deprived areas are faced with the worst healthcare inequalities (NHS England). [confidential information submitted separately- AIC] This would suggest that there is a proportion of users who are faced with inequalities in terms of access to full range of products/health services. Any further restrictions to access or unfavourable changes would likely have further impact on health outcomes for those in need of catheters. We do not think that this LSA has fully appreciated the impact that the guidance recommendations will have on underserved communities and their ability to access a catheter option which meets their needs and preferences. Financial pressures inordinately impact these areas, increasing the incentive to reduce	Thank you for your comment. Extra wording has been added to section 3.7 of the guidance, 'what this means in practice' and equality impact assessment to highlight the need for people to have access to most suitable catheters, to have training and regular review of catheter suitability which may change over time.

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			costs. We know there is already a post-code lottery on catheters, where some low cost formularies exist, and list only two options. We fear this LSA will create a two-tier healthcare system, where deprived areas are made to sacrifice quality of care to reduce costs. Therefore, we would like to ask if the Committee has adequately considered Core20PLUS5 - the NHS England approach to inform action to reduce healthcare inequalities at both national and system level.	
81.	Consultee 12 Coloplast	Not specified	We are pleased to see in the Equality Impact Assessment that the experts 'agreed it was important to empower people and offer them a choice, and for clinicians to be aware of the range of catheters available' however, as stated in other comments in this document, the current draft guidance would not support this in real life.	Thank you for your comment. Please see response to comment 80.

Theme 10. Clinical evidence and study selection

Comment no.	Consultee	Section no.	Comments	Responses
82.	Consultee 5 B. Braun Medical	Not specified	B. Braun does not believe that all relevant evidence has been taken into account. The EAG report stated that Chartier-Kastler (2022) was excluded as it had "a potential mix of catheters, EAG unable to verify additional features." B. Braun accepts this to be correct. However, the heretofore unpublished (and therefore commercial in confidence) Lampuré et al (2020) was also excluded by the EAG because its "data [is] in public domain in Chartier-Kastler (2022)" which is incorrect. Chartier-Kastler (2022) reported only on one sub-analyses within the study, whereas Lampuré et al (2020) reports all sub-analyses, including head-to-	Thank you for your comment. The EAG has reviewed the study by Lampure et al. 2020 again and have made the following observations: • The 128 page report provided CiC was dated 18th December 2020, a subset have been published in Chartier-Kastler 2022 however the EAG has not been able to

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			head comparisons of Actreen and Speedicath and therefore does not have a “mix of catheters” and the EAG would be able to “verify additional features”, unlike Chartier-Kastler (2022). Therefore, by omitting Lampuré et al (2020), NICE has not considered all relevant evidence.	identify any peer-reviewed publication of the remaining results. • The EAG can see analysis for Actreen and SpeediCath, however the EAG note that these are families of catheters, and as described in Appendix A of the original EAG report, the catheters included in these families have different features. Therefore without knowing the exact catheters used the EAG would not be able to use the analysis described by the Lampure et al. 2020 CiC report. Should data become available then it could be incorporated should this LSA be updated.
83.	Consultee 12 Coloplast	3.11 Key evidence and feature categories	The use of outdated evidence, including a study in a French population from 1980-1988 (see Comment 106 on the EAG Report), highlights the lack of generalisability and high levels of uncertainty in the modelling, and underscores the need to interpret its results with caution. Recommendation 1.1 is, therefore, not a reasonable interpretation of the available evidence. It assumes that an absence of evidence is evidence of absence, which is not justified. The recommendation should be removed and all references to the results of the modelling should be presented with a high level of caution.	Thank you for your comment. The EAG iterated the limitations of the CNMA and economic modelling throughout its report, conclusions and Executive Summary. The guidance (section 3.11) highlights that the outdated evidence was included, and the committee recognised that some of the evidence was outdated, and this might not reflect current practice.
84.	Consultee 12 Coloplast	3.13 Results of the CNMA	This conclusion has been drawn without consideration to all of the available evidence. As noted in Comments 31 and 40 on the EAG report, Bagi et al 2010 was excluded improperly due to using a patient population of healthy volunteers, but this should not impact haematuria.	Thank you for your comment. The EAG previously excluded a study by Bagi et al. 2011 due to being exclusively conducted in a healthy population (see Appendix C5 in

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				the original EAG report). The EAG has reviewed this study again and notes that it includes 28 healthy volunteers who were catheterised twice with a compact catheter and twice with a regular catheters, where "All catheterizations were performed by 1 of 3 trained study nurses according to standard hospital guidelines". Therefore it is unclear how these results would be considered generalisable to a long-term intermittent catheter population in a community or primary care setting as defined by the Final Scope. No change has been made.
85.	Consultee 12 Coloplast	3.21 Results of the economic model	We do not believe all available evidence has been considered for the model. As described in Comment 19 on the EAG report, evidence demonstrating the effect of micro-hole zone technology on one measure of residual volume (RV1), which is an important risk factor for UTI, was not fully considered. Additionally, evidence demonstrating the impact of perceived bladder emptiness on UTIs was not used in the analysis on micro-hole zone technology (Comment 104 on the EAG report). Several other studies were improperly excluded as highlighted in EAG report Comment 41. Furthermore, as stated in Comment 81 of the EAG report, due to the rushed and constrained nature of the LSA process generally, unpublished evidence identified through ClinicalTrials.gov and ICTRP that may have been useful was also not included. The evidence pool for this analysis was already limited, and	Thank you for your comment. The EAG utilised rapid review methodology and prioritised published evidence where results could be incorporated into the CNMA (over ongoing studies were results were not yet available). The consultation comment does not highlight specific ongoing studies which have results published recently which have been missed by the companies submission or EAG literature search which are pivotal to the analysis undertaken, therefore the EAG cannot comment further.

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			exclusion of potentially valuable evidence only adds more uncertainty to the already uncertain modelling. The Committee should remove Recommendation 1.1 from the guidance as no recommendations on cost should be made on such an uncertain foundation.	

Theme 11. CNMA and results

Comment no.	Consultee	Section no.	Comments	Responses
86.	Consultee 3 Convatec	3.13 Results of the CNMA	Convatec would suggest that this description is inadequate and that it does not fairly represent 'enhanced lubrication'	Thank you for your comment. The scope states 'enhanced lubrication or coating' which covers IAS. The EAG used 'enhanced coating' as an aggregate and covered IAS in the feature definition. The EAG has explored an alternative, independent categorisation of features and their impact on CNMA (see addendum). IAS has also been considered in this alternative categorisation and discussed by the committee (section 3.15 of the guidance).
87.	Consultee 12 Coloplast	Not specified	NICE has focused this assessment on the impact of each individual feature of intermittent catheters showing their incremental improvements, when the fact is that most catheters contain multiple features, which together significantly differentiate from a basic catheter. This approach poses high demands on the required evidence supporting each individual	Thank you for your comment. For the evaluation of combined features, the draft guidance and the EAG's report acknowledge that there is evidence for catheters with different features. However, this

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			feature, which is not realistic for low-cost products like intermittent catheters. Intermittent catheters should be evaluated based on their combined features, 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 also due to the vast number of individual products needed for each range.	assessment is to determine whether price variation between different intermittent urethral catheters can be justified and attributed to any specific feature, a CNMA was conducted to isolate the impact of individual features on the chosen outcomes even when those features were provided alone or in combination with other features. As a result, there is not enough evidence of the effectiveness of individual features separately, or how each feature contributes to the reported outcomes. So, more information is needed to estimate the effect size of individual features.
88.	Consultee 12 Coloplast	3.13 Results of the CNMA	As noted in Comment 23 on the EAG report, the analysis undertaken for UTIs included a definition of UTI that changed between the agreement of the final scope and the analysis. We recommend that the Committee include a statement reflecting this change from the final scope in the guidance and noting that there are several outcome measures designed for detecting catheter-related infection.	Thank you for your comment. The EAG selected a definition of UTI that was most used in the published literature to maximise the number of studies included in component network meta-analysis (as per description in section 4.2.4.1). CAUTI is a different outcome and not explicitly reported in the published literature. All definitions of UTI were considered in the report, and all results extracted (see Appendix C4 of the EAG's report).
89.	Consultee 12 Coloplast	3.13 Results of the CNMA	As mentioned in Comment 68 on the EAG report, we still find this hard to explain from a clinical perspective. Features like thumb holes or ring pulls should not have an impact on UTI rates. The EAG's suggested mechanism is 'easier to hold, better	Thank you for your comment. The EAG's report describes 'possible mechanism' for several findings and

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			drainage or used more frequently,' but this is simply conjecture. We once again feel that this calls the modelled results into question and believe that the Committee should not be using them to develop recommendations on price variation beyond appealing for more evidence.	summarises the CNMA results with a number of caveats. The EAG's report also repeatedly highlights the low or very low certainty associated with these results. The draft guidance states that there is a lack of information about how the reported outcome can be attributed to that feature.
90.	Consultee 12 Coloplast	3.15 Uncertainty about the effectiveness of individual features	In Comment 59 on the EAG report, we suggest alternative methods for assessing the relative importance of treatment outcomes. We acknowledge that the DCE from Pinder et al was not aligned with the scope in terms of features/outcomes however it is clear that methods used were not fit for purpose to fully address the decision problem. 'The committee acknowledges in this section 'the lack of consensus on the feature categories, heterogeneity of the data, uncertainties of the outcomes.'	Thank you for your comment. The EAG considered the current methods used to be the most appropriate. The committee discussed the methods used for this assessment. As a result, it agreed that a CNMA was an appropriate method to analyse the benefits of the components, as described in the draft guidance.

Theme 12. Economic model and limitations

Comment no.	Consultee	Section no.	Comments	Responses
91.	Consultee 9 Urology Trade Association	3.17 Economic model structure	The EAG economic model applied an annual all-cause mortality rate to a monthly cycle, which can skew the consequential analysis of products. Also, during the committee meeting on 16th January, it was explained that given that the patients' disease severity would be greater, they would have an arguable higher mortality rate.	Thank you for the comment. The annual all-cause mortality rates were previously replaced with the monthly estimates and the cost-effectiveness results updated. Higher mortality rates would reduce costs for all

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				options and potentially reduce the magnitude of cost differences. However, this is unlikely change the direction of results or conclusions of the EAG report.
92.	Consultee 3 Convatec	Not specified	Convatec would offer opinion that further consideration needs to be given to Spinal Cord Injury patients (SCI); it is well evidenced, that this group pf people can take longer to perform intermittent catheterisation due to dexterity issues. They also have an increased risk of sediment and increased risk of fragile sperm leading to potential reduced fertility and should be made aware of the options and increased risks with certain catheters. SCI and other disabilities with dexterity issues, such as those who are bed-bound, or wheelchair users, the time required for catheterisation can increase significantly (Velaer et al, 2021.) thus increasing the risk of trauma using a PVP catheter which may begin to dry and stick. All PVP based catheters can impact sperm mobility and viability (including 'triple coated'), PVP residue in urethra is a risk for males who may want to conceive. This risk is increased for SCI users whose sperm could be more fragile (Kathiresan ASQ et al, 2012, Quinn et al 2024). This sub group should have informed choice regarding this. Sediment and mucus in the bladder can be problematic (Skountrianos et al, 2024.). ISC users often have higher propensity, leading to increased risk of stone formation and UTIs (Vaidyanathan et al, 2005.). Spinal Cord injury patients, MS, patients and BPH patients are at greater risk of stones (Vaidyanathan et al, 2005; Ganesan et al, 2017; Hassan AM et al, 2022.). So, reducing presence of sediment and mucus is important, thus having eyelets compared to micro holes can	Thank you for your comment. The EAG did include evidence from patients with spinal cord injury (see "Indication for intermittent catheterisation" within Table 4 of the EAG report). A total of 9 included studies were exclusively conducted in a population with spinal cord injury, and the generalisability of evidence between neurogenic and non-neurogenic patients was sought from clinical experts (as evidence in section 4.2.2 of the EAG report).

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			offer patient increased confidence that optimal drainage of sediment and mucus is achieved (Pollard et al 2024).	
93.	Consultee 12 Coloplast	Not specified	While we thank the EAG for amending the health economic model as a result of the factual accuracy comments, we still see large issues with the model. We recommend that a 'Model Limitations' section be added to this guidance. The economic modelling performed was highly uncertain, lacked generalisability and should be interpreted with great caution. We have highlighted many limitations to the model, and we feel that the current guidance is understated in its description of the model's limitations. We would argue that until more work is done to substantiate the modelling, no recommendations should be formulated on the basis of its conclusions on cost effectiveness (i.e. use the least expensive catheter). Previous relevant comments, which were not addressed substantively during the fact check process and did not result in changes to the EAG report, include -Mismatch between the scope and available evidence (EAG Report Comment 27) -Poor generalisablility of the included evidence to the population (EAG Report Comment 28, 32, 58, 101, 106, and 110) -Uncertainty in the modelling (EAG Report Comment 49, 103, 105, 107, and 109) -Limitations to the time horizon (EAG Report Comment 55 and 108)	Thank you for your comment. The EAG's report describes the limitations associated with its evidence synthesis and economic model. The committee was aware when making the decisions. The guidance states key model limitations (sections 3.17 to 3.23) based on the committee's discussions. For the previous relevant comments on the EAG's report, the EAG reconsidered these and the detailed responses are in the EAG's responses to factual accuracy check comments.
94.	Consultee 12 Coloplast	3.19 Model assumptions	We thank the committee for recognising this limitation in the modelling and, as we also highlighted in Comment 39 on the EAG report, generic quality of life measures are typically insensitive to the benefits offered by catheter features. Work to encourage greater acceptance of disease-specific measures,	Thank you for your comment. A section on the strengths and limitations of the economic modelling is present in section 6.3 of

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			and methods to incorporate them in quantitative modelling, would improve our ability to measure the value of these features. However, we would argue that there is a broader range of limitations to the model that lead to highly uncertain results. These limitations warrant a section of their own in this guidance (as seen in the One-Piece Colostomy Bag LSA guidance) to help provide context for readers on all the work that went into the EAG's analysis and why the main conclusion was that more evidence is needed to determine whether the prices associated with individual catheter features is justified by the clinical and economic benefits they provide.	the EAG report, and further highlighted in the conclusions and executive summary. The guidance states key model limitations (sections 3.17 to 3.23) based on the committee's discussions.
95.	Consultee 12 Coloplast	3.20 Model assumptions	As stated in Comment 28 and 29, the generalisability of the economic analysis overall is called into question by the high proportion of information derived from a neurogenic/spinal cord injured population. In its response to Comment 29, the EAG noted that 'one clinical expert said that UTI and residual volume outcomes would not be expected to be different between groups.' This is not enough evidence to justify the lack of generalisability, and EAU guidelines indicate that all neurogenic patients should be considered complicated. Please can the Committee add, as previously stated, a more complete summary of the model limitations which describes this issue with generalisability. Additionally, we once again ask that the Committee consider removing the 'least expensive' component of Recommendation 1.1 to reflect the lack of convincing and generalisable evidence to support such a recommendation.	Thank you for your comment. Please see response to comments 92 and 94. The wording and order of the draft recommendations have been amended.

Comment no.	Consultee	Section no.	Comments	Responses
96.	Consultee 12 Coloplast	3.20 Results of the economic model	The EAG responded to many of our comments on assumptions and inputs into the model (e.g. EAG report Comments 98, 107, 109, 110) by describing how scenario and sensitivity and analyses had been performed which demonstrated the input did not impact conclusions. While we understand that the analyses were performed, this does not overwrite the poor assumptions and high level of uncertainty in the model due to data limitations, therefore we recommend that the modelling not be used to generate recommendations about the cost of catheter features or the prescribing practices of experienced clinicians.	Thank you for your comment. The EAG would contend that the assumptions made were not poor but reflective of the limited evidence base available. Further as a consequence of the limited evidence available there was little evidence on the additional effectiveness of a given feature that could offset any additional costs of that feature. Please see response to comment 94.

Theme 13. Resource impact assessment

Comment no.	Consultee	Section no.	Comments	Responses
97.	Consultee 10 Hollister Ltd	3.23 Resource impact	Given the limitations in relation to the calculations, together with the statement " the cost of each feature from the regression model might not be a true representation, so the costs or savings from the scenario analysis might not be realizable." it is very difficult to draw any meaningful conclusions in relation to the RIA.	Thank you for your comment. The EAG's report highlights the limitations associated with the multiple regression model and features categorisation. The draft guidance and the resource impact summary also describe the key issues and uncertainties.
98.	Consultee 12 Coloplast	3.23 Resource impact	The summaries are not a reasonable interpretation of the evidence given the high levels of uncertainty and key issues surrounding the regression analysis (see Comment 91 and 96 on the EAG Report) and the categorisation of features (see	Thank you for your comment. Please see response to comment 97. Some text has been removed from section 3.23, including

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			Comment, 22, 61 and 83 on the EAG Report). We ask that the summaries of the RIA are replaced with 'too uncertain to make any conclusions'	the annual costs of catheter features based on the resource impact assessment. This section has been renumbered as 3.24. It was understood that the cost of each feature that contributed to the price of a catheter might not be a true representation, because market intervention might change feature prices. Despite the accepted uncertainties, the results of the regression modelling were the best available in terms of the estimated contributor to catheter price for each feature.

Theme 14. Methods and process

Comment no.	Consultee	Section no.	Comments	Responses
99.	Consultee 9 Urology Trade Association	3.15 Uncertainty about the effectiveness of individual features	UTA members feel that this paragraph highlights how the LSA process was not properly adapted to the particular situation of intermittent catheters. More should have been done to understand that the methods and process for the LSA should be different and tailored to the specific category. Some categories are prescribed entirely by clinicians, others (including continence wearables for instance) have more heavy patient involvement. The process, questions and methodology should have been tailored to account for this variation. The overall approach to the LSA was also questioned during the	Thank you for your comment. The guidance acknowledges the lack of consensus on the original features categorisation. To explore this area of uncertainty, an alternative feature categorisation and updated CNMA results are in the addendum. The committee has also considered this extra work in their deliberations (see section 3.15 of the final guidance).

Comment no.	Consultee	Section no.	Comments	Responses
			committee meeting on 16th January, where Special Committee Members flagged the difficulty in defining terminology and features, and wondered whether an alternative approach would have been better suited.	The methods used for this assessment were in line with the LSA interim methods and process statement and the NICE health technology evaluation: the manual (pmg36). Following the completion of these LSA topics, feedback received through after action reviews and a consultation period will be used to finalise the process and methods for LSAs.
100.	Consultee 10 Hollister Ltd	Not specified	Fundamentally it would seem that the LSA process is inappropriate to use with this type of product. NICE level evidence has historically never been required for either reimbursement or regulatory authorities so it is unavailable across the market. It therefore seems totally unsuitable to apply the LSA methodology to these products. If companies are required to produce NICE level evidence to be assessed by future LSAs, then it is essential that adequate time is allowed for this to be gathered and that very specific criteria as to evidence requirements is given. The EAR report made numerous references to lack of consensus regarding features/definitions, large uncertainties and significant limitations in data/assumptions. It therefore seems very difficult to make any robust and meaningful recommendations.	Thank you for your comment. Please see response to comment 30 and 99.
101.	Consultee 12 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.	Thank you for your comment. All comments received during the consultation period were reviewed by the committee. Following the completion of these LSA topics,

Comment no.	Consultee	Section no.	Comments	Responses
			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.	feedback received through after action reviews and a consultation period will be used to finalise the process and methods for LSAs.
102.	Consultee 12 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-focussed approach is methodologically appropriate for value 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.	Thank you for your comment. The methods used for this assessment were in line with the LSA interim methods and process statement and the NICE health technology evaluation: the manual (pmg36). The use of an interim process and methods statement to trial an assessment was used to develop NICE's early value assessment. This LSA guidance is one of 8 topics which were selected to be developed using the LSA interim process and methods statement. Following the completion of these LSA topics, feedback received through after action reviews and a consultation period will be used to finalise the process and methods for LSAs. .

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103.	Consultee 12 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 not support this; there has also been little or no evidence of learning between topics.	Thank you for your comment. Please see response to comment 101 and 102.
104.	Consultee 12 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 intermittent catheters 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 intermittent catheters - 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 harmonise processes and methods for healthtech, please can NICE explain why this inconsistency is justified?	Thank you for your comment. The recommendations outlined in the 'types of NICE recommendations' page relate to NICE's existing guidance products which are made in the context of evaluating technologies for adoption by the NHS. Late stage assessment is placed at a different point in the lifecycle. Its purpose is to assess technologies that are in widespread or established use in the NHS to support procurement and commissioning decisions. It does this by assessing whether the value added by incremental innovation justifies the price variation. This is why the recommendations to date have been drafted in line with the interim

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				process and methods for late-stage assessment (see sections 4.35 and 4.36). The scope of a LSA assess a category of products in widespread use, this is inclusive of products within that category that are new to the market. There is an expectation that these technologies should have evidence to support their proposed benefits to the NHS over existing technologies in order to justify any increases in price.
105.	Consultee 12 Coloplast	Not specified	Recommend changing the wording to: 'The aspiration of the NICE Late-Stage Assessment (LSA) was to evaluate categories of technologies that are already in widespread use within the NHS. The process was designed to assess whether price variations between technologies in the same category are justified by differences in innovation, clinical effectiveness and patient benefits. The overall aim was for assessments to support NHS commissioners, procurement teams, patients and health care professionals to choose technologies that maximise clinical effectiveness and value for money. ' As this is a pilot which has not concluded on anything very specific, the context for any reader of this document should be the aspiration/intention behind the LSA pilots rather than setting a tone that leads a reader to interpret that the intended process has worked.	Thank you for your comment. This is a pilot which helps to finalise the process and methods but the aim of the NICE late-stage assessment remains the same. No changes to the wording of the guidance have been made in response to this comment.

Other comment

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106.	Consultee 9 Urology Trade Association	Not specified	the Urology Trade Association (UTA) is the leading urology industry membership organisation for manufacturers and suppliers of urology products in the UK, and this is its response to the consultation.	Thank you for your comment.