NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance
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Your responsibility

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

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

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

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

Contents

This guidance replaces HTE28.

1 Recommendations

1.1 There is not enough evidence to determine whether price variation is justified between different intermittent urethral catheters for chronic incomplete bladder emptying in adults.

1.2 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.

1.3 A healthcare professional and the person with chronic incomplete bladder emptying should decide together which intermittent urethral catheters to use (see the NICE page on shared decision making). Decisions should take into account:

- ease and comfort of use
- risk of infection.

1.4 If more than 1 catheter meets the person's needs and preferences and is clinically appropriate, choose the least expensive.

What information is needed

More information is needed to show if price variation between different intermittent urethral catheters can be justified and attributed to any specific feature.

Evidence should compare catheter features with each other to show if a specific feature affects outcomes and the preferences of people using intermittent urethral catheters. Evidence should be generated across different groups of people who use intermittent catheters for bladder drainage, through formal research studies or real-world evidence.

A core outcome set, including validated patient-reported outcomes, should be developed

so that outcomes can be reported consistently. Features should be classified consistently so they can be assessed in a standardised way.

Key outcomes and information that should be captured include:

- details of the catheter features
- incidence of urinary tract infection
- incidence of haematuria, in particular macroscopic or visible haematuria
- residual urine volume (the volume of urine remaining in the bladder after catheterisation)
- comfort during catheterisation (insertion and removal)
- ease of use
- health-related quality of life
- patient-reported outcomes, including patient satisfaction
- adverse events
- how a feature contributes to an outcome.

What this means in practice

Considerations for procurement and commissioning

- In 2023 to 2024, a total of 95,437,405 intermittent catheters were prescribed in the NHS, and the price per catheter ranged from £0.40 to £3.28 (as of November 2024).
- Some features might be needed for specific groups or people in specific situations. For example, people with mobility issues might benefit from catheters with an integrated drainage bag. People with reduced manual dexterity might need catheters with specially designed packaging for ease of opening or catheters with handles or grippers for ease of handling.

Considerations for healthcare professionals

- Many factors can influence which type of intermittent catheter is most appropriate and how effective it might be.
- 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.
- More than 1 type of catheter may need to be prescribed to suit different settings and situations. Recommendation 1.4 should be considered for each type of catheter that a person needs.
- Inform people with chronic incomplete bladder emptying that there is a range of catheters available and offer them:
  - a choice of catheters
  - training on how to use each type of catheter
  - regular review of the chosen catheter's suitability, which may change over time.
- These recommendations are not intended to affect existing catheter use if the person's catheter is clinically appropriate and meets their needs. The

recommendations should be considered when people are changing catheter or reviewing their catheter use.

Information for people with chronic incomplete bladder emptying

- You should be told about the range of catheters available and given a choice of catheters that are suitable for you.
- You should be given training on how to do intermittent catheterisation.
- If catheters that you are using cause complications, such as pain or discomfort, urinary tract infection or bleeding, you should be supported to see if changing the catheter type helps.

NICE has produced tools and resources to support the implementation of this guidance.

Why the committee made these recommendations

Intermittent catheters are used for catheterisation for bladder emptying, particularly for long-term bladder management. There are many intermittent catheters available, which vary in features and cost. This assessment aims to determine whether the differences in clinical, economic and non-clinical outcomes attributed to those features could justify price variation.

There is no robust clinical evidence of the effectiveness of individual features of catheters. The available evidence also does not consistently report on the most important outcomes. Where there is limited evidence for a particular feature, there is a lack of information about how the reported outcome can be attributed to that feature. Evidence from people who use intermittent catheters for bladder drainage shows that the most important factors for them are ease and comfort of insertion and risk of infection. It also shows that their needs, preferences and experiences of using intermittent catheters vary.

There is not enough evidence to determine whether price variation between catheters with different features is justified, and more information is needed.

2 The technology

2.1 The technology identified for this assessment is single-use and sterile intermittent urethral catheters for bladder drainage. Intermittent catheters are used for catheterisation for medical bladder emptying, particularly for long-term (more than 28 days) bladder management. Intermittent catheterisation is usually done several times a day.

2.2 The NHS Supply Chain bladder and bowel framework describes an intermittent catheter as 'a smooth, flexible tube with holes, used for short term drainage of urine from the bladder and the catheter has no balloon'. Intermittent catheters can be made of different materials, are available in different sizes, and have different coatings and tips. The basic requirements of single-use and sterile catheters are detailed in the scope.

2.3 This feature-based assessment included 838 intermittent catheters, across 86 catheter product lines (aggregated by catheter size, male or female and tip type) from 17 manufacturers. Based on the NHS Drug Tariff (part IXA), the price of each catheter ranged from £0.40 to £3.28 (as of November 2024). This indicated that the maximum price difference could be £2.88 per catheter.

2.4 To determine whether pricing variation is justified, this assessment considered the following 8 additional features (detailed in the scope):

- integrated drainage bag
- integrated handle or markings
- insertion sleeve or grip
- tip protector or introducer
- microhole zone technology
- enhanced lubrication or coating (referred to here as 'enhanced coating')
- specially designed catheter case

- specially designed packaging.

3 Committee discussion

The medical technologies advisory committee considered evidence on additional features of intermittent urethral catheters for chronic incomplete bladder emptying in adults from several sources. The evidence included clinical evidence from targeted literature searches, evidence from company submissions and expert feedback. The committee also considered the economic evidence from a review of the published literature and the evidence submitted by the companies, an economic evaluation done by the external assessment group (EAG), and 3 pieces of user-centred work. Full details are available in the project documents for this guidance.

The condition

3.1 Chronic incomplete bladder emptying can be caused by neurological or non-neurological conditions. People with this condition need to use intermittent catheters for long-term bladder management.

Current practice

3.2 NICE's guideline on the management of lower urinary tract symptoms in men recommends that intermittent catheterisation should be offered for bladder drainage before indwelling urethral or suprapubic catheterisation.

3.3 Intermittent catheterisation can be done by adults of any age. The Royal College of Nursing's 2021 guidance on catheter care recommends that people who do catheterisations should be educated about and trained in the procedure. It also recommends that training should be provided by a healthcare professional who is competent in providing training. The European Association of Urology Nurses' guideline on urethral intermittent catheterisation recommends follow-up training and ongoing support. The frequency of doing intermittent catheterisations varies depending on the person's presenting symptoms. The frequency should be reviewed regularly, as symptoms can improve or deteriorate depending on the person's circumstances. But, there can be variation in the quality of training, support offered and review provided.

User experiences, needs and preferences

3.4 The patient experts talked about their experiences of using intermittent catheters for bladder drainage and the challenges they faced. They felt that doing intermittent catheterisation is a lifestyle change. They also explained their needs and highlighted the importance of choice and informed decision making. The patient experts emphasised the need to adhere to catheterisation to prevent infection, and the importance of comfort during catheterisation, from insertion to removal.

3.5 User-centred work by NICE included a thematic review of the literature, a user preference assessment and an online survey. This user-centred work suggested that people's needs, preferences and experiences of using intermittent catheters varied. The most common factors that people consider important when selecting catheters are ease and comfort of insertion, and risk of infection. Different catheters need to be available to suit people's lifestyles and meet their needs across a range of situations and settings. Some people were concerned about the environmental impact of catheters and sustainability. People face various challenges and are more likely to have difficulties when using a catheter away from their home. Shared decision making is important when choosing catheters, but in practice choice is not always available.

3.6 The committee discussed the evidence from the user-centred work. It acknowledged the various needs of people in different settings and situations, and highlighted the importance of shared decision making. The clinical and patient experts agreed it was important to empower people and offer them a choice based on their needs, and for healthcare professionals and people using the intermittent catheters to be aware of the range of catheters available. The clinical experts highlighted that regular review of catheter suitability is key to ensuring that the catheters used are the most appropriate and meet people's needs and preferences. But, in practice there can be variation in the regular review offered. Overall, the committee noted that the user preference assessment lacked data on the preferences of people with mobility issues.

Equality considerations

3.7 The needs of people with chronic incomplete bladder emptying vary from person to person. Additional support or adaptations may be needed to enable people who would otherwise not benefit from intermittent catheterisation to use this procedure. For example, people with mobility issues might benefit from using catheters that have an integrated bag or can be connected to an external collection bag. People should be made aware of, and have access to, a range of intermittent catheters that meet different needs. The most suitable catheter may change over time, so catheter suitability needs to be regularly reviewed. The committee noted that there was no evidence of the clinical benefit of an integrated bag feature, but it agreed that this feature might be needed for specific groups or people in specific situations.

Clinical effectiveness

Key evidence and feature categories

3.8 The clinical review included 18 comparative studies evaluating intermittent catheters with additional features. Across the 18 studies, from 1997 to 2024, there were 3 randomised controlled trials (RCTs), 12 crossover RCTs, 1 cross-sectional study, 1 prospective comparative cohort study, and 1 in vitro study. The follow-up durations varied across studies from 1 day to 1 year. There was variation across studies in who did the intermittent catheterisation. Most studies were company funded or included authors who were company employees.

3.9 The included evidence covered all additional features identified. There was a difference between the feature of focus (hypothesis tested) of the study and the features present within that study. Most studies aimed to compare coated and uncoated catheters. The features of the interventions and comparators varied across studies, and some studies compared more than 2 types of catheter. There was substantial variation in outcome definitions, measures and reporting.

3.10 The committee discussed the variations in features and outcomes reported across studies, and understood that there was a lack of consensus about how

features were categorised. The committee heard that there is currently no agreement or national standard on categorisation of features for intermittent catheters.

3.11 The committee recognised that some of the evidence was outdated, and might not reflect current practice.

3.12 The committee acknowledged the lack of evidence on the effectiveness of individual features. It agreed that a component network meta-analysis (CNMA) was an appropriate method to analyse the benefits of the components.

Results of the CNMA

3.13 The clinical evidence reported on 5 key outcomes, but the CNMA was feasible for 3 outcomes and isolated the effects of 4 features. When compared with a basic uncoated catheter, there was a possible reduction in urinary tract infection with enhanced coating or specially designed packaging. Microhole zone technology may reduce the risk of haematuria, defined as the presence of blood in the urine (relating only to microscopic haematuria), whereas specially designed catheter cases may increase the risk of haematuria. But the committee noted there was no information about how a specially designed catheter case could have this effect and questioned the validity of this result. It was also unclear on how enhanced coating or specially designed packaging could reduce urinary tract infection. The committee discussed the clinical importance of microscopic and macroscopic haematuria. It agreed that only macroscopic and visible haematuria should be considered clinically important. There was insufficient evidence for the other 4 features (integrated drainage bag, integrated handle or marking, insertion sleeve or grip, tip protector or introducer) to isolate their effectiveness.

3.14 The committee noted that the number of studies included in the analysis was limited because of the variation in features and outcomes reported. It also discussed the potential benefits of microhole zone technology and specially designed packaging, but the certainties were very low across all CNMA outcomes.

Alternative categorisation and updated CNMA results

3.15 The committee discussed an alternative, independent categorisation of catheter features, in particular the lubrication types (which covers integrated amphiphilic surfactant). It also considered the revised CNMA results using the alternative categorisation (detailed in the addendum). The committee noted that there was still a lack of comparative evidence for intermittent catheters and their features, and that all evidence was very uncertain. So, recategorising features did not increase the certainty around the effectiveness of individual features. The updated CNMA using the different categorisation did lead to some minor differences compared with the previous analysis. But, the committee concluded that there were no changes to the overall conclusions and a high level of uncertainty remained.

Uncertainty about the effectiveness of individual features

3.16 The committee acknowledged the lack of consensus on the feature categories, heterogeneity of the data, uncertainties of the outcomes and that some evidence was outdated. It concluded that, although there is evidence for catheters with different features, 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 catheter features. This should include the details of the features, and plausible relationships between the features and outcomes.

Cost effectiveness

Regression analysis

3.17 Catheters listed on the NHS Drug Tariff have multiple additional features and basic features. To estimate the average cost of individual features, a multiple regression model was used based on the price of 838 intermittent catheters. The model suggested that about 78% of the difference in prices could be accounted for by the basic and additional features. But, based on one-way sensitivity

analysis, the results of the regression model were sensitive to changes. The committee noted that, based on the regression analysis, not all features contributed to price variation and led to price increases. But, it 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.

Economic model structure

3.18 The EAG developed a multi-state Markov model to estimate the cost effectiveness of individual catheter features. This was informed by an economic model used in NICE's guideline on prevention and control of healthcare-associated infections. The model used a time horizon of 2 years and was restricted to people with urinary retention. The committee considered the structure of the model to be appropriate.

Model assumptions

3.19 The model assumed that people used the same type of catheter over the 2-year time horizon. The committee noted that this assumption did not reflect people's experience. The survey results showed that most people used intermittent catheters for more than 2 years and used more than 1 type of catheter. The committee understood that the model focused on features alone rather than real-world analysis, and there was very limited quality-of-life data and no long-term evidence. Sensitivity analysis showed that longer time horizons (up to a lifetime) had little impact on the direction or magnitude of effect, because most of the costs attributed to the catheter and differences in quality-adjusted life-years (QALYs) were small.

3.20 The committee discussed the use of assumptions for the quality-of-life and ease-of-use parameters. The EAG explained that there were different ways of measuring ease of use, and it was challenging to attribute it to individual features. It added that there was very limited data for quality of life, and that ease of use impacted on quality of life indirectly. The committee recognised the uncertainty in these assumptions and noted it as a limitation of the model.

3.21 The committee queried the standardised mortality ratio of 5.41 used in the model, because it was used for people recovering from spinal cord injury. But, it recognised that mortality was not a key driver for the analysis because of the model's relatively short time horizon of 2 years.

Results of the economic model

3.22 Over a 2-year time horizon, the base-case model found that 4 features (integrated handle or markings, insertion sleeve or grip, microhole zone technology, and specially designed packaging) were dominant (cost less and were more effective). The model also found that 1 feature (specially designed catheter case) was less costly and slightly less effective. But, this feature was considered cost effective at the £20,000 per QALY threshold. The cost effectiveness of enhanced coating was uncertain, and integrated drainage bag and tip protector were not considered cost effective at a £20,000 willingness-to-pay threshold. Extensive one-way sensitivity analysis did not markedly change these findings.

3.23 The committee considered the model's results and noted that all modelling was restricted to people with urinary retention. Given a lack of robust evidence and the assumptions used, the model's results were subject to parameter uncertainty. The committee concluded that the model's results needed cautious interpretation, but acknowledged that not all features correlated with price variation.

Resource impact

3.24 The committee considered a resource impact assessment (RIA) that calculated the financial impact of catheter features. The RIA used the results of the EAG's multiple regression model. The committee recalled that 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 realisable.

Justification for price variation

3.25 The committee discussed the clinical and economic evidence and the work on user preferences. It concluded that it was not possible, based on the included evidence, to determine whether the differences in costs between intermittent catheters were justified by benefits derived from additional features. It emphasised the importance of shared decision making and offering a choice of catheter, as well as having access to a range of catheters with different features, so that people with chronic incomplete bladder emptying can have the appropriate catheters in different settings and situations.

Evidence needed to show additional value

3.26 The committee concluded that more evidence is needed to justify the price variation between intermittent catheters with additional features. It acknowledged the limited evidence for the effect of individual features, and that it was unclear how particular features improved clinical outcomes and related to user needs and preferences. So, the committee noted that further evidence should include details of the features, and plausible relationships between features, reported outcomes and user preferences.

4 Committee members and NICE project team

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

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

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

Chair

Tom Clutton-Brock
Chair, interventional procedures advisory committee

NICE project team

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

Xia Li
Technical lead

Rebecca Owens
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Project manager and project coordinator

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Update information

Minor changes since publication

December 2025: Health technology evaluation 28 has been migrated to HealthTech guidance 753. The recommendations and accompanying content remain unchanged.

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