

Late-stage assessment

GID-HTE10049 Intermittent urethral catheters for long-term urinary management in adults

Final scope

1 Introduction

The topic has been identified for late-stage assessment (LSA) by NICE. LSA aims to assess technologies that are in widespread or established use in the NHS. Over time, technologies in use often undergo continuous or incremental innovation and adaptation. LSA will assess whether price variations between technologies are justified by the incremental differences and advancements, and which technologies, or features of technologies, in a category represent value for money. It will support clinical practitioners, managers and commissioners in using NHS resources as effectively as possible and ensure that patient and system benefits are maximised.

The technology identified for this assessment is intermittent urethral catheters available for use in the NHS. The assessment will evaluate the clinical and economic benefits of intermittent urethral catheters for urinary management in adults. The assessment will also address the decision question, does the value added by incremental innovation justify the price variation caused by distinguishing or innovative features? In addition, the assessment will seek to understand user views, experience, need and preference of the technology.

1.1 Population

People with medical conditions, such as bladder dysfunction, neurologic deficits, and urethral obstruction from an enlarged prostate, strictures or tumours, may experience chronic incomplete bladder emptying. When this happens, an artificial means of draining the bladder is needed. Intermittent urethral catheterisation is a procedure for bladder drainage for long-term

bladder management, and intermittent urethral catheters are used to perform this procedure. Intermittent (in/out) catheterisation is defined as drainage or aspiration of the bladder or a urinary reservoir with subsequent removal of the catheter (EAUN 2024). Intermittent catheterisation (also known as intermittent self-catheterisation or clean intermittent catheterisation) can be done by people themselves.

In the UK, more than 90,000 adults are estimated to have a urinary catheter. Although evidence of the prevalence of the use of intermittent catheters is limited, statistics show that approximately 50,000 individuals in the UK use intermittent catheters (Wilks et al. 2020). According to the Prescription Cost Analysis for England (2022), there are around 51,440 adult users of intermittent urethral catheters each year based on a mean catheter use of 4 per day. This means approximately 75 million intermittent urethral catheters are used in the NHS in England each year.

1.2 Current management

Intermittent urethral catheters, also called intermittent catheters, are used to perform intermittent catheterisation for medical bladder emptying. A catheter is passed through the channel to the bladder (urethra), and urine is drained as needed. The catheter is removed immediately after urine drainage until the next void is necessary. Intermittent catheterisation can be done several times per day.

Alternative bladder emptying methods to intermittent catheterisation are available, such as suprapubic catheterisation and indwelling urethral catheterisation. However, intermittent catheterisation should be offered for bladder drainage before indwelling urethral or suprapubic catheterisation (National Institute for Health and Care Excellence [NICE] 2015). This is because intermittent catheterisation reflects normal filling and emptying of the bladder, with a specially designed catheter. The catheter does not have a retaining balloon, or the drainage tubing and bag of a permanent catheter (Prieto et al. 2021). It helps maintain normal bladder function and protects the upper urinary tract from reflux. It has shown to reduce urinary tract infections

(UTIs) (Yates 2013; 2017), promote a 'normal' pattern of urination, and can improve independence and quality of life (Leaver 2024).

Although intermittent catheterisation has its own advantages, it does not come without its limitations and complications. The most common complication is UTIs, but when comparing with indwelling catheterisation, the risk of catheter-associated UTIs is shown to be lower (2.6 and 2.7 per person per year) because intermittent catheters pose no risk of biofilm formation due to their short time in the body (European Association of Urology Nurses [EAUN] 2024). Before commencing intermittent catheterisation, an individual's symptom severity profile, renal function, risk assessment, psychological and physical ability to perform intermittent catheterisation, and their residual urine status must be considered and assessed (NICE 2015).

Intermittent catheterisation can be done by adults of all ages (users or carers). People who perform self-catheterisation and carers should be educated about and trained in this procedure, and all training should be undertaken by a healthcare professional who is competent in providing training (Royal College of Nursing [RCN] 2021). Follow-up training and ongoing support of people who perform self-catheterisation and carers should be available to improve quality of life and prevent complications (EAUN 2024). However, there can be variation in the quality of training and support offered.

The frequency of performing intermittent catheterisation varies depending on individual's presenting symptoms. It is often recommended between 2 times and 6 times in 24 hours (typically every 4 to 6 hours) or as frequently as required to prevent urinary leakage in between catheterisations, but no more than 2 hourly (EAUN 2013). Despite that, frequency should be reviewed on a regular basis, as symptoms can improve but also deteriorate depending on individual circumstances.

Regarding catheter selection, there are many types of intermittent catheters available in NHS England, and each type has numerous variants, with each variant holding its own benefits and drawbacks. It is important to ensure that the right catheter can be used to meet individual needs. To achieve this,

catheter selection should be guided by clinical needs and personal choice (RCN 2021).

In clinical practice, intermittent catheters are often prescribed by Nurse Prescribing Teams, Continence Services, or community nurses in primary and community care, who may use local formularies if available. In secondary care, specialist nurses often prescribe intermittent catheters. After clinical assessments and consultations with healthcare professionals, people who perform self-catheterisation are often given a few samples to try and then decide which one is suitable for use. The dispensing appliance contractors also play a role in providing advice, training and ongoing support to improve the uptake of intermittent catheterisation. Currently, there is no prescribing guideline for catheter selection for both primary and secondary care.

2 Technologies

This section describes the purpose and features of intermittent urethral catheters used for urinary management in adults, as well as the NHS market based on information provided to NICE by companies and experts, and information available in the public domain.

2.1 Description of the technologies

Intermittent catheters are usually used for self-catheterisation for medical bladder emptying, in particular for long-term (more than 28 days) bladder management. Intermittent catheters are mainly single-use. Although reusable catheters (single person use) are available, these catheters are rarely used in the UK (Yates 2023).

For this assessment, NICE will consider single-use intermittent urethral catheters for bladder drainage used in adults listed on the Drug Tariff. The use of intermittent urethral catheters in children and young people (under 18s) will be excluded from this assessment. The list of technological features included in this evaluation is not exhaustive and other features may be available to the NHS currently or in the future.

2.2 Technology features

Part IXA of the [Drug Tariff](#) contains a list of intermittent catheters that have been approved by NHS Prescription Services for prescribing at NHS expense by an appropriate practitioner in primary or community care. Under the ‘catheters’ subgroup, the list of intermittent catheters captures the majority of catheter usage in the NHS. NHS Supply Chain also procures intermittent catheters for use in secondary care, but usage in hospitals is much smaller than in primary and community care. Despite that, features evaluated in this assessment would be applicable to intermittent catheters listed on the NHS Supply Chain.

Intermittent catheters have been through continuous improvement and incremental innovation over the years. The range of intermittent catheters can differ by catheter material (such as polyvinyl chloride, silicone and ethylene vinyl acetate), coating (lubricated, hydrophilic coating, and gel coating) and tip (such as rounded tip [Nelaton] and Tiemann tip), and some have other distinguishing or innovative features.

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.” The framework highlights the following essential requirements:

- catheters must be available in a range of sizes
- must have colour-coded sizes
- must be available in standard and short lengths which is displayed on packaging
- must be provided sterile.

Before catheter insertion, all the intermittent catheters need lubrication (NICE 2023; Yates 2023). Lubrication can be incorporated into the catheter device (pre-lubricated) or externally applied, such as using water/saline, gel, or a separate lubricant (EAUN 2024; Yates 2023). The purpose of using lubrication is to reduce friction and thus protect the sensitive urethral mucosa during catheter insertion and removal (EAUN 2024). In addition, NICE (2023)

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guideline on healthcare-associated infections recommends offering a choice of either single-use hydrophilic or gel reservoir catheters for intermittent catheterisation. Therefore, intermittent catheters with traditional lubrication (pre-lubricated or externally applied) or hydrophilic coated are considered one of the basic technology requirements for this assessment.

Basic technology requirements

Sterile catheters that:

- have traditional lubrication (pre-lubricated or lubrication applied externally) or hydrophilic coated
- have 2 to 4 drainage eyelets (drain holes or catheter eyes)
- are available in a range of sizes and lengths
- have Nelaton tip or other tip types
- have catheter drainage funnels or connectors
- clearly labelled sizes.

Additional features, adaptations, and potential innovations

Additional features, adaptations and potential innovations include, but not limited to:

- Integrated drainage bag
- Integrated handle or markings
- Insertion sleeve or grip
- Tip protector or introducer
- Micro-hole zone technology
- Enhanced lubrication or coating technology (such as multi-layer coating and hydrophilic integrated amphiphilic surfactant)
- Specially designed catheter case (such as hard case, compact design, telescopic catheter, and resealable case)
- Specially designed packaging (such as ring pull and flip top).

It is important to note that the features and potential innovations are listed in this section are not exhaustive and other distinguishing or innovative features are available.

2.3 Current NHS market for the technologies

In primary and community care, intermittent urethral catheters are supplied using an NHS prescription for technologies listed in Part IXA of the [Drug Tariff](#) under the 'catheters' subgroup (substance code of '2102'). In secondary care, intermittent catheters are purchased through NHS Supply Chain or in some instances provided to hospitals free of charge by dispensing appliance contractors or companies.

It is indicated that 1.5 million prescriptions were issued in England in 2021 at a cost of £145.8 million (Bladder Interest Group 2021). However, this figure covers both intermittent catheters and indwelling catheters, without a distinction being made. Prescription Cost Analysis (PCA) for England (2017, 2022) indicates that costs to the NHS for intermittent catheters in the community rose from around £120 million in 2017 to about £165 million in 2022. In secondary care, costs for intermittent catheters are much smaller.

Currently, there are 20 companies listed as supplying 'intermittent catheters' in Part IXA of the Drug Tariff. They supply approximately 1,130 items listed on the Drug Tariff, with most catheters used in adults. The majority of the market share come from only a small number of these companies (PCA 2022).

Across all the intermittent catheters used for adults listed on the Drug Tariff, the prices range from £0.40 to £3.23 per catheter, with a mean of £2.20 per catheter (including features).

2.4 Technology user issues and preferences

Given the large number of catheters available in the market, the majority of people who perform self-catheterisation do not have a breadth knowledge of catheters, so they are often given a few samples to try and then decide which one is suitable after clinical assessments and consultations with healthcare

professionals. When deciding on which catheter to use, it is important to consider the person's preference and clinical needs (RCN 2021; EAUN 2024).

Intermittent catheterisation is usually considered the 'gold standard' for incomplete bladder emptying (RCN 2021), adherence plays a key role for ensuring good clinical outcome of the intermittent catheterisation therapy. However, not all individuals adopt and adhere to intermittent catheterisation in the long term (Herbert 2023). Barriers for practicing intermittent catheterisation can be both internal and external. Internal factors include physical disabilities and psychological barriers. The former covers difficulty positioning to insert the catheter, problems with dexterity, visual impairment, anatomical reasons, and cognitive impairment. The latter includes misconceptions and anxiety, embarrassment and poor confidence, stigma and fears (Seth et al. 2014; Yates 2023). External factors cover, but are not limited to, the following aspects:

- lack of access to public toilets
- inadequate facilities in public toilets
- availability of appropriate catheters and assistance appliances
- quality of teaching and the training environment
- community follow-up access to help or advice
- availability of experienced nurse specialists (Herbert et al. 2023; Seth et al. 2014).

Hence, it is important to educate and instruct people who perform self-catheterisation and carers appropriately while encouraging them to comply with intermittent catheterisation. Also, any internal or external factors that might affect the person's adherence of intermittent catheterisation should be taken into account when choosing the appropriate catheter. Furthermore, it is worth considering the following suggestions for improving adherence:

- adequate instructions with a healthcare professional with experience in teaching intermittent catheterisation

- seeking advice for managing anatomical obstructions or other conditions
- use of catheter appliances to help locate the urethra
- ensuring regular follow ups when needed
- engaging with carer or partner when appropriate
- access to locked disabled toilets or smartphone app to help locate toilet facilities (Seth et al. 2014).

If this is done correctly, intermittent catheterisation should improve bladder dysfunctions and quality of life (Yates 2023), even with the complications outlined.

3 Decision problem

Population	Adults (18 and over) with chronic incomplete bladder emptying using intermittent urethral catheters to perform catheterisation for bladder drainage.
Subgroups	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> • by gender • people needing life-long intermittent catheterisation • people with UTIs or being significantly vulnerable to UTIs (e.g. people with renal transplant) • people with mobility or cognitive impairment • intermittent catheterisation done by carers or others rather than people who perform self-catheterisation themselves
Intervention	<p>Intermittent urethral catheters, that are single-use and sterile, with:</p> <ul style="list-style-type: none"> • traditional lubrication (pre-lubricated or externally applied), hydrophilic coated, or enhanced lubrication or coating technology • other basic requirements • one or more additional or innovative features (see section 2.2) <p>Please note the additional or innovative features listed in section 2.2 are not exhaustive, and others are available and will be addressed in the assessment.</p>

Comparator(s)	Intermittent urethral catheters, that are single-use and sterile, with traditional lubrication (pre-lubricated or externally applied) or hydrophilic coated and other basic requirements, but without any additional or innovative features (see section 2.2).
Healthcare setting	Primary and community care
Outcomes	<p>Outcome measures for consideration may include but are not limited to:</p> <p>Intermediate outcomes</p> <ul style="list-style-type: none"> • successful drainage, e.g. post-void residual volume • frequency of use per day <p>Clinical outcomes</p> <ul style="list-style-type: none"> • UTIs and recurrent UTIs, <ul style="list-style-type: none"> ○ catheter-associated UTIs • sepsis • urethral trauma, bleeding, haematuria, strictures and urethritis • bladder or kidney stones • other device-related adverse events, e.g. retained fragment • hospitalisation <p>Patient reported outcomes</p> <ul style="list-style-type: none"> • adherence and compliance rate • comfort and ease of use • satisfaction • preference • health-related quality of life <p>Costs and resource use</p> <ul style="list-style-type: none"> • cost of the technology and supporting products • costs of medicines • costs of other resource use including: <ul style="list-style-type: none"> ○ healthcare professional appointments or visits ○ costs associated with managing catheter-associated complications ○ hospital admissions ○ staff time: such as training people who perform self-catheterisation or carers to do intermittent catheterisation <p>User views, experience, need and preference will be captured to understand the features of the technology that</p>

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

Please note that, in the assessment, comparison can be made between innovative features within the intervention if needed, in addition to comparing intervention with comparator. If appropriate, subcategories of comparing intervention with comparator can be presented, e.g. enhanced coating technology vs traditional lubrication, enhanced coating technology vs hydrophilic PVP coated.

3.1 Potential equality issues or considerations

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

Additional support or adaptations should be provided if needed to enable people who would otherwise not benefit from intermittent catheterisation to use this procedure. Also, the availability of different catheter designs and assistant appliances should be considered to meet different user needs in order to enable people to perform intermittent catheterisation.

Religious or cultural beliefs may also play a role in the uptake of intermittent catheterisation, and these need to be taken into account (EAUN 2013; Yates 2023).

People who experience chronic incomplete bladder emptying may have an underlying condition such as cancer or neurologic deficits. People who have

been diagnosed with cancer or neurological conditions may be considered disabled under the Equality Act (2010).

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

4 Stakeholders

4.1 Healthcare professional organisations

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

- Association for Continence Professionals
- Association of Chartered Physiotherapists in Neurology
- Association of Physicians' Assistants
- British Association of Urological Nurses
- British Association of Urological Surgeons
- British Infection Association
- British Nursing Association
- British Society of Urogynaecology
- Community District Nurses Association
- Infection Prevention Society
- National Association of Primary Care
- Royal British Nurses' Association
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Physicians
- Royal College of Surgeons of England

- Society of British Neurological Surgeons
- UK Kidney Association

4.2 Patient and carer organisations

NICE's [Public Involvement Programme](#) have identified the following patient and carer organisations for advice:

- Action Bladder Cancer UK
- Bladder and Bowel Community
- Bladder and Bowel UK
- Bladder Health UK
- Brain and Spine Foundation (UK)
- Chronic UTI Global Support
- Fight Bladder Cancer
- Kidney Cancer UK
- Kidney Care UK
- Kidney Research UK
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- National Kidney Federation
- Prostate Cancer UK
- Spinal Injuries Association
- Urology Foundation
- Urostomy Association
- WellBeing of Women
- Women's Health Concern

4.3 Additional non-clinical professional organisations

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

- Association of British HealthTech Industries (ABHI)
- Absorbent Hygiene Products Manufacturers Association (AHPMA)
- British Healthcare Trades Association (BHTA)
- British Services Authority (BSA)
- British Urology Trade Association (BUTA)
- NHS Supply Chain (NHSSC)

5 Authors

Topic lead: **Xia Li, Analyst**

Topic advisers: **Lizzy Latimer, Associate Director; Rebecca Owens, Technical Adviser**

Project manager: **Deonee Stanislaus, Project Manager**

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Appendix A Related NICE Guidance

- **Related Medical Technologies Guidance:**

[UroShield for preventing catheter-associated urinary tract infections](#)

(2022). NICE medical technologies guidance 69.

[Axonics sacral neuromodulation system for treating refractory overactive bladder](#) (2020). NICE medical technologies guidance 50.

- **Related Guidelines:**

[Urinary incontinence in neurological disease: assessment and management](#) (2023). NICE guideline CG148. Last updated October 2023

[Pelvic floor dysfunction: prevention and non-surgical management](#) (2021). NICE guideline NG210.

[Urinary incontinence and pelvic organ prolapse in women: management](#) (2019). NICE guideline NG123.

[Urinary tract infection \(catheter-associated\): antimicrobial prescribing](#) (2018). NICE guideline NG113.

[Healthcare-associated infections: prevention and control in primary and community care](#) (2017). NICE guideline CG139.

[Lower urinary tract symptoms in men: management](#) (2015). NICE guideline CG97

- **Related Interventional Procedures:**

[Transcutaneous electrical neuromuscular stimulation for urinary incontinence](#) (2022). NICE interventional procedures guidance 735

[Transvaginal laser therapy for stress urinary incontinence](#) (2021). NICE interventional procedures guidance 696

[Extraurethral \(non-circumferential\) retropubic adjustable compression devices for stress urinary incontinence in women](#) (2017). NICE interventional procedures guidance 576

[Single-incision short sling mesh insertion for stress urinary incontinence in women](#) (2016). NICE interventional procedures guidance 566

[Intramural urethral bulking procedures for stress urinary incontinence in women](#) (2005). NICE interventional procedures guidance 138

[Sacral nerve stimulation for urge incontinence and urgency-frequency](#) (2004). NICE interventional procedures guidance 64

- **Related Quality Standards:**

[Urinary incontinence in women](#) (2021). NICE quality standard 77. Last updated December 2021

[Lower urinary tract symptoms in men](#) (2013). NICE quality standard 45

Appendix B Abbreviations

EAUN	European Association of Urology Nurses
IC	Intermittent catheterisation
LSA	Late-stage assessment
NICE	National Institute for Health and Care Excellence
PCA	Prescription Cost Analysis
RCN	Royal College of Nursing
UTI	Urinary tract infection