1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline scope
4 5	Lower urinary tract symptoms in men and other people with a prostate: assessment and management (update)
6 7	This guideline will update the NICE guideline on lower urinary tract symptoms in men: management (CG97).
8 9	The guideline will be developed using the methods and processes outlined in developing NICE guidelines: the manual.
10 11	This guideline will also be used to update the <u>NICE quality standard</u> for lower urinary tract symptoms in men (QS45).
12	1 Why the update is needed
13 14 15 16	New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the surveillance review decision .
17 18 19 20 21	The update will include newer surgical treatments and minimally invasive alternative procedures to manage lower urinary tract symptoms (LUTS) caused by benign prostatic enlargement (BPE) in people with a prostate. The update will also consider specialist assessment with urodynamic investigations and developments in drug treatments for managing LUTS.
22	Why the guideline is needed
23	Key facts and figures
242526	LUTS comprise storage, voiding and post-micturition symptoms affecting the lower urinary tract. Storage symptoms include urgency, frequency, urgency incontinence and nocturia. Voiding symptoms include weak or intermittent urinary stream,
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- 1 straining, hesitancy, terminal dribbling and incomplete emptying. Post-micturition
- 2 dribbling is a common post-micturition symptom. In people with a prostate the most
- 3 common cause is BPE, which obstructs the bladder outlet. BPE happens when the
- 4 number of cells in the prostate increases, a condition called benign prostatic
- 5 hyperplasia. Other conditions that can cause LUTS include detrusor muscle
- 6 weakness or overactivity, prostate inflammation (prostatitis), urinary tract infection,
- 7 prostate cancer and neurological disease.
- 8 Age is an important risk factor for LUTS and the prevalence of LUTS increases with
- 9 age. Bothersome LUTS can occur in up to 30% of people with a prostate older than
- 10 65 years and this is a large group potentially needing treatment. Although LUTS do
- 11 not usually cause severe illness they can have a major impact on the quality of life of
- the person and their partners, and may point to serious pathology of the urogenital
- 13 tract.

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Current practice

- 15 Voiding LUTS secondary to BPE is usually managed by drug treatment followed by
- surgery. Surgery may involve transurethral resection of the prostate (TURP),
- 17 transurethral vaporisation of the prostate (TUVP) or laser endoscopic enucleation of
- 18 the prostate with techniques such as HoLEP. New surgical techniques including
- 19 Urolift, and other methods using steam (Rezum) or laser vaporisation (GreenLight)
- 20 have been developed and are used in some centres but their place in therapy is not
- 21 included in the current NICE guideline.
- 22 In addition, some pharmacological therapies, including the use of combination drug
- 23 treatment for overactive bladder is not covered by the current NICE guideline. There
- 24 may also be newly recognised risks with anticholinergics, which are not described in
- 25 the current NICE guideline.

Policy, legislation, regulation and commissioning

- With a documented reluctance to come forward for medical treatment, many people
- 28 may have LUTS but see it as a normal part of the ageing process so may not seek
- 29 help, despite the adverse effect on their quality of life. There is currently no national

- 1 strategy but the availability of more successful and less invasive treatments may
- 2 encourage more people to request help and treatment for their symptoms.
- 3 There is currently a wide variation in the commissioning of LUTS procedures across
- 4 England, with variation in procedures for LUTS, and unequal provision across the
- 5 country of newer treatments such as Urolift and Rezum, with some centres already
- 6 adopting them and others restricting treatment to TURP, TUVP or HoLEP only.

7 2 Who the guideline is for

- 8 This guideline is for:
- healthcare professionals in primary, secondary or tertiary care who treat people
- 10 with a prostate who have LUTS
- commissioners and providers of NHS healthcare services for people with a
- 12 prostate who have LUTS
- people with a prostate who have suspected or diagnosed LUTS, their families and
- 14 carers and the public.
- NICE guidelines cover health and care in England. Decisions on how they apply in
- other UK countries are made by ministers in the Welsh Government, Scottish
- 17 Government and Northern Ireland Executive.

18 **Equality considerations**

- 19 NICE has carried out an equality impact assessment during scoping. The
- 20 assessment:
- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.
- 23 The guideline will look at inequalities relating to age, disability, gender reassignment,
- sex and people in under-served groups.

1 3 What the updated guideline will cover

2 3.1 Who is the focus?

3 Groups that will be covered

- Men and other people with a prostate (such as trans women and non-binary
- 5 people), aged 18 or older, with a clinical working diagnosis of LUTS.
- 6 No specific subgroups of people have been identified as needing specific
- 7 consideration.

8 3.2 Settings

9 Settings that will be covered

- The guideline will cover all settings where NHS-commissioned treatment for LUTS
- in people with a prostate is provided, including primary, secondary and tertiary
- 12 care.

13 3.3 Activities, services or aspects of care

14 Key areas that will be covered in this update

- We will look at evidence in the areas below when developing this update. We will
- 16 consider making new recommendations or updating existing recommendations in
- 17 these areas only.
- 18 1 Specialist assessment.
- 19 2 Drug treatment.
- 20 3 Surgery for voiding symptoms.
- 21 Note that guideline recommendations for medicines will normally fall within licensed
- 22 indications; exceptionally, and only if clearly supported by evidence, use outside a
- 23 licensed indication may be recommended. The guideline will assume that prescribers
- 24 will use a medicine's summary of product characteristics to inform decisions made
- with individual patients.

1 Proposed outline for the guideline

- 2 The table below outlines all the areas that will be included in the guideline. It sets out
- 3 what NICE plans to do for each area in this update.

4 Proposed outline for the guideline

Area of care	What NICE plans to do
1.1 Initial assessment	No evidence review: retain recommendations from existing guideline
1.2 Specialist assessment	Review evidence: update existing recommendations as needed
1.3 Conservative management	No evidence review: retain recommendations from existing guideline
1.4 Drug treatment	Review evidence on phosphodiesterase- 5 inhibitors and anticholinergics combined with beta-3 agonists: update existing recommendations as needed
	Cognitive function: The committee will discuss cognitive decline due to anticholinergics and review the relevant recommendations from the NICE guideline on urinary incontinence in women: update existing recommendations as needed
1.5 Surgery for voiding symptoms	Review evidence: update existing recommendations as needed
1.6 Surgery for storage symptoms	No evidence review: retain recommendations from existing guideline
1.7 Treating urinary retention	No evidence review: retain recommendations from existing guideline
1.8 Alternative and complementary therapies	No evidence review: retain recommendations from existing guideline
1.9 Providing information	No evidence review: retain recommendations from existing guideline

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Recommendations in areas that are being retained from the existing guideline may

7 be edited to ensure that they meet current editorial standards, and reflect the current

8 policy and practice context.

Related NICE guidance

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- Transcutaneous electrical neuromuscular stimulation for urinary incontinence
- 4 (2022) NICE interventional procedures guidance 735
- UroShield for preventing catheter-associated urinary tract infections (2022) NICE
- 6 medical technologies guidance 69
- Axonics sacral neuromodulation system for treating refractory overactive
- 8 <u>bladder</u> (2020) NICE medical technologies guidance 50
- Prostatitis (acute): antimicrobial prescribing (2018) NICE guideline NG110
- Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention
- 11 (2015) NICE interventional procedures guidance 536 (currently being updated,
- 12 publication date to be confirmed)
- Mirabegron for treating symptoms of overactive bladder (2013) NICE technology
- 14 appraisal guidance 290. This guideline will be updated with a cross-reference to
- the NICE technology appraisal guidance on mirabegron.
- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome
- 17 (2010) NICE interventional procedures guidance 362
- Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE
- 19 interventional procedures guidance 326
- Sacral nerve stimulation for urge incontinence and urgency-frequency (2004)
- 21 NICE interventional procedures guidance 64

22 In development

- Urinary tract infections in adults (update) NICE quality standard. Publication
- 24 expected February 2023.
- Botulinum toxin injection into the urethral sphincter for idiopathic chronic non-
- 26 <u>obstructive urinary retention NICE interventional procedures guidance. Publication</u>
- expected May 2023.

1	NICE guidance	that will be t	taken into accour	nt during the	auideline u	ıpdate
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- Prostatic urethral temporary implant insertion for lower urinary tract symptoms
- 3 <u>caused by benign prostatic hyperplasia</u> (2022) NICE interventional procedures
- 4 guidance 737
- 5 The PLASMA system for transurethral resection and haemostasis of the
- 6 prostate (2021) NICE medical technologies guidance 53
- 7 <u>UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia</u>
- 8 (2021) NICE medical technologies guidance 58
- Rezum for treating lower urinary tract symptoms secondary to benign prostatic
- 10 <u>hyperplasia</u> (2020) NICE medical technologies guidance 49
- Transurethral water jet ablation for lower urinary tract symptoms caused by benign
- 12 prostatic hyperplasia (2018) NICE interventional procedures guidance 629
- 13 (currently being updated, publication expected September 2023)
- Transurethral water vapour ablation for lower urinary tract symptoms caused by
- benign prostatic hyperplasia (2018) NICE interventional procedures guidance 625
- Prostate artery embolisation for lower urinary tract symptoms caused by benign
- 17 prostatic hyperplasia (2018) NICE interventional procedures guidance 611
- GreenLight XPS for treating benign prostatic hyperplasia (2016) NICE medical
- technologies guidance 29 (currently being updated, publication expected
- 20 November 2022)
- Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms
- 22 secondary to benign prostatic hyperplasia (2014) NICE interventional procedures
- 23 guidance 475
- Laparoscopic prostatectomy for benign prostatic obstruction (2008) NICE
- 25 interventional procedures guidance 275
- Holmium laser prostatectomy (2003) NICE interventional procedures guidance 17
- Transurethral electrovaporisation of the prostate (2003) NICE interventional
- 28 procedures guidance 14

29 NICE guidance about the experience of people using NHS services

- 30 NICE has produced the following guidance on the experience of people using the
- 31 NHS. This guideline will not include additional recommendations on these topics

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1		there are specific issues related to lower urinary tract symptoms in men and
2	other p	eople with a prostate:
3	• Sha	red decision making (2021) NICE guideline NG197
4	• <u>Med</u>	icines optimisation (2015) NICE guideline NG5
5	• Patie	ent experience in adult NHS services (2012) NICE guideline CG138
6	• Serv	rice user experience in adult mental health (2011) NICE guideline CG136
7	• <u>Med</u>	icines adherence (2009) NICE guideline CG76
8	3.4	Economic aspects
9	We will	take economic aspects into account when making recommendations. We will
10	develo	o an economic plan that states for each review question (or key area in the
11	scope)	whether economic considerations are relevant, and if so whether this is an
12	area th	at should be prioritised for economic modelling and analysis. We will review
13	the ecc	nomic evidence and carry out economic analyses, using an NHS and
14	person	al social services (PSS) perspective, as appropriate.
15	3.5	Key issues and draft questions
16	While w	vriting the scope for this updated guideline, we have identified the following
17	key iss	ues and draft questions related to them:
18	1 S	pecialist assessment
19		1.1 What is the effectiveness and cost-effectiveness of urodynamic
20		investigations in the diagnosis of bladder outlet obstruction or weakness
21		for people with a prostate who have LUTS?
22	2 D	rug treatment
23		2.1 What is the effectiveness and cost-effectiveness of
24		phosphodiesterase-5 inhibitors for the treatment of LUTS secondary to
25		BPE?

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people with a prostate?

2.2 What is the effectiveness and cost-effectiveness of anticholinergics

combined with beta-3 agonists for the treatment of overactive bladder in

1 3 Surgery for voiding sympto	oms
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- 2 3.1 What is the effectiveness and cost-effectiveness of surgical treatments
- 3 (for example, transurethral resection of the prostate, laser endoscopic
- 4 enucleation of the prostate or steam vapour treatment) for the treatment of
- 5 LUTS secondary to BPE?
- 6 The key issues and draft questions will be used to develop more detailed review
- 7 questions, which guide the systematic review of the literature.

8 3.6 Main outcomes

- 9 The main outcomes that may be considered when searching for and assessing the
- 10 evidence are:
- validated measures of LUTS (for example, International Prostate Symptom Score
- 12 [IPSS])
- incontinence episodes
- urinary flow measurements (for example, average flow, voided volume, voided
- time, maximum urinary flow rate, Qmax)
- side effects and adverse events (for example, erectile and ejaculatory dysfunction,
- decreased libido, gynaecomastia, antimuscarinic side-effects)
- 18 length of hospital stay
- 19 re-operation rate
- health-related quality of life.

21 4 NICE quality standards

- 22 NICE quality standards that may need to be revised or updated when this
- 23 guideline is published
- Lower urinary tract symptoms in men (2013) NICE quality standard 45

1 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 1 November to 29 November 2022.

The guideline is expected to be published in March 2024.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.

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