

# Clinical Commissioning Policy

# CMICB\_Clin107

Benign prostatic hyperplasia-related bladder outlet obstruction, surgical

referral

Category 2 Intervention - Only routinely commissioned when specific criteria are met

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## Last Reviewed: May 2025

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

# 1. Policy statement

- 1.1 Referral for surgery in adult men with benign prostatic hyperplasia-related bladder outlet obstruction will routinely be commissioned in patients who:
- a)
- have not had a satisfactory response to conservative measures and pharmacological treatments and continue to exhibit bothersome symptoms or
- are experiencing intolerable side effects which are impacting on quality of life **OR**
- OF
- b) who exhibit one or more of the following:
  - renal insufficiency or
  - hydronephrosis or
  - recurrent UTIs or
  - refractory urinary retention or
  - recalcitrant gross haematuria or
  - overflow incontinence or
  - recurrent bladder stones

#### AND

1.2 It is expected that the chosen surgical technique will be driven by the clinical presentation, the patient's expectations and preferences, local availability of equipment, expertise and following a joint decision-making discussion between the patient and surgeon.

## 2. Exclusions

2.1 None

# 3. Core Eligibility Criteria

- 3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.
- 3.2 These core clinical eligibility criteria are as follows:
  - Any patient who needs 'urgent' treatment will always be treated.
  - All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
  - In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
    NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
  - Reconstructive surgery post cancer or trauma including burns.
  - Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
  - Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
  - For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the <u>NHS England gender</u>

services programme - https://www.england.nhs.uk/commissioning/spec-services/npccrg/gender-dysphoria-clinical-programme/

# 4. Rationale behind the policy statement

- 4.1 The evidence accompanying the current Cheshire CCG policy is old (at least 12 years) and the inclusion criteria in the policy statement are not supported by any of the references.
- 4.2 The new developed inclusion criteria take into account the EBI list 2 (2020) recommendations but are principally based on more recent evidence from Europe (2022) and USA (2021).

## 5. Summary of evidence review and references

- 5.1 Lower urinary tract symptoms (LUTS) are a common complaint in adult men and can have a major impact on quality-of-life. They are divided into problems with urinary storage or voiding and post micturition symptoms. The most common conditions which cause LUTS include urinary retention, over/under activity of the bladder muscles and bladder outlet obstruction.<sup>1</sup> Although not always due to this, a frequent cause of bladder outlet obstruction is benign prostatic hyperplasia (BPH).
- 5.2 This is a condition where the cells in the prostate gland (a walnut -sized organ in men, located below the urinary bladder, encircling the urethra )<sup>2</sup> multiply resulting in prostate enlargement, constriction of the urethra and resultant outflow obstruction. Strictly speaking, BPH is an histological diagnosis which may cause prostatic enlargement which may (or may not) cause urinary outflow obstruction.<sup>3</sup> The more up-to-date term to describe this condition is benign prostatic obstruction (BPO).
- 5.3 Voiding symptoms include weak or intermittent urinary stream, straining, hesitancy, terminal dribbling and incomplete emptying. Storage symptoms include urgency, frequency, urgency incontinence and nocturia. The major post-micturition symptom is dribbling. <sup>4</sup> Although BPH (by definition) is "benign", carcinoma of the prostate is always a concern. The prevalence of moderate severe LUTS increases with age and has been reported to occur in 26% of men in their 60s and up to 46% of men in their 90s.<sup>3,4</sup> BPH is said to occur in 50% of men aged 50 years and older.<sup>5</sup>
- 5.4 Initial management of LUTS involves conservative treatment which includes watchful waiting, behavioural and dietary modifications, and pharmacological management.<sup>1</sup> When surgery is indicated, a wide variety of options is available. Published in 2021, a UK audit of surgery for bladder outlet obstruction found that the most common forms of surgery at that time were bipolar TURP (38%), monopolar TURP (23%) and other minimally invasive procedures (17%).<sup>6</sup> In terms of adverse events, the survey revealed that 5% of men had complications within 30 days of surgery with <1% receiving a blood transfusion and 2% being readmitted.</p>
- 5.5 A more comprehensive list <sup>3,7-9</sup> of surgical options includes:-
  - Transurethral Resection of the Prostate (TURP),
  - Simple prostatectomy,
  - Transurethral Incision of the Prostate (TUIP),
  - Transurethral Vaporisation of the Prostate (TUVP),
  - Photoselective Vaporisation of the Prostate (PVP),
  - Prostatic Urethral Lift (PUL),
  - Transurethral Microwave Therapy (TUMT),
  - Water Vapour Thermal Therapy (WVDT),
  - Transurethral Needle Ablation (TUNA) and
  - Holmium Laser Enucleation of the Prostate (HoLEP).

- 5.6 With the increasing popularity of minimally invasive techniques, the Cochrane database have recently performed a systematic review to assess the comparative effectiveness of these techniques. The review found that these treatments may result in similar or worse effects compared to TURP in the short term. They may also result in fewer major adverse events. However, the main conclusion was future high quality studies with extended follow-up and improved trial quality are required to provide more information on the relative effectiveness of these interventions.<sup>2</sup>
- 5.7 Collectively, these treatments vary in their intensity, need for anaesthesia, risk of morbidity, potential functional outcomes, durability, effect on patients' quality-of-life and accessibility. Unsurprisingly, this growing armamentarium may be overwhelming, challenging and time-consuming for both patients and urologists to ensure patients make the most appropriate choice. To this end, an online patient decision aid has been developed.<sup>5</sup>
- 5.8 In addition, surveys have shown that men generally prefer lower risk management options with fewer associated sexual side effects and good efficacy at improving urgency incontinence and nocturia.<sup>10</sup>
- 5.9 The indications for men who might benefit from surgery have been developed over the years. A 2013 guide from the Royal College of Surgeons suggested that men with severe symptoms or where conservative management or drug treatment has failed should be eligible for surgery.<sup>11</sup> The most up-to-date and perhaps the most authoritative guideline was published in 2022 by the European Association of Urology (EAU).<sup>1</sup> In those patients who have failed conservative and/or pharmacological therapies, the EAU lists the surgical indications:-
  - recurrent or refractory urinary retention,
  - overflow incontinence,
  - recurrent UTIs,
  - bladder stones or diverticula,
  - treatment resistant macroscopic haematuria or
  - renal insufficiency.
- 5.10 The American Urological Association (AUA) suggested that surgery may be appropriate in men who wish to avoid taking daily medication or are suffering intolerable side effects or in whom medical therapy has failed.<sup>3,7</sup> The AUA also provide a similar list of indications to the above which include:-
  - renal insufficiency (acute and/or chronic),
  - refractory urinary retention,
  - recurrent UTIs,
  - recurrent bladder stones and
  - recalcitrant gross haematuria.
- 5.11 Similar indications for surgery have previously been proposed by the urological associations in Japan<sup>12</sup> and Canada.<sup>13</sup>
- 5.12 Finally, the Academy of Medical Royal Colleges (AMRC) have produced guidance (2020) on surgical intervention for benign prostatic hyperplasia. This is located in the Evidence-Based Interventions (EBI) List 2 guidance <sup>14</sup> i.e. the EBI programme (originally initiated by NHS England). This guidance briefly describes various surgical procedures for benign enlargement of the prostate and suggests that men with severe symptoms, in whom, conservative management or drug treatment have been unsuccessful, and with chronic urinary retention, renal impairment, UTIs or bladder stones should be considered for surgery using a shared decision-making approach. This guideline heavily relies on NICE CG 97 <sup>4</sup> which was written 12 years ago.

- 5.13 *In summary*, benign prostatic hyperplasia (BPH) is an extremely common presentation of lower urinary tract symptoms (LUTS) in men which can have a major impact on their quality-of-life. Moderate severe symptoms can usually be controlled by a combination of conservative measures and pharmacological management. When these fail, surgical intervention may be necessary.
- 5.14 Although transurethral resection of prostate (TURP) has remained the gold standard for many years, there are several other techniques which are now available, each one with its own particular advantages and drawbacks. Selection of the most appropriate technique will depend on the clinical presentation, the man's individual preferences and expectations, the skill of the urologist and following an informed discussion between patient and surgeon.
- 5.15 When conservative and other measures have failed and symptoms persist, surgery is likely to be indicated in patients with refractory urinary retention, recurrent UTIs, recurrent bladder stones, renal insufficiency or resistant haematuria. Most of the neighbouring CCGs have no policy at all or are similar to the current Cheshire policy (i.e. Mersey & North Staffordshire).

#### REFERENCES

- 1. EAU guidelines on management of non-neurogenic male lower urinary tract symptoms (L UTS), including benign prostatic obstruction (BPO). Arnhem, The Netherlands: European Association of Urology, 2022:112.
- 2. Franco JVA, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benign prostatic hyperplasia: a network meta-analysis. *Cochrane Database of Systematic Reviews* 2021(7) doi: 10.1002/14651858.CD013656.pub2
- 3. Dornbier R, Pahouja G, Branch J, et al. The New American Urological Association Benign Prostatic Hyperplasia Clinical Guidelines: 2019 Update. *Current Urology Reports* 2020;**21**(9):32. doi: <u>https://dx.doi.org/10.1007/s11934-020-00985-0</u>
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- 11. Commissioning guide: lower urinary tract symptoms. *Royal College of Surgeons of England* (*RCS*) 2013
- 12. Homma Y, Gotoh M, Kawauchi A, et al. Clinical guidelines for male lower urinary tract symptoms and benign prostatic hyperplasia. *Int J Urol* 2017;**24**(10):716-29. doi: <a href="https://dx.doi.org/10.1111/iju.13401">https://dx.doi.org/10.1111/iju.13401</a>

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- 13. Canadian Urological Association guideline on male lower urinary tract symptoms/benign prostatic hyperplasia (MLUTS/BPH) : 2018 update. *Canadian Urological Association* 2018
- 14. Evidence-based interventions: List 2 guidance. London: Academy of medical Royal colleges, 2020:156.

## 6. Advice and Guidance

#### 6.1 Aim and Objectives

- 6.1.1 This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.
- 6.1.2 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- 6.1.3 This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.
- 6.1.4 At the time of publication, the evidence presented per procedure/treatment was the most current available.
- 6.1.5 The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - · Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.
- 6.1.6 Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

#### 6.2 Core Principles

- 6.2.1 Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:
  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
  - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

#### 6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- 6.3.1 If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.
- 6.3.2 The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: <u>https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-</u> <u>ifr/</u>

#### 6.4 Cosmetic Surgery

- 6.4.1 Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.
- 6.4.2 Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.
- 6.4.3 A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: <u>Cosmetic procedures - NHS</u>

#### 6.5 Diagnostic Procedures

- 6.5.1 Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.
- 6.5.2 Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

#### 6.6 Clinical Trials

6.6.1 The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

## 7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

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- 7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.
- 7.3 This policy may be subject to continued monitoring using a mix of the following approaches:Prior approval process
  - Post activity monitoring through routine data
  - Post activity monitoring through case note audits
- 7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

## 8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

## 9. Clinical Coding

#### 9.1 Office of Population Censuses and Surveys (OPCS)

#### Any in prime position

- M61.1 Total excision of prostate and capsule of prostate
- M61.2 Retropubic prostatectomy
- M61.3 Transvesical prostatectomy
- M61.4 Perineal prostatectomy
- M61.8 Other specified open excision of prostate
- M61.9 Unspecified open excision of prostate
- M64.1 Open resection of outlet of male bladder
- M65.1 Endoscopic resection of prostate using electrotome
- M65.2 Endoscopic resection of prostate using punch
- M65.3 Endoscopic resection of prostate NEC
- M65.4 Endoscopic resection of prostate using laser
- M65.5 Endoscopic resection of prostate using vapotrode
- M65.8 Other specified endoscopic resection of outlet of male bladder
- M65.9 Unspecified endoscopic resection of outlet of male bladder
- M66.1 Endoscopic sphincterotomy of external sphincter of male bladder
- M66.2 Endoscopic incision of outlet of male bladder NEC
- M68.1 Endoscopic insertion of prostatic stent
- M68.3 Endoscopic insertion of prosthesis to compress lobe of prostate

#### 9.2 International classification of diseases (ICD-10)

#### Must include

N40 Hyperplasia of prostate

# **Document Control**

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**Version History** 

Version 0.1 – April 2019 – Within Cheshire CCG Commissioning Policy Document

Version 0.2 – July 2023 – Updated to reflect recent clinical evidence

Version 0.3 – April 2025 – Updated following clinical feedback from public engagement exercise. Section 1.1a has been updated to reflect RCS terminology and criteria, sections 5.2 & 5.5 have been updated to reflect the latest terminology