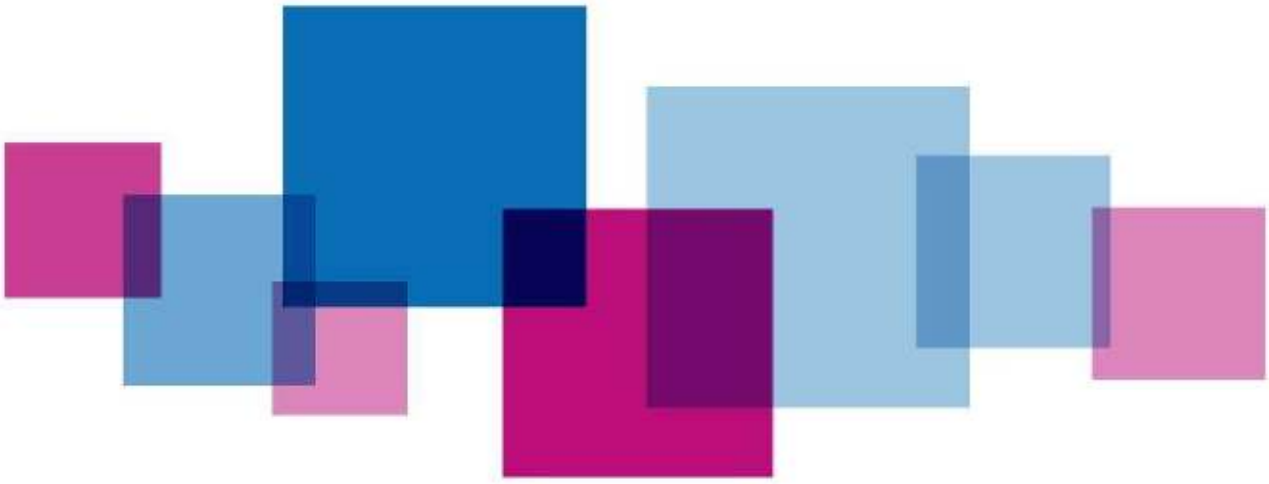
NHS
Bristol, North Somerset
and South Gloucestershire
Integrated Care Board

Commissioning Policy

Prostatic Urethral Lift (UroLift® System)

Criteria Based Access



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Document Control

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Version control

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1718.4.00	15/11/2017	IFR Manager	Prepared for discussion at the November CPRG meeting
1718.4.01	17/05/2018	IFR Coordinator	Prepared for review at June 2018 CPRG
1819.2.00	01/10/2018	IFR Coordinator	Smoking and BMI references updated following Sept CPRG and PALS info updated

THIS IS A CRITERIA BASED ACCESS POLICY
TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW

THIS POLICY RELATES TO ALL PATIENTS

Prostatic Urethral Lift (UroLift® System) Policy

General Principles

Treatment should only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB Exceptional Funding Request Panel.

1. Clinicians should assess the patients against the criteria within this policy prior to referring patients seeking treatment. Referring patients to secondary care that do not meet these criteria not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment.
2. Patients will only meet the criteria within this policy where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment and the EFR team should be approached for advice.
3. On limited occasions, the ICB may approve funding for a further assessment in secondary care only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meets the criteria to access treatment in this policy.
4. Where funding approval is given by the Exceptional Funding Request Panel, it will be available for a specified period of time, normally one year.
5. Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery. https://www.sciencedirect.com/science/article/pii/S1198743X15007193 (Thelwall, 2015).
6. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing (ASH, 2016)
7. In applying this policy, all clinicians and those involved in making decisions affecting patient care will pay due regard to the need to eliminate unlawful discrimination,

harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

Background

The current treatment options for patients presenting with Lower Urinary Tract Symptoms (LUTS) is watchful waiting, prescription drugs and elective surgery. Men are offered surgery only if voiding symptoms are moderate to severe or if drug treatment and conservative management have been unsuccessful or are not appropriate. The most common surgical procedure performed is a Transurethral Resection of the Prostate (TURP). Although widely considered the gold standard surgical intervention for LUTS, TURP can be associated with significant morbidity and even mortality, with adverse outcomes including blood-transfusion, prolonged length of stay, post-operative complications, intervention, and perioperative mortality. Permanent side effects include erectile dysfunction, retrograde ejaculation and urinary incontinence. It also necessitates the use of a catheter for several days after the procedure, increasing the risk of infection.

This alternative intervention, a Prostatic Urethral Lift (UroLift® System) procedure, will be commissioned for clinically eligible patients who would otherwise have been offered a TURP procedure. A Prostatic Urethral Lift procedure is a short, minimally invasive day-case procedure with no overnight stay requirement. It is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue. The adjustable, permanent implants pull excess prostatic tissue away so that it does not narrow or block the urethra.

Prostatic Urethral Lift has been supported by NICE as a cost saving alternative to TURP due to fewer inpatient bed days, reduced pre-operative process costs, reduced theatre time and follow-up appointments. There are also superior benefits in terms of minimal side effects and post-operative complications compared with the current standard of care.

It is estimated that approximately 25% of patients requiring surgery for LUTS would be eligible for a Prostatic Urethral Lift.

Risks

Common side effects of the Prostatic Urethral Lift are generally mild, typical of all endoscopic procedures, resolve within 2 weeks, and require no further intervention. Side effects are typically controlled by paracetamol and anti-inflammatory drugs, such as Ibuprofen. Severe

side effects, such as those associated with TURP, have not been observed in any study.

NICE state:

> "Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is
>
> adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit." (NICE, 2014)

Manufacturer Guidelines

The makers of UroLift® state (UROLIFT) that the device is not recommended for patients who have or are:

- Aged less than 50 years
- A Prostate volume of >80 cc (80ml)
- An obstructive or protruding median lobe of the prostate
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross haematuria
- A known allergy to nickel

Clinicians planning treatment should be mindful of these recommendations which do not form part of the access criteria below.

POLICY CRITERIA – COMMISSIONED

CRITERIA BASED ACCESS

Funding approval for surgical treatment with Prostatic Urethral Lift (UroLift® System) will only be provided by the NHS for patients meeting the criteria set out below:

The patient:

1. is suffering from LUTS causing moderate to severe voiding symptoms which has not responded to drug treatment and/or conservative management (or this is clinically inappropriate),
   AND
2. Has a prostate of less than 100ml without an obstructing middle lobe.**Invalid source specified. AND**
3. TURP, TUVP or Laser procedures are
   a) clinically inappropriate for high risk patients (with multiple co-morbidities), high anaesthesia risk patients, and patients on anti-coagulants
   OR
   b) not desired by the patient who does not want a more severe, invasive procedure

Note: Whilst there is some developing evidence that UroLift® may reduce impact of treatment on sexual function, this is a not a primary indicator for electing to be treated with UroLift® instead of other surgeries.

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the ICB's Individual Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net**

This policy has been developed with the aid of the following references:

Ash. (2016). *Ash.org.uk.* Retrieved Sept 24, 2018, from www.ash.org.uk: www.ash.org.uk/briefings

NICE. (2014, Jan). *Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia.* Retrieved from Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia: https://www.nice.org.uk/guidance/ipg475/chapter/1-Recommendations

Nice. (2015, Sept). *MTG 26: Urolift for treating lower urinary tract symptoms of benign prostatic hyperplasia.* Retrieved from Nice: www.nice.org.uk/guidance/mtg26

Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases,* , vol. 21, no. 11, p. 1008.e1.

UROLIFT. (n.d.). *Urolift* . Retrieved November 15, 2017, from https://urolift.com/

OPCS Procedure codes – For completion at a later date
