

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Greenlight XPS for treating benign prostatic hyperplasia

1 Technology

1.1 *Description of the technology*

The GreenLight XPS (Boston Scientific) is intended for laser vaporisation of the prostate in the treatment of benign prostatic hyperplasia (BPH). The GreenLight procedure, known as photoselective vaporisation of prostatic tissue, is performed by inserting a laser cystoscope with a camera system trans-urethrally. During the procedure a laser fibre is passed through a cystoscope to vaporise the enlarged prostate, leaving a clear urethral channel. If bleeding occurs, Greenlight XPS can utilise its 'coagulation' mode, which uses a pulsating laser light to seal (cauterise) any bleeding vessels that may result from photoselective vaporisation. The GreenLight XPS laser operates at a shorter wavelength (532 nanometres) than other laser systems used to treat BPH. The shorter wavelength light is absorbed by oxyhaemoglobin (in blood and tissue), which vaporises the tissue, leaving no fragments behind. GreenLight XPS uses a proprietary MoXy laser fibre, which is actively cooled using a flow of saline to minimise degradation and improve fibre durability.

The GreenLight console and its associated fibres have been developed and upgraded since its first introduction in 2005. The latest version of Greenlight XPS uses a 180w, 532nm wavelength laser. This system is designed to allow the use of 1 fibre per patient in all but the largest prostate.

The procedure can be done either as day-case or inpatient treatment. The system requires training, and a mentoring scheme is in place with the NHS for urological surgeons to carry this out.

1.2 *Relevant diseases and conditions*

Greenlight XPS is indicated for the treatment of benign prostatic hyperplasia (BPH). BPH is the most common cause of lower urinary tract symptoms (LUTS). Growth of the prostate causes outflow obstruction and surgical treatments seek to improve symptoms secondary to BPH by removing excess prostate tissue. LUTS can be categorised into voiding, storage and post-micturition symptoms. Voiding symptoms are the most common and include: weak or intermittent urinary stream; straining; hesitancy; terminal dribbling and incomplete emptying. However, storage symptoms are more bothersome and include: urgency; frequency; urgency incontinence and nocturia. Mixed symptoms (both storage and voiding) are common in patients with bladder outflow obstruction (BOO) secondary to BPH. Increasingly severe LUTS are also associated with a rising prevalence of erectile and ejaculatory dysfunction.

Benign prostate hyperplasia (BPH) is common in men over 50 and increases with age with the incidence of BPH estimated to increase from 50% among men between the ages of 50 and 60 years, to 90% for men older than 80 years of age ([Urology Foundation](#)). The effect of LUTS on quality of life can be assessed using the International Prostate Symptoms Score (IPSS). A score of 8-19 is classified as moderate, while 20-35 is classified as severe. Moderate-to-severe LUTS are present in about 40% of men older than 50 years of age, rising to 90% of men in their eighties ([Patient UK](#)). Moderate to severe LUTS are estimated to affect up to 3.4 million men in the UK ([Rees, 2014](#)).

1.3 *Current management*

Current management for men with lower urinary tract symptoms is outlined in [NICE guideline Lower urinary tract symptoms \(2010\)](#) and in the NICE pathway, [Lower urinary tract symptoms in men overview](#). Mild symptoms are usually managed conservatively including containment products, lifestyle

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factors and observation. Drugs such as alpha blockers and 5-alpha-reductase inhibitors may also be used. If symptoms worsen over time, or conservative management or drug treatment options are inappropriate or unsuccessful, surgical options may be discussed. There are several considerations to inform the most appropriate management options for individuals, which include the severity of symptoms, size and shape of the prostate and median lobe and any additional comorbidities.

Surgical options include monopolar or bipolar TURP, transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). Transurethral incision of the prostate (TUIP) may be offered if the prostate is estimated to be smaller than 30ml. Open prostatectomy should only be offered if the prostate is estimated to be larger than 80ml. More recently, alternative surgical approaches including [prostatic urethral lift \(PUL\)](#), [water vapour thermal therapy](#), [transurethral resection and haemostasis of the prostate](#) and [photoselective laser vaporisation techniques](#) have been demonstrated to be alternatives each in their own indications.

1.4 Regulatory Status

The current version of Greenlight XPS (180w) and its associated liquid cooled fibre system received CE marking class IIB in 2010. The GreenLight XPS console is a class IIB device, and the MoXy disposable laser fibre is a class IIA device. The first version of GreenLight was CE marked in 2005.

1.5 Claimed benefits

The benefits of GreenLight XPS to patients by the company are:

- Shorter hospital length of stay, because the GreenLight XPS procedure can be done as a day-case procedure
- Shorter duration of catheterisation
- Quicker return to normal activity following treatment
- Lower likelihood of rehospitalisation within 30 days post procedure

- Reduction in patient stress and anxiety because typically no overnight stay is needed
- Reduction in pain leading to improved quality of life
- May be used in patients with comorbidities; those older in age, taking anticoagulants, with larger prostates and with urinary retention.
- Reduced risk of excessive or severe bleeding, TUR syndrome
- Reduced requirement for blood transfusion.

The benefits to the healthcare system claimed by the company are:

- Procedure performed as a day case rather than as an inpatient
- Reduced length of stay in hospital
- Reduced risk of adverse events from bleeding and transurethral resection of the prostate (TURP) syndrome
- Reduction in hospital readmissions within 30 days post procedure
- Reduced requirement for blood transfusion.

2 Decision problem

Population	People with urinary outflow obstruction secondary to benign prostatic hyperplasia in whom surgical intervention is indicated, especially those with prostates that are larger than ≥ 30 ml.
Intervention	Greenlight XPS Photoselective Vaporisation of the Prostate (PVP)
Comparator(s)	<ul style="list-style-type: none"> • Monopolar and bipolar transurethral resection of the prostate (TURP) • Holmium laser enucleation of the prostate (HoLEP)
Outcomes	<p>The outcome measures to consider to be included:</p> <p>Patient outcomes</p> <ul style="list-style-type: none"> • symptoms of BPH (International Prostate Symptom Score [IPSS]) • change in prostate volume • maximum flow rate (Qmax) • post void residual volume (PVR) • duration of catheterisation • rate of dysuria (pain) • quality of life measures, e.g., International Prostate Symptom Score Quality of Life (IPSS-QOL) • preservation of sexual function <p>System outcomes</p> <ul style="list-style-type: none"> • length of hospital stay

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	<ul style="list-style-type: none"> • frequency of completion as a day case • rate of re-admission • procedural blood loss and blood transfusion requirement <p>Adverse effects</p> <ul style="list-style-type: none"> • rate of transurethral resection syndrome (TUR) • rate of capsular perforation • device related adverse events
<p>Cost analysis</p>	<p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Comparators: monopolar TURP, bipolar TURP and holmium laser enucleation of the prostate (HoLEP). Monopolar, and bipolar TURP should be included as in-patient procedures in the cost model to reflect the setting they are routinely used in the NHS.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p>
<p>Subgroups to be considered</p>	<ul style="list-style-type: none"> • High risk patients should be considered as a subgroup due to the different resource consequences for this population. This group may include: <ul style="list-style-type: none"> • people with pacemakers or defibrillators and those at risk of bleeding sequelae (including people on anti-coagulation therapy, with a history of bleeding disorders, an implanted prosthetic heart valve, implanted coronary stents, patients on aspirin therapy for prior coronary events, patients with prior deep vein thrombosis [DVT] or a high risk of DVT, stroke survivors, haemophiliacs, and patients who do not wish to have blood transfusions). • people with a prostate size greater than 100ml • people with urinary retention • Settings of the procedure should be considered as separate groups given the cost implications from this. The procedure is expected to be carried out as a day case, but a small proportion of individuals may be admitted as inpatients.
<p>Special considerations, including those related to equality</p>	<p>The condition of BPH is most common in men over the age of 50, so the GreenLight XPS laser system is primarily for use in this population. This is a function of the clinical condition for which the technology is indicated and is not likely to be considered an equalities issue. LUTS secondary to BPH are more prevalent in black men than men of white or Asian origin. This is also a function of the clinical condition, not of the technology itself.</p> <p>Laser vaporisation technology such as GreenLight has the potential to reduce the risk of bleeding compared with other surgical options and so may improve access to medical treatment for BPH in these previously excluded groups. These may include</p>

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	<p>people on anticoagulant therapies, those with bleeding disorders and those whose beliefs prevent them from receiving blood transfusions, many of whom may be covered under the 2010 Equality Act.</p> <p>This technology may be appropriate for individuals who do not identify as male but have a prostate and may have BPH that requires treatment. Gender is a protected characteristic under the 2010 Equality Act.</p> <p>Greenlight is contraindicated for people with prostate cancer. Cancer is recognised as a disability. Disability is a protected characteristic under the 2010 Equality Act.</p>	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	People who wish to preserve sexual function and fertility.	

3 Related NICE guidance

Published

- UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. NICE medical technologies guidance, May 2021 [MTG58]
Available here: <https://www.nice.org.uk/guidance/mtg58>
- The PLASMA system for transurethral resection and haemostasis of the prostate. NICE medical technologies guidance, January 2021 [MTG53]
Available here: <https://www.nice.org.uk/guidance/mtg53>
- Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE medical technologies guidance, June 2020 [MTG49]. Available here: <https://www.nice.org.uk/guidance/mtg49>
- Lower urinary tract symptoms in men. NICE pathway, last updated April 2020. Available from: <https://pathways.nice.org.uk/pathways/lower-symptoms-in-men>

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- Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE interventional procedures guidance IPG641. January 2019. Available here: <https://www.nice.org.uk/guidance/IPG641>
- Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE Interventional procedures guidance IPG625. August 2018. Available here: <https://www.nice.org.uk/guidance/ipg625/chapter/1-Recommendations>
- Prostate artery embolization for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE IPG611. April 2018. Available here: <https://www.nice.org.uk/guidance/ipg611>
- Memokath-028, 044 and 045 stents for urethral obstruction. NICE medtech innovation briefing MIB123, October 2017. Available from: <https://www.nice.org.uk/advice/mib123>
- Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE IPG475. January 2014. Available here: <https://www.nice.org.uk/guidance/ipg475/history>
- Lower urinary tract symptoms in men: management. Clinical guideline [CG97], May 2010. Available from: <https://www.nice.org.uk/Guidance/CG97>

In development

NICE is developing the following guidance:

- Guidelines update to CG97: Lower urinary tract symptoms in men: management. Clinical Guideline update, publication date to be confirmed as stated here: <https://www.nice.org.uk/guidance/cg97/resources/2019-surveillance-of-lower-urinary-tract-symptoms-in-men-management-nice-guideline-cg97-6965648749/chapter/Surveillance-decision?tab=evidence>
- Interventional Procedure Guideline in development for prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia. Publication date to be confirmed, as stated here: <https://www.nice.org.uk/guidance/indevelopment/gid-ipg10214>

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4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Day Surgery
- The Royal College of Anaesthetists
- The Association of Anaesthetists
- British Association of Urological Surgeons
- The Association for Perioperative Practice
- British Prostate Group
- Royal College of Surgeons of England
- The British association of Urological Nurses (BAUN)
- Getting it right first time (GIRFT)

4.2 Patient

NICE's [Public Involvement Programme](#) contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Anticoagulation UK
- Bladder Health UK
- Bladder and Bowel UK
- Everyman
- Orchid (for penile, prostate and testicular cancer)
- Men's Health Forum (MHF)
- Prostate Cancer UK
- Prostate Help Association
- Sexual Advice Association
- Tackle prostate cancer
- The Haemophilia Society
- The Urology Foundation

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