

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

GreenLight XPS for treating benign prostatic hyperplasia (update of MTG29)

How medical technology guidance supports innovation

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Provisional recommendations

- 1.1 GreenLight XPS is recommended as an option to treat benign prostatic hyperplasia (BPH) in adults.
- 1.2 More comparative data should continue to be collected on cost saving outcomes when using GreenLight XPS in people that may be considered as high-risk, including those with larger prostates and a higher risk of bleeding.

Why the committee made these recommendations

NICE previously recommended GreenLight XPS for BPH in people in non-high-risk groups. But it asked for more data on people in high-risk groups (previously defined

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as people with urinary retention, prostates over 100 ml in volume, and a higher risk of bleeding).

Clinical experts advised that urinary retention is now not considered high risk in practice. In the remaining high-risk groups, clinical evidence suggests that GreenLight XPS is as effective as transurethral resection of the prostate (TURP) in treating BPH symptoms. GreenLight XPS is associated with a reduction in hospital stay and less postoperative catheterisation. Sexual function is also more likely to be maintained after the procedure.

The cost modelling suggests GreenLight XPS is likely to be cost saving compared with TURP and holmium laser enucleation of the prostate (HoLEP). By how much depends on day case proportions, length of stay and procedure length.

Although there is enough evidence to recommend GreenLight XPS for people in high-risk groups, comparative data is still needed to be more certain about cost savings.

2 The technology

Technology

- 2.1 GreenLight XPS (Boston Scientific) is a 180 W, 532 nm wavelength laser system intended to treat benign prostatic hyperplasia (BPH). It works by removing excess prostate tissue using laser vaporisation (a procedure known as photoselective vaporisation of the prostate [PVP]). A laser fibre is passed through a cystoscope to vaporise the enlarged prostate, leaving a clear urethral channel. In 'coagulation' mode, GreenLight XPS can also seal (cauterise) any bleeding vessels that may result from photoselective vaporisation.
- 2.2 The GreenLight XPS system consists of a reusable laser console and a single-use fibre optic delivery device. It uses a proprietary MoXy liquid-cooled laser fibre, which is designed to handle high power and reduce fibre degradation.

2.3 The procedure can be done either as a day case or on an inpatient basis. It is carried out under general or spinal anaesthetic. Using GreenLight XPS requires training, and the NHS has a mentorship scheme.

Care pathway

2.4 Current surgical treatment for BPH when conservative management has been unsuccessful, or is not appropriate, is in [NICE's guideline on managing lower urinary tract symptoms in men](#) and includes:

- monopolar or bipolar transurethral resection of the prostate (TURP) (see [NICE's medical technologies guidance on the PLASMA system for transurethral resection and haemostasis of the prostate](#))
- transurethral vaporisation of the prostate (TUVVP)
- holmium laser enucleation of the prostate (HoLEP)
- transurethral incision of the prostate (TUIP; only in prostates smaller than 30 ml)
- open prostatectomy (only in prostates larger than 80 ml).

2.5 Other surgical approaches include:

- prostatic urethral lift (see [NICE's medical technologies guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia](#))
- water vapour thermal therapy (see [NICE's guidance on Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia](#))
- photoselective laser vaporisation techniques.

Innovative aspects

2.6 GreenLight XPS uses a proprietary MoXy laser fibre, which is actively cooled using a flow of saline to improve fibre durability. Because the laser operates at a shorter wavelength (532 nm) than other laser systems, it is absorbed by oxyhaemoglobin, vaporising the tissue without leaving

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fragments behind. GreenLight XPS can also seal (cauterise) any bleeding vessels which result from PVP in 'coagulation' mode.

Intended use

2.7 GreenLight XPS is intended for PVP to treat BPH. It is contraindicated for people with prostate cancer. For a full list of contraindications and details on using GreenLight XPS, see the instructions for use.

Costs

2.8 The company said that it usually provides the GreenLight XPS laser to the NHS for free, as part of a contractual arrangement in which the NHS agrees to buy a minimum number of laser fibres over a specified time period at an average price of £500 per fibre (excluding VAT). The company also said that if more than 1 fibre is needed per person, it will provide it for free.

For more details, see the [website for GreenLight XPS](#).

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the [project documents on the NICE website](#).

Clinical evidence from the original guidance

The GOLIATH trial shows GreenLight XPS is as clinically effective as TURP

3.1 The company submissions included 3 publications of a single trial (GOLIATH study: Bachmann et al. 2014, Bachmann et al. 2015, Thomas et al. 2015) that compared GreenLight XPS with transurethral resection of the prostate (TURP). GOLIATH was a European multicentre randomised controlled trial in 281 people with benign prostatic hyperplasia (BPH; who were not considered as high risk). Results showed no statistically significant difference in BPH symptom improvement (measured on the

International Prostate Symptom Score [IPSS] or maximum urinary flow [Qmax]) between GreenLight XPS and TURP up to 2 years, and using GreenLight XPS resulted in a significantly shorter duration of catheterisation and shorter lengths of stay. The committee at the time of the original guidance concluded that GreenLight XPS was as effective as TURP in treating BPH in non-high-risk groups.

There was not enough evidence in the high-risk population at the time of the original guidance

3.2 The EAC identified 10 studies in total, including 2 from the 3 that the company submitted, that were relevant to the high-risk groups. High risk was defined in the previous guidance as people with a higher risk of bleeding (such as those on anticoagulants), larger prostates (over 100 ml) and urinary retention. Five of these studies included comparative clinical data. There were significant improvements from baseline in all clinical outcomes ($p < 0.001$). The clinical experts said that GreenLight XPS may be a safe alternative to TURP in this population. However, the committee agreed that there was not enough evidence to show any notable differences in effectiveness or adverse events using GreenLight XPS in the high-risk population compared with TURP and holmium laser enucleation of the prostate (HoLEP). The committee therefore concluded in the original guidance that multicentre prospective studies with GreenLight XPS were needed in this population.

3.3 Following a review of the evidence base in 2019, NICE decided to update the guidance to consider the new evidence on its use in high-risk groups since the original guidance.

New clinical evidence

The EAC prioritised 37 studies out of 58 new publications

3.4 For the guidance update, the EAC considered a total of 58 new studies relevant to the decision problem. Because of the size of the evidence base, the EAC prioritised 37 of these studies:

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- 1 randomised controlled trial (RCT) comparing standard GreenLight XPS 180 W photoselective vaporisation of the prostate (PVP) with GreenLight XPS ejaculatory hood-sparing technique (Abolazm et al. 2020)
- 3 propensity-matched cohorts (Azizi et al. 2017, Castellani et al. 2018, Cimino et al. 2017)
- 7 non-randomised, non-propensity-matched comparative studies (Cindolo et al. 2017, Gondran-Tellier et al. 2021, Hibon et al. 2017, Mathieu et al. 2017, Mattevi et al. 2020, Mesnard et al. 2021, Reimann et al. 2019)
- 9 cohort studies that stratified by patient risk (Campobasso et al. 2020, Eken and Soyupak 2018, Goueli et al. 2017, Knapp et al. 2017, Lee et al. 2016, Meskawi et al. 2019, Meskawi et al. 2017, Waters et al. 2021) or procedure setting (Xu et al. 2021)
- 17 single arm studies that reported on rare adverse events (Aboutaleb et al. 2018, Berquet et al. 2015, Castellucci et al. 2020, Chen and Chiang 2016, Ferrari et al. 2021b, Gasmi et al. 2021, Ghahhari et al. 2021, Ghahhari et al. 2018, Law et al. 2021, Liu et al. 2020, Rajih et al. 2017, Reimann et al. 2018, Tao et al. 2019, Thomas et al. 2019, Trail et al. 2021, Trujilo et al. 2021, Zhou et al. 2017).

For full details of the clinical evidence, see section 3 of the assessment report update (2022).

There was no new randomised evidence comparing GreenLight XPS with TURP or HoLEP

3.5 No new RCTs comparing GreenLight XPS with TURP or HoLEP were identified at guidance update. The GOLIATH trial remained the only randomised controlled evidence comparing GreenLight XPS with TURP. There was no randomised evidence comparing GreenLight XPS with HoLEP. At guidance update, 6 observational studies compared GreenLight XPS with TURP. The EAC said that further randomised comparative studies in people at high risk exclusively may not be ethical.

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This is because of the increased risk of bleeding, complications and longer hospital stays associated with TURP.

Evidence suggests clinical benefits with GreenLight XPS, including in high-risk groups

- 3.6 The new evidence suggested that, when compared with TURP, GreenLight XPS was associated with a significantly shorter hospital stay, significantly shorter postoperative catheterisation period and significantly higher preservation of ejaculatory function at 12 months (Reimann et al. 2019, Cimino et al. 2017, Mattevi et al. 2017, Gondran-Tellier et al. 2021, Mathieu et al. 2017). While most of this new evidence included people at high risk (50 of 58 studies), only 4 reported on high-risk populations exclusively. Two were comparative studies (Gondran-Tellier et al. 2021, Mesnard et al. 2021) and 2 were retrospective cohorts (Meskawi et al. 2017, Eken and Soyupak 2018). An additional 4 cohort studies stratified by anticoagulation status (Lee et al. 2016, Knapp et al. 2017, Meskawi et al. 2019, Eken and Soyupak et al. 2018). Details of these studies are in section 4.2 of the assessment report update overview (2022).

Cost evidence

Published economic evidence reports cost benefits using GreenLight XPS

- 3.7 The original guidance included 2 published cost-effectiveness studies, both of which compared GreenLight XPS with TURP (Thomas 2015a, Bunejam-Gual 2014). Both studies suggested that reduced length of stay, or an increased proportion of procedures done as day cases would be associated with a cost saving when using GreenLight XPS.
- 3.8 The EAC identified 6 economic studies published since the original guidance. None were done in the UK. Two studies reported GreenLight XPS to be cost saving against TURP (Masucci et al. 2018, Ulchaker and Martinson 2018), 1 reported GreenLight XPS to be more costly but more effective than TURP (Caicedo et al. 2019), 2 studies reported TURP to be more cost effective (Erman et al. 2018, Ulchaker and

Martinson 2018) and 1 reported cost savings when compared with HoLEP or ThuLEP in people with a prostate volume greater than 80 ml (Mathieu et al. 2017). For full details of the cost evidence, see section 9 of the assessment report update (2022).

The EAC updated the original decision tree cost model

3.9 In the original guidance the company developed a decision tree model, which was used to inform the committee's recommendation. These compared the cost consequences of using GreenLight XPS with:

- monopolar or bipolar TURP in a non-high-risk BPH population (people who did not have urinary retention, not taking anticoagulation therapy or with prostates less than 100 ml)
- HoLEP in a high-risk BPH population (people with urinary retention, taking anticoagulation therapy or with prostates more than 100 ml).

The model used a 6-month time horizon. The EAC corrected some minor errors and updated the model costs and clinical parameters, including: shortening the length of stay, reducing the calculated cost for HoLEP and removing excess bed day costs. For full details see the assessment report update (2022).

The updated decision tree model suggests that GreenLight XPS is cost saving compared with TURP but cost incurring compared with HoLEP

3.10 With the updated clinical and cost parameters, the EAC's base case results suggested that GreenLight XPS remains cost saving by £70 per person compared with TURP, but cost-incurring when compared with HoLEP (an additional cost of £114 per person). The latter was because of reduced capital costs associated with increased use per year of HoLEP in the updated model. Base case estimates assume 4% of TURP procedures and 36% of GreenLight XPS procedures were done as a day case procedure. The key driver of the cost saving was the proportion of procedures that could be carried out as day cases. The EAC's threshold

analysis suggested that when maintaining 68% of GreenLight XPS done as a day-case procedure, using GreenLight XPS would be cost-incurring if the proportion of day-case procedures for TURP or HoLEP increased above 43.6% and 56% respectively.

The company presented a new Markov model, which included a high-risk population scenario

3.11 The company submitted a new cost model during the guidance update. It applied a Markov model structure and had a 4-year time horizon. The model included everyone who needed treatment for BPH and had a high-risk group scenario, which was informed by the results of an unpublished systematic review. The model allowed for retreatment.

The EAC modelled all people treated for BPH because there was limited comparative evidence in high-risk groups

3.12 The EAC considered that the company's unpublished review was low quality, and its results were not robust enough to inform economic modelling for high-risk populations. The EAC noted that the GOLIATH trial remained the most robust comparative evidence and that there was no new prospective comparative evidence specifically on using GreenLight XPS in high-risk populations, since the original guidance. The EAC considered that modelling all people whose BPH was treated was more appropriate and more generalisable to the NHS. The EAC made some changes in the model costs and clinical parameters, including: extending the time horizon to 5 years, reducing the capital cost of HoLEP, and increasing the length of stay. Full details are in the assessment report update (2022).

The revised EAC base case results from the Markov model show that GreenLight XPS is cost-saving compared with TURP or HoLEP

3.13 The EAC's revised base case analysis for the Markov model showed that GreenLight XPS is cost saving, per person, by £304.83 compared with TURP and £269.52 compared with HoLEP. The EAC conducted limited

probabilistic sensitivity analysis, varying two parameters due to availability of data. Base case cost savings were driven by the duration of procedures and the length of stay after procedures. Additional threshold analyses suggested that GreenLight XPS would become cost-incurring if TURP and HoLEP were done less than 43.7 and 60.0 minutes respectively (relative to 49.6 minutes for GreenLight XPS). GreenLight XPS would also become cost-incurring if the length of hospital stay following TURP or HoLEP were less than 1.5 and 0.9 days respectively (relative to 1.6 days for GreenLight XPS).

4 Committee discussion

Clinical-effectiveness overview

GreenLight XPS is effective and has clinical benefits for the general population

- 4.1 The committee concluded that the new evidence on GreenLight XPS showed its effectiveness in relieving the lower urinary tract symptoms associated with benign prostatic hyperplasia (BPH). Evidence also suggested that, compared with transurethral resection of the prostate (TURP), GreenLight XPS was associated with significantly shorter hospital stays, significantly shorter postoperative catheterisation, and significantly higher preservation of ejaculatory function at 12 months compared with TURP. The clinical experts confirmed that, in their experience, GreenLight XPS is an effective treatment option for people with BPH. The committee noted that there are no randomised trials that directly compare GreenLight XPS with holmium laser enucleation of the prostate (HoLEP), and no new randomised trials with TURP (other than the GOLIATH study). But it was satisfied that the available trial evidence, alongside real-world evidence and expert opinion, showed the clinical benefits associated with GreenLight XPS in practice.

There is new evidence in high-risk populations, but comparative evidence is limited

4.2 The committee noted that most of the evidence included people considered as high risk, but there was little comparative data in these groups exclusively. The external assessment centre (EAC) highlighted the possible ethical challenges in getting randomised comparative evidence in these high-risk groups. The committee agreed that a large volume of evidence has been published after the original guidance but the comparative evidence in high-risk populations remains limited.

Clinicians do not consider people with urinary retention to have a higher risk of complications

4.3 Clinical experts described how the risk profile of people with BPH has changed in practice since the previous guidance. They explained that urinary retention is common in people being treated for BPH (up to 50% of the population). The committee was satisfied that GreenLight XPS has been used for treating BPH in people with urinary retention, who are not now considered as a high-risk group in practice.

GreenLight XPS is considered to be a safe and effective treatment option for people with a higher risk of bleeding and large prostates

4.4 The clinical experts said that they considered GreenLight XPS to be a safe treatment option for people at a higher risk of bleeding or who were taking anticoagulants. They estimated that 20% of people having GreenLight XPS were in this high-risk group. The clinical experts said that anticoagulants can usually be taken through GreenLight XPS surgery, unlike with TURP. They said this means people who were at risk of bleeding could be referred across hospitals for treatment with GreenLight XPS. The clinical experts also advised that treatment for people with large prostates may be more varied because of laser technology availability and clinicians' experience. All of them considered that using GreenLight XPS to treat BPH was safe with prostates up to 100 ml in volume. They agreed that up to 150 ml was appropriate for

GreenLight XPS if the clinician was experienced. People with prostates bigger than 150 ml are more likely to be considered for HoLEP treatment. The committee understood prostate size was a key factor in how long the procedure may take, so patient selection and the clinician's experience were important considerations in this high-risk group. The committee was satisfied that the evidence showed the clinical effectiveness of GreenLight XPS in BPH in larger prostates and people with a high risk of bleeding but concluded that more comparative evidence on the use of GreenLight XPS in these groups is needed.

Side effects and adverse events

Risk of bleeding is low with GreenLight XPS

4.5 Evidence from 12 studies reported that between 0% and 2.2% of people needed blood transfusions intraoperatively and 0.6% and 0.8% within 30 days. Seventeen studies recorded 0.1% to 5.6% of people with capsular perforation. Six studies reported no adverse events. The clinical experts explained that GreenLight XPS was rarely associated with postoperative bleeding. They said that continuous bladder irrigation (to prevent clot formation) was not normally needed after GreenLight XPS surgery, which reduces nursing requirements and improves the patient experience. Three-way catheters can help identify any issues with secondary bleeds, but clinical experts reported bleed risk to be low. The committee was satisfied that the risk of bleeding is low with GreenLight XPS.

Fibre breakage is rare and does not affect the person having treatment

4.6 The company said that fibre breakage was rare, and that it had modified the device to promote the cooling of the fibres, to minimise breakage. The EAC confirmed that there were no concerns over device safety and no adverse events related to patient harm. The clinical experts agreed that fibre breakage was rare (around 1 in 200 cases) and was not associated with patient harm. They explained that fibre breakage is more likely when a clinician first started to use the device because they may position the

fibre too close to the tissue. The committee was satisfied that there were no patient or clinician safety concerns about fibre breakage.

Relevance to the NHS

GreenLight XPS is available for treating BPH in the NHS

4.7 The company confirmed that GreenLight XPS is used in 26 specialist centres in the UK. The clinical experts explained that GreenLight XPS is used routinely in people needing surgical treatment for BPH, including those in the high-risk groups (people with large prostates, people with higher risk of bleeding). GreenLight XPS is one of the technologies covered by the [MedTech funding mandate in 2022 to 2023](#).

NHS considerations overview

GreenLight XPS can be done as a day case procedure, but some people need to stay overnight

4.8 The evidence reported that 68% of GreenLight XPS procedures were done as a day case (Trail et al. 2021). The clinical experts said that in their experience most people having GreenLight XPS are seen as a day case and do not need hospital admission. One said that, compared with TURP or HoLEP, GreenLight XPS is more likely to be a day case procedure. But they added that it depended on individual circumstances, such as the size of their prostate gland, social reasons, and the use of anaesthetics, which may mean some people needed an overnight stay.

There may be benefits to GreenLight XPS with respect to learning curves and training

4.9 The clinical experts explained that urologists need specialist training to use GreenLight XPS. But they suggested that GreenLight XPS may be quicker to learn than TURP or HoLEP. The clinical experts also highlighted the importance of minimum procedure levels across centres to ensure skills are maintained.

Laser equipment and safety training are required, but the costs are negligible

4.10 The clinical experts said that laser treatment is available across urology departments for treating conditions such as kidney stones and BPH. Urologists are routinely trained in laser techniques and laser safety. Using GreenLight XPS requires laser equipment, including goggles. The cost of the equipment was not included in the cost model. The EAC considered that laser equipment is reusable with a long life span and that costs would be negligible. The committee was satisfied that this would not be a significant additional cost requirement for services.

Equality considerations

Two people who identify as women have had GreenLight XPS

4.11 The committee was told that 2 people who identified as women and retained a prostate had GreenLight XPS treatment. No change in technique or concerns in carrying out the procedure in this population were reported.

Cost modelling overview

GreenLight XPS is estimated to be cost saving compared with standard treatments but by how much is uncertain in high-risk groups

4.12 The EAC's cost modelling results from the Markov model showed that GreenLight XPS is likely to be cost saving compared with TURP by £305 per person over 5 years. They showed that it was also likely to be cost saving compared with HoLEP by £270 per person over 5 years. The estimates applied to all people with BPH, including those considered to be high risk. The EAC considered the model to accurately reflect treatment complication and retreatment costs but that the size of the cost savings was uncertain in high-risk groups because of a lack of comparative evidence. The clinical experts also advised that modelling high-risk populations collectively may not be appropriate or generalisable to clinical practice. The committee concluded that the EAC's approach to modelling

using the GOLIATH data was appropriate, and that using GreenLight XPS is likely to be cost saving but by how much is uncertain in high-risk groups.

Main cost drivers in the Markov model

Length of stay affects GreenLight XPS's cost case

4.13 Length of stay was one of the key drivers of the estimated cost savings with GreenLight XPS compared with standard treatments such as TURP in the Markov model. GreenLight XPS becomes cost-incurring if the length of stay with TURP is reduced to a level similar to GreenLight XPS. Length of stay was not a key driver in the original guidance, because the decision tree model presented it as the proportion of day cases, which was the key driver (assessment report update, 2022). The clinical experts said that people having GreenLight XPS are likely to be discharged on the day and are not usually admitted to hospital after the procedure. However, the length of stay is likely to be influenced by personal factors and hospital infrastructure (for instance, some hospitals have extended opening hours for day-case surgery). The clinical experts agreed that the scenarios of length of stay or proportion of day cases that would make GreenLight XPS cost-incurring are unlikely in clinical practice. However, given there is uncertainty in the size of the cost saving from length of stay in the Markov model, the committee suggested more data collection on this would be valuable.

Length of procedure affects GreenLight XPS's cost case

4.14 The economic analysis included an assumed average procedure length of 49.6 minutes for GreenLight XPS, 66 minutes for TURP and 80 minutes for HoLEP. The clinical experts considered these procedure durations to be reasonable. However, they advised that duration is affected by prostate size and the clinician's experience. The clinical experts said that using GreenLight XPS for larger prostates might extend procedure duration. This could reduce the cost saving of using GreenLight XPS

compared with TURP or HoLEP. However, it should be noted that there is a lack of data on procedural duration. The committee agreed that more comparative data, including audit data, would be helpful to inform the uncertainty in the cost benefit of length of stay across the comparators.

Further data collection

The committee would like to see more robust comparative evidence in high-risk groups

4.15 The committee agreed that more data on the efficacy of GreenLight XPS compared with other treatments is needed in the high-risk groups (higher risk of bleeding and large prostates, greater than 100 ml). It recommended collecting more data to address the efficacy of GreenLight XPS directly compared with other treatments, including the length of hospital stay and the procedure duration, in high-risk groups.

5 Committee members and NICE project team

Committee members

This topic was considered by [NICE's medical technologies advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of the medical technologies advisory committee](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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