

This National Institute for Health and Care Excellence (NICE) guidance is the current, unaltered NICE guidance at time of publication. BJUI publishes selected NICE guidance relevant to urologists to extend their distribution and promote best practice.

GreenLight XPS for treating benign prostatic hyperplasia

© NICE (2016) GreenLight XPS for treating benign prostatic hyperplasia

1 Recommendations

- 1.1 The case for adopting GreenLight XPS for treating benign prostatic hyperplasia is supported in non-high-risk patients. GreenLight XPS is at least as effective in these patients as transurethral resection of the prostate (TURP), but can more often be done as a day-case procedure, following appropriate service redesign.
- 1.2 There is currently insufficient high-quality, comparative evidence to support the routine adoption of GreenLight XPS in high-risk patients, that is those who:
 - have an increased risk of bleeding or
 - have prostates larger than 100 ml or
 - have urinary retention.

NICE recommends that specialists collaborate in collecting and publishing data on the comparative effectiveness of GreenLight XPS for high-risk patients to supplement the currently limited published evidence.
- 1.3 Cost modelling indicates that in non-high-risk patients, cost savings with GreenLight XPS compared with TURP are determined by the proportion of procedures done as day cases. Assuming a day-case procedure rate of 36%, and that the GreenLight XPS console is provided at no cost to the hospital (based on a contracted commitment to fibre usage), the estimated cost saving is £60 per patient. NICE's resource impact report estimates that the annual cost saving for the NHS in England is around £2.3 million. In a plausible scenario of 70% of treatments being done as day cases, the cost saving may be up to £3.2 million.
- 1.4 NICE recommends that hospitals adopting GreenLight XPS plan for service redesign to ensure that day-case treatment can be delivered appropriately.

2 The Technology

Description of the Technology

- 2.1 GreenLight XPS (Boston Scientific) is intended to treat benign prostatic hyperplasia (BPH) using photoselective vaporisation of prostatic tissue. The procedure can be done either as day-case or inpatient treatment. 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 laser operates at a shorter wavelength (532 nanometers) than other laser systems used to treat BPH. 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 improve fibre durability.
- 2.3 Since its introduction in 2005, the GreenLight console has been upgraded to provide an increase in power output. This allows procedures to be done on larger prostates in less time. The first clinical studies used an 80 watt system; this was then upgraded to a 120 watt system (GreenLight HPS) and a further upgrade in 2010 introduced GreenLight XPS, the 180 watt system currently in use. GreenLight XPS also has an improved laser fibre design to accommodate the increase in power output to avoid fibre degradation. This is designed to allow the use of 1 fibre per patient in all but the largest prostates.
- 2.4 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; GreenLight XPS and its associated MoXy fibre were CE marked in 2010.

- 2.5 The company submission stated that the GreenLight XPS laser console is usually provided at no cost to the NHS, as part of a contractual arrangement with the company to purchase a minimum number of laser fibres over a specified time period at an average price of £550 per fibre (excluding VAT).
- 2.6 The claimed benefits of GreenLight XPS in the case for adoption presented by the company were:
- 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.
 - 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 taking anticoagulants and those with larger prostates.
 - Reduction in hospital readmissions.
 - Reduced risk of adverse events from capsular perforation, bleeding and transurethral resection of the prostate (TURP) syndrome.

Current Management

- 2.7 Current management for men with BPH is outlined in NICE's guideline on lower urinary tract symptoms (<http://www.nice.org.uk/guidance/CG97>) and in the NICE pathway on lower urinary tract symptoms in men (<http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men?fno=1>). Surgical options recommended by NICE include:
- monopolar or bipolar TURP (see NICE medical technologies guidance on the TURis system for transurethral resection of the prostate [<https://www.nice.org.uk/guidance/mtg23>])
 - transurethral vaporisation of the prostate (TUVAP)
 - 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).
- 2.8 Minimally invasive treatments such as transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), high-intensity focused ultrasound (HIFU), transurethral ethanol ablation of the prostate (TEAP) and laser coagulation are not recommended by NICE. In NICE's guideline on lower urinary tract symptoms (<http://www.nice.org.uk/guidance/CG97>), laser vaporisation techniques (such as GreenLight XPS) are recommended for use only as part of a randomised controlled trial that compares these

techniques with TURP. NICE has also recommended the UroLift prostatic urethral lift system as an alternative treatment option (see NICE medical technologies guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [<https://www.nice.org.uk/guidance/mtg26>]).

3 Clinical Evidence

Summary of Clinical Evidence

- 3.1 The key clinical outcomes for the GreenLight XPS system presented in the decision problem were:
- symptoms of benign prostatic hyperplasia (BPH; using the International Prostate Symptom Score [IPSS] and International Prostate Symptom Score Quality of Life [IPSS-QOL], change in prostate volume, maximum flow rate [Q_{max}], post-void residual volume [PVR])
 - duration of catheterisation
 - rate of dysuria (pain)
 - quality of life
 - length of hospital stay
 - frequency of completion as a day-case
 - rate of re-admission
 - procedural blood loss and blood transfusion need
 - rate of transurethral resection of the prostate (TURP) syndrome
 - rate of capsular perforation
 - device-related adverse events.

Non-High-Risk Patients with GreenLight XPS

- 3.2 The company submission of clinical evidence for non-high-risk patients was based on a single trial that compared GreenLight XPS with TURP (the GOLIATH study: Bachmann et al. 2014, Bachmann et al. 2015, Thomas et al. 2015).
- 3.3 The external assessment centre carried out an independent literature search and identified 1 additional trial that compared GreenLight XPS with TURP (Jovanovic et al. 2014).
- 3.4 The GOLIATH study was a European multicentre randomised controlled trial including 281 patients with BPH who were not considered to be at high risk (not on anticoagulant therapy, with prostates smaller than 100 ml and without urinary retention). Patients were randomised to either GreenLight XPS or TURP (monopolar or bipolar) and followed up for 2 years. The comparator was either monopolar or bipolar to reflect standard practice at participating centres, but results from the monopolar and bipolar subgroups were not reported separately.
- 3.5 Results were reported at 6 months (Bachmann et al. 2014), 1 year (Bachmann et al. 2015) and 2 years

(Thomas et al. 2015). When compared with TURP, GreenLight XPS resulted in a significantly shorter duration of catheterisation (40.8 hours compared with 59.5 hours, $p<0.001$) and shorter lengths of hospital stay (65.5 hours compared with 96.9 hours, $p<0.001$). However, procedures with GreenLight XPS were longer than with TURP (49.6 minutes compared with 39.3 minutes, $p<0.001$). There was no statistically significant difference between groups in regard to symptoms of BPH as measured by IPSS or Qmax. Rates of adverse events and the percentages of patients who were complication-free after 180 days were similar between groups.

- 3.6 Jovanovic et al. (2014) studied 62 patients with lower urinary tract symptoms secondary to BPH in a single-centre study in Serbia. Patients in this study were not taking anticoagulants and had prostates smaller than 100 ml, but 11 patients had indwelling catheters. Patients were randomised to either GreenLight XPS or TURP (monopolar or bipolar not specified). GreenLight XPS was associated with a significantly shorter hospital stay (1.9 days compared with 4.4 days, $p<0.0001$) and duration of catheterisation (1.1 days compared with 2.9 days, $p<0.0001$), but longer operating times (92 minutes compared with 82 minutes, $p<0.01$) when compared with TURP. There were statistically significantly fewer adverse events with GreenLight XPS than with TURP, including blood transfusions, capsule perforations and TURP syndrome. In both groups, IPSS and Qmax improved from baseline but no statistically significant differences between GreenLight XPS and TURP were reported.

High-Risk Patients with GreenLight XPS or GreenLight HPS

- 3.7 The company identified 3 studies of GreenLight XPS or GreenLight HPS in the high-risk subgroup populations of interest (Woo et al. 2008, Woo and Hossack 2011, Chung et al. 2012). These included patients with a higher risk of bleeding (such as those on anticoagulants), patients with larger prostates and patients with urinary retention.
- 3.8 The external assessment centre considered 1 study in the submission not to be relevant (Chung et al. 2012), because results were not stratified by high-risk subgroup. The external assessment centre identified 10 further studies, 5 of which had comparative clinical data (Chen et al. 2013, Sohn et al. 2011, Tao et al. 2013, Hueber et al. 2015, West and Woo 2015).
- 3.9 Woo et al. (2008) was a case series of 305 patients with BPH who had GreenLight HPS at 8 centres across 6 countries. Patients considered to be at high risk (prostates larger than 80 ml, taking anticoagulants or in urinary retention) were compared with those without high-risk factors, with a mean follow-up of 4.2 months. For all patients, clinical outcomes improved significantly from baseline ($p<0.001$). For patients with large prostates, the only difference when compared with those with smaller prostates was in regard to prostate volume reduction ($p<0.001$). There were no differences in outcomes for patients taking anticoagulants compared with those not taking them. For patients with or without urinary retention, the only significant difference between groups was in Qmax (16 ml/sec compared with 22.7 ml/sec, $p<0.001$).
- 3.10 Woo and Hossack (2011) reported a retrospective case series of 43 high-risk patients with BPH taking anticoagulants who had the GreenLight HPS procedure at a single centre in Australia. For the whole cohort, the mean hospital stay was 32 hours. Outcomes were reported at 3 months, including a subgroup of patients with urinary retention at baseline. There were no significant differences in outcomes between these groups except for IPSS score, which was significantly worse in patients with urinary retention than those without (6.7 compared with 12.6, $p<0.01$).
- 3.11 Chen et al (2013) reported a retrospective case series studying 132 patients having GreenLight HPS in Taiwan, who were divided into 4 high-risk subgroups (aged >80 years, prostate size >80 ml, high anaesthetic risk [American Society of Anesthesiologists score of 3], taking anticoagulants). Patients taking anticoagulants ($n=21$) and with larger prostates ($n=32$) were compared with patients without high-risk factors ($n=72$). There were no significant differences reported in IPSS, quality of life score, Qmax or PVR for the anticoagulant group or larger prostate group compared with the group without risk factors. For the anticoagulant group, hospital stay and duration of catheterisation were significantly longer than for the group without risk factors (2.3 days compared with 1.7 days, $p=0.033$ and 28.8 hours compared with 19.1 hours, $p=0.045$). The larger prostate group had significantly longer operation times (35.5 minutes compared with 29.7 minutes, $p=0.022$), hospital stays (2.5 days compared with 1.7 days, $p=0.01$) and duration of catheterisation (30.8 hours compared with 19.1 hours, $p=0.021$) than the group without risk factors. No patients were given blood transfusions in any group and there were no significant differences in postoperative complications between groups, except for more urinary tract infections in patients taking anticoagulants (3 compared with 1, $p=0.035$).
- 3.12 Sohn et al. (2011) described a retrospective study of 60 patients having GreenLight HPS in Korea, which compared 30 patients who stopped anticoagulants before surgery with 30 patients who continued them. Operating time in the 2 groups was not significantly different (24.9 minutes compared with 16.9 minutes;

$p=0.628$). There were no statistically significant differences between groups in IPSS, quality of life score or PVR at 3-month follow-up and no patients in either group developed complications.

- 3.13 Tao et al. (2013) described a prospective study of 188 high-risk patients having GreenLight HPS treatment in China. A subgroup taking anticoagulants ($n=45$) were compared with the entire high-risk cohort ($n=188$), but statistical analysis was not done. Perioperative outcomes were similar between the anticoagulant group and the entire cohort, with comparable operation times (49.5 minutes compared to 50.8 minutes), admission times (4.5 days for both) and lengths of catheterisation (1.8 days compared to 1.9 days). Follow-up results were not reported for the anticoagulant group.
 - 3.14 Hueber et al. (2015) described a large retrospective study of 1196 patients having GreenLight XPS treatment in 6 centres in Canada, the US, France and England. Subgroups of patients with larger prostates (>80 ml, $n=741$) were compared with those with smaller prostates (<80 ml, $n=387$) with a 2-year follow-up. The population included some patients on anticoagulants and in urinary retention. Perioperative results in groups with larger versus smaller prostates showed that operation times and length of catheterisation increased with prostate size (80 minutes compared with 45 minutes, $p<0.01$; 34 hours compared with 26 hours, $p<0.01$), but mean hospital stay was 24 hours in both groups. There were no significant differences in adverse events, apart from a greater conversion to TURP in the larger prostate group (8.4% compared with 0.6%, $p<0.01$). Improvements in IPSS, quality of life score, Qmax and PVR from baseline were not significantly different between groups.
 - 3.15 West and Woo (2015) described a retrospective study of 137 patients having GreenLight XPS treatment at a single centre in Australia, who were divided into subgroups according to prostate size: <40 ml ($n=27$), 40–79 ml ($n=56$), 80–119 ml ($n=38$), >120 ml ($n=22$). Operating time increased with prostate size ($p<0.01$ between groups) and there were no statistically significant differences across groups in other reported outcomes, including duration of catheterisation, length of hospital stay, incidence of adverse events and proportion discharged home catheter-free within 24 hours.
- vaporisation techniques (Elshal et al. 2015). The external assessment centre also identified a randomised controlled trial which compared GreenLight HPS with HoLEP (Elmansy et al. 2012).
- 3.17 Elshal et al. (2015) described a randomised controlled trial of 103 patients with LUTS secondary to BPH, randomised to either vapo-enucleation with GreenLight XPS or HoLEP done by a single surgeon in Canada. The population included high-risk subgroups, including patients taking anticoagulants, and those with urinary retention and larger prostates. Peri- and postoperative outcomes at 12 months did not differ significantly between GreenLight XPS and HoLEP, apart from Qmax (18.5 ml compared with 31.1 ml, $p=0.01$) and the percentage of patients with a hospital stay of more than 1 night (23.5% compared with 6.4%, $p=0.02$). GreenLight XPS vapo-enucleation is a different technique to photoselective vaporisation and is described as 'off-label' use by the company, so this study was not included in the submission. The external assessment centre included this study in its assessment as the only direct evidence available comparing GreenLight XPS with HoLEP. Expert opinion stated that using GreenLight XPS for vapo-enucleation is a valid but novel technique that does not represent standard care in the NHS.
 - 3.18 Elmansy et al. (2012) studied 80 patients with LUTS secondary to BPH with prostates larger than 60 ml, who were randomised to GreenLight HPS or HoLEP treatment in a single centre in Canada. The population included high-risk patients taking anticoagulants, those in urinary retention and those with large prostates (62–160 ml). Results showed no difference in operative time or duration of catheterisation between groups. Functional outcomes at 12 months were similar for GreenLight HPS and HoLEP, apart from Qmax (24.1 ml compared with 30.5 ml, $p=0.02$) and PVR (64.8 ml compared 29.4 ml, $p=0.02$). Adverse event rates were similar between groups, except for 8 cases with GreenLight HPS that required conversion to TURP or HoLEP because of bleeding or inadequate tissue removal. No blood transfusions were needed in either group.
 - 3.19 The external assessment centre undertook a comparative review of studies that compared GreenLight XPS and GreenLight HPS treatment. The review concluded that operating times and mean hospital stays tend to be shorter with GreenLight XPS. The external assessment centre concluded that fewer laser fibres tend to be used with GreenLight XPS, but it also carries a slightly greater risk of capsular perforation. At follow-up, there were few consistent differences in terms of readmissions and complications with the 2 devices, but the numbers of events were low for both treatments.

Additional Work by the External Assessment Centre

- 3.16 The external assessment centre identified 1 trial that compared GreenLight XPS and holmium laser enucleation of the prostate (HoLEP) using GreenLight XPS for vapo-enucleation instead of standard

- 3.20 The external assessment centre appraised a systematic review of HoLEP compared with TURP (Li et al. 2014). This meta-analysis of 8 randomised controlled trials showed that HoLEP operations take longer than TURP, but the average length of hospital stay is shorter. There were few statistically significant differences in postoperative complications, but HoLEP had statistically significantly better curative outcomes at 12-month follow-up as compared with TURP.

Committee Considerations

- 3.21 The committee concluded from the evidence that GreenLight XPS and TURP are equally effective in treating BPH in non-high-risk patients. The committee also noted evidence of fewer complications and readmissions with GreenLight XPS when compared with TURP.
- 3.22 The committee noted that published evidence to support the use of GreenLight XPS in high-risk patients was limited in quantity and quality. The committee was advised by experts that in high-risk patients, TURP would often not be considered and that GreenLight XPS offers a safe alternative to TURP. The committee was advised that, because TURP is not normally used in high-risk patients, randomised studies compared with TURP in this group of patients are not considered ethical. The committee therefore concluded that multicentre prospective studies with GreenLight XPS were needed in this population.
- 3.23 The committee heard expert advice that a 10-minute longer procedure time with GreenLight XPS compared with TURP would be unlikely to have a negative effect on operating theatre lists.
- 3.24 The committee discussed the lack of long-term outcomes data with GreenLight XPS when compared with TURP for both non-high-risk and high-risk groups. The committee was advised that in the absence of long-term clinical data, other outcomes that were measured and reported in the GOLIATH trial serve as valid surrogates of the durability of symptomatic relief. In this regard, the volume of prostatic tissue resected, reduction in prostate serum antigen (PSA) and 1-year re-operation rates were similar between GreenLight XPS and TURP. Experts highlighted that the 10-year re-operation rate with TURP is approximately 16% and that this may be lower with HoLEP.
- 3.25 The committee noted that long-term catheterisation is associated with considerable patient morbidity and NHS resource use. The committee also noted comments received during consultation regarding the risk of urinary incontinence after treatment for lower urinary tract symptoms. It accepted expert advice that

in the GOLIATH study, urinary incontinence rates at 1-year follow-up were similar for GreenLight XPS and TURP and that all cases of incontinence reported in the study were mild.

- 3.26 The committee considered its recommendations regarding the use of GreenLight XPS in high-risk patients, having noted that this cohort includes people with comorbidities who may be considered as having a disability under the Equalities Act 2010. Expert advisers stated that GreenLight XPS may provide a safe alternative to TURP in this cohort of patients. However, the committee decided that the current evidence was not sufficiently robust to support a recommendation for the device's routine use for high-risk patients. Instead, the committee recommended collaborative data collection on the effectiveness of GreenLight XPS to supplement the currently limited published evidence for high-risk patients.

4 NHS Considerations

System Impact

- 4.1 The company claimed that using GreenLight XPS would reduce hospital length of stay and increase NHS efficiency because it can be done as a day-case procedure. The company also claimed that using the GreenLight XPS system could lead to cost savings by avoiding adverse events and hospital readmissions.
- 4.2 All experts noted that training was needed to use the GreenLight XPS system. Although TURP is part of the core curriculum of urological surgical training, experts commented that the GreenLight XPS procedure is less challenging to learn than TURP, and 1 expert stated that it was also less challenging to learn than HoLEP. Experts highlighted that the company provides a mentorship programme, training courses and simulator technology; 1 expert indicated that 25 mentored cases would be enough to gain adequate expertise in the technique.
- 4.3 The company also claimed that GreenLight XPS may be used for high-risk patients for whom surgical intervention for BPH is unsuitable, such as those with a higher risk of bleeding or at a higher risk of anaesthetic complications.

Committee Considerations

- 4.4 Based on expert advice and limited published evidence, the committee concluded that using GreenLight XPS would allow more procedures to be done on a day-case basis. The committee noted that in the GOLIATH study, 70% of the UK cohort had a 'time to stable health' of less than 24 hours (defined as being able to void without a catheter or the time to discharge), suggesting these procedures can be done as day cases. In addition, day-

case rates of up to 80% had been achieved in a single UK centre. In contrast, experts advised that less than 10% of TURP procedures could be done as day cases because of longer catheterisation times and the need for irrigation.

- 4.5 The committee was advised that the British Association of Day Surgery has recommended that within the next 5 years, over 90% of urological surgeries should be done as day-case procedures. Experts advised that although people living alone may not be suitable for day-case treatment, the presence of a post-operative urinary catheter should not necessarily be a barrier to discharge. Urinary catheters can safely be removed in the community by community nurses, at GP surgeries or, in some cases, by the patients themselves.
- 4.6 The committee noted that an increase in day-case treatment rates as a result of adopting GreenLight XPS would necessitate planning for service redesign. It was advised by the experts that this had already been achieved in a number of UK centres and is associated with significant potential staff and cost efficiencies compared with inpatient treatment. Examples of service redesign to facilitate day-case treatment that were highlighted include 23-hour patient hotels, 5-day wards and morning surgery to allow discharge by the end of the day.

5 Cost Considerations

Cost Evidence

- 5.1 The company presented 2 published economic studies, both of which compared GreenLight XPS with transurethral resection of the prostate (TURP; Thomas et al. 2015a and Benejam-Gual et al. 2014). The external assessment centre did not identify any further studies.
- 5.2 Thomas et al. (2015a) included 1-year data from the GOLIATH study (Bachmann et al. 2014). The authors used a Markov model with a lifetime horizon to estimate quality-adjusted life years (QALYs) gained and costs from a UK NHS perspective. The main cost driver was found to be the proportion of treatments done as day-case procedures. Using GOLIATH data, sensitivity analyses showed the costs were almost equal for GreenLight XPS and TURP. If more than 32% of patients had day-case procedures with GreenLight XPS, it became cost saving when compared with TURP. However, the external assessment centre found some uncertainties with the risk ratios and day-case rates used in the model. It also highlighted that the capital costs of the GreenLight XPS equipment were not included, only the cost of the fibres. Therefore, the findings apply to the current funding arrangements, where the NHS incurs no capital costs in adopting the technology.
- 5.3 Benejam-Gual et al. (2014) used retrospective data from 79 patients in 4 centres in Spain to estimate the direct costs of procedures and complications over 3 months. The external assessment centre identified uncertainties with how the resource costs were collected and noted differences in lengths of stay at different hospitals. However, it agreed with the conclusions that GreenLight XPS is associated with shorter lengths of stay than TURP and may therefore be cost saving.
- 5.4 The company presented 2 *de novo* cost model analyses comparing the cost consequences of using GreenLight XPS in different populations with different comparators:
 - A primary analysis compared GreenLight XPS with monopolar/bipolar TURP in a non-high-risk BPH population (patients without urinary retention, not taking anticoagulation therapy or with prostates less than 100 ml).
 - A secondary analysis compared GreenLight XPS with HoLEP in a high-risk BPH population (patients with urinary retention, taking anticoagulation therapy or with prostates more than 100 ml).
- 5.5 Both cost models used the same decision-tree structure, in which patients entered the model at the point of having surgery (either GreenLight XPS or monopolar/bipolar TURP or HoLEP) and were then routed through 4 potential pathways. The post-treatment pathways included options for discharge on the day of surgery or after an inpatient stay, as well as the potential to develop new symptoms or post-surgical complications (which may or may not lead to readmission). At the end point of the model, patients were either asymptomatic or continued to have symptoms. The model was constructed from an NHS perspective with a 6-month time horizon and a discount rate of 3.5% on the capital costs.
- 5.6 In the primary (non-high-risk) model, the clinical outcome parameters used included IPSS score, the probability of being complication-free and the proportion of adverse events, all derived from the 6-month GOLIATH study (Bachmann et al. 2014). Mean excess bed days were 10.36 days for GreenLight XPS and 10.65 for TURP, sourced from 2014/15 NHS Hospital Episode Statistics (HES). The company model allowed 4 different day-case discharge rates for GreenLight XPS informed by different sources: 35.96% from HES data; 80% from a single UK hospital specialising in GreenLight; 57.71% from French health service data and 71.5% from the US Medicare population. The company used the HES day-case discharge rate of 4.08% for TURP. Resource costs included hospital resource costs (procedure costs, cost per day of hospital stay, excess bed days) and the costs of treating adverse events (acute [classified as grade 3, treated in hospital] or non-acute [classified as grade 2, treated in primary care]), which

were derived from national tariffs and NHS reference costs.

- 5.7 For the secondary (high-risk patients) model, the only additional clinical outcome parameter included was a 1.5% additional risk of bleeding (Woo et al. 2008) for both GreenLight XPS and HoLEP. All other clinical parameters were the same as in the primary model, which assumed that GreenLight XPS and HoLEP have the same day-case rates and efficacy and safety outcomes. The company justified this on the basis that there were no head-to-head clinical trial data comparing GreenLight XPS with HoLEP. In the absence of any UK-specific data for HoLEP, the company assumed that the same HES day-case rate (35.96%) could be used for both GreenLight XPS and HoLEP.
- 5.8 The company calculated the equipment costs for each technology from internal sales data (GreenLight XPS and HoLEP) and expert opinion (TURP). No capital costs were calculated for TURP or GreenLight XPS: the TURP device was assumed to be already present in NHS hospitals and the GreenLight XPS console can be provided on loan if a minimum number of consumable laser fibres are purchased at £550.00 each. For TURP consumables, it was assumed that 50% of procedures were monopolar and 50% were bipolar, with an average cost of £190.50 per surgery. HoLEP capital costs of the laser and morcellator were included, based on a 5-year lifespan and treating 25 high-risk patients per year. HoLEP consumables were assumed to be 50% multi-use and 50% single-use laser fibres (plus a fibre stripper and cleaver for multi-use only), in addition to a morcellator blade, suction tubing, omni-jugs and Ellik evacuator for all procedures. Maintenance and training costs were assumed to be zero for GreenLight XPS and were not considered for the other comparators.
- 5.9 The results of the company's primary analysis in non-high-risk patients found that when applying day-case discharge rates of between 36% and 80%, GreenLight XPS was associated with cost savings of between £29 and £443 per patient when compared with TURP.
- 5.10 The company performed a deterministic sensitivity analysis in which clinical costs were varied by upper and lower limits of the 95% distribution and other costs were varied by 20% in each direction. The analysis determined that when the lowest day-case rate was applied, the most sensitive cost drivers were inpatient procedure costs, GreenLight XPS consumable costs and day-case procedure costs. Varying these costs resulted in GreenLight XPS being slightly more or less costly than TURP, which led the company to conclude that GreenLight XPS is cost neutral when compared with TURP.
- 5.11 The results of the company's secondary analysis in high-risk patients showed that GreenLight XPS

produced cost savings of between £591 and £1,059 per patient compared with HoLEP. Because all clinical parameters were assumed to be the same between treatments, the key driver in the high-risk model was the capital cost of HoLEP (compared with zero capital costs for GreenLight XPS).

- 5.12 NICE has published a resource impact report (<https://www.nice.org.uk/guidance/mtg29/resources>) on GreenLight XPS. Assuming that around 6,800 people have GreenLight XPS, the estimated annual cost saving across the NHS in England ranges from £1.3 million when 36% of GreenLight XPS cases are done as day cases to £3.2 million when 70% are day cases.

Additional Work by the External Assessment Centre

- 5.13 The external assessment centre considered the economic evidence for the company's primary analysis in non-high-risk patients to be robust. However, it considered the adverse event parameters in the company's model to be unclear, so revised the model using mean inpatient costs and simplified adverse event data. The revised model allowed for multiple adverse events per patient and used average cost estimates of treating a typical adverse event in different settings.
- 5.14 The external assessment centre found that GreenLight XPS produced a cost saving of £60.19 per patient compared with TURP, when using the company's assumptions of a 36% day-case rate and zero capital costs for GreenLight XPS. The greater savings compared with the company's model were due to the greater adverse event-related treatment costs with TURP than with GreenLight XPS.
- 5.15 Sensitivity analyses by the external assessment centre determined that GreenLight XPS becomes cost saving compared with TURP in non-high-risk patients when the day-case rate is 30% or higher.
- 5.16 In response to consultation comments, the external assessment centre carried out additional sensitivity analyses exploring how varying the ratio of monopolar to bipolar TURP comparator procedures affected the cost model. When compared with monopolar TURP in 100% of cases, the cost saving with GreenLight XPS fell from £60 to £5 per patient. The external assessment centre also added the cost of a laser bridge to the cost of GreenLight XPS (£700 for 50 cases, based on expert opinion). Including the cost of a laser bridge, the cost saving with GreenLight XPS was £46 per patient.
- 5.17 The external assessment centre considered that there was uncertainty about the clinical and cost assumptions of the company's secondary model in high-risk patients. In response to consultation comments, the external assessment centre revised the high-risk model with the following changes to HoLEP treatment:

- increasing the lifespan from 5 to 10 years
- increasing the number of patients having the procedure from 25 to 76 per year
- removing the cost of the Ellik evacuator and fibre stripper
- assuming that the morcellator blades and holmium fibres were reusable.

In this revised model, using the company's capital cost for HoLEP, GreenLight XPS was found to be cost incurring compared with HoLEP by £315 per patient. Using an alternative UK supplier's capital cost for HoLEP, GreenLight XPS was found to be cost incurring by £141 per patient. Because all clinical parameters were assumed to be the same (in the absence of clinical data to the contrary), the main cost driver was how many patients could have HoLEP per year. If 25 or fewer patients have HoLEP each year, GreenLight XPS becomes cost saving. Experts noted that some NHS centres do not re-use HoLEP fibres because of concerns about infection control, which would add to the costs of HoLEP.

- 5.18 The external assessment centre concluded there was insufficient information to develop a robust cost case for GreenLight XPS compared with HoLEP.

Committee Considerations

- 5.19 The committee noted the results of the cost modelling that suggested that cost savings with GreenLight XPS are dependent on rates of day-case treatment and are potentially realised once this exceeds 30%. The committee accepted expert advice that this threshold for cost saving would be achievable for most urology centres.
- 5.20 The committee noted that the cost of adopting GreenLight XPS does not involve a capital outlay for the console. It was informed that such an agreement is negotiated with the company on the basis of a minimum number of laser fibres purchased over a defined time period and is a practicable and realistic arrangement in the context of current NHS practice.
- 5.21 The committee was advised that the 10-minute difference in procedure time between GreenLight XPS and TURP would not influence the cost modelling conclusions.
- 5.22 The committee considered the potential need for using more than 1 laser fibre per GreenLight XPS procedure. The committee was reassured by experts about the durability of fibres and was informed that additional fibres would only usually be needed when vaporising extremely large prostates. The company also stated that the need for more than 1 fibre per procedure is rare, and if additional fibres are needed it has a fibre replacement programme that typically allows the

additional fibres to be given to the hospital at no additional charge. The committee therefore concluded that this issue was unlikely to influence the cost case.

- 5.23 The committee considered the different costs of monopolar and bipolar TURP procedures in light of the results of the additional external assessment centre analysis and concluded that using monopolar or bipolar TURP does not fundamentally alter the cost case supporting the use of GreenLight XPS.

6 Conclusions

- 6.1 The committee concluded that GreenLight XPS is as effective as transurethral resection of the prostate (TURP) for treating benign prostatic hyperplasia in non-high-risk patients. The committee considered that the evidence for the use of GreenLight XPS in high-risk patients is limited, but accepted expert advice that the clinical benefits of its use in this population are plausible. It concluded that further comparative clinical evidence of the benefits of GreenLight XPS in high-risk patients is needed before recommending the procedure for routine adoption in this population.
- 6.2 The committee considered that the evidence for GreenLight XPS allowing more procedures to be done on a day-case basis than current practice was both convincing and compelling. The committee concluded that adopting the GreenLight XPS system is likely to drive an increase in rates of day-case surgery and that planning for the redesign of urological services would be required to accommodate this.
- 6.3 The committee concluded that, in non-high-risk patients, adopting the GreenLight XPS system is likely to be cost saving compared with TURP, only if the current arrangement where consoles are provided at no cost to the hospital based on a contracted commitment to fibre usage is continued (see Section 5.20), and that high rates of day-case treatment are achieved.

Other Information

The following additional information is available on the NICE website (<https://www.nice.org.uk/guidance/mtg29>)

- Committee members and NICE lead team
- Sources of evidence considered by the committee
- About this guidance

Copyright

© NICE [2016]. All rights reserved and subject to NICE 'Notice of Rights'. Available from <https://www.nice.org.uk/guidance/mtg29>. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this publication.