

HERC Coverage Guidance – Surgical Alternatives to Transurethral Resection of the Prostate for Lower Urinary Tract Symptoms in Men Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	American Medical Systems, Minnetonka, MN <i>[submitted October, 27, 2014]</i>
B	Urologist, Oregon Health & Science University, Portland, OR (appointed expert)

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Ident.	#	Comment	Disposition
A	1	American Medical Systems (AMS), an operating company of Endo, appreciates the opportunity to provide comments on the draft coverage guidance <i>Surgical Alternatives to Transurethral Resection of the Prostate for Lower Urinary Tract Symptoms (LUTS) in Men</i> .	Thank you for taking the time to comment. In the future, it would be helpful to identify the products you make.
	2	AMS congratulates the Oregon Health Evidence Review Commission on promoting the use of evidence based medicine in the development of coverage guidelines for the treatment of LUTS. A strong guiding principle to the response we are providing relate to a basic incorrect assumption in the original National Institute for Health and Care Excellence (NICE) LUTS guidelines published in 2010. In 2008, NICE commissioned a ‘systematic review’ from the Kleijnen Systematic Reviews Ltd. Consulting group. This group of health economic consultants scanned published literature for strong evidence for all treatment modalities for BPH. A key assumption was made – that all laser systems provide clinically equivalent outcomes, therefore, the data for these systems compared to the standard of care (SOC), TURP, could be pooled. This assumption has been since proven incorrect.	Thank you for the information.
	3	As seen below, laser light at various wavelengths produce very different mechanisms of action when in contact with tissue.	Thank you for providing this information.

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		<p>Tissue is vaporized when the laser light is attracted to and absorbed by blood (oxyhemoglobin), however, tissue is effectively cut when the laser light is attracted more readily by water. Therefore, PVP (GreenLight) vaporizes tissue, and Thulium and Holmium lasers cut tissue. As such, we contend that it is inaccurate to draw clinical equivalence for photoselective vaporization techniques with Thulium or Holmium resection. Additionally, as described in detail below, although Holmium lasers have a broad base of relevant clinical evidence, this is not the case for Thulium.</p>	
	4	<p><u>Recommended for coverage (strong recommendation): Thulium laser resection</u></p> <p>We would like to request reconsideration of this recommendation based on the principle of evidence-based medicine. Although we recognize the perception of potential cost saving with the use of a reusable fiber and a Thulium based laser system, several HTA authorities have found a distinct lack of evidence supporting the use of Thulium, including NICE, IQWiG (the HTA body within the German health system (G-BA)), and AUA.</p>	Thulium has been modified to a weak recommendation for coverage.
	5	The current NICE guideline for the treatment of Lower Urinary Tract Symptoms (LUTS), CG97, recommends only one laser for	Lourenco 2008 is a SR and

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		<p>surgical intervention to treat BPH(E) – Holmium laser Enucleation of the prostate (HoLEP). Lourenco, et. al, 2008, describes available published clinical trials for laser treatment of BPH. No thulium laser trials were deemed methodologically of high enough quality to be eligible for inclusion in the review. As a result, the use of thulium based lasers is not referenced, nor is thulium included in the resulting NICE guideline published in 2010. The NICE CG97 guideline explicitly states in section 1.5.7 that:</p> <p style="padding-left: 40px;">“...only consider offering laser vaporization techniques, bipolar TUVP (button TURP) or ...TURVP as part of a randomized controlled trial that compares these techniques with TURP.”</p> <p>GreenLight laser vaporization (PVP) performed at 532 nm wavelength is the only BPH laser treatment technology to perform the recommended RCT – the GOLIATH study. As a result, NICE is in process of revising CG97 with an expected publication date of May 2015. Given the lack of additional thulium evidence, the use of thulium laser is not expected to be included in the new LUTS guidance from NICE.</p>	<p>economic modelling of surgical treatments for BPH completed by the NIHR HTA Programme, which does not mention Thulium. Thulium is referenced in the full NICE guideline. One RCT was included, which had serious limitations. It reported no statistically significant difference versus TURP in symptoms, flow, QoL or complications. It is correct that Thulium is not mentioned in the NICE recommendations (page 279). The GOLIATH study compared greenlight laser vaporization to TURP (n=281), and found no significant difference in IPSS, Qmax and PVR, but shorter length of catheterization and hospital stay, and significantly lower rate of reintervention within 30 days.</p>
	6	<p>In 2009, the German HTA body, the Institute for Quality and Efficiency in Health Care (IQWiG) performed a comprehensive HTA on the treatment of BPH as directed by the higher authority, the G-BA. IQWiG is a subgroup of the G-BA, which is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. The resulting G-BA guidelines published in 2010 state that HoLRP and HoLEP be included with monopolar and bipolar TURP as ‘Standard of Care’ procedures.</p>	<p>Thank you for providing this information. The IQWiG HTA executive summary is available in English, but the full report is not, therefore, unable to verify these comments. Unable to access the G-BA guidelines.</p>
	7	<p>Other techniques were deemed to have inadequate evidence to prove additional benefit including:</p> <ul style="list-style-type: none"> • Contact laser ablation of the prostate (CLAP) • Visual laser ablation of the prostate (VLAP) 	<p>See comment A6</p>

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		<ul style="list-style-type: none"> Photoselective Vaporization of the Prostate (PVP – GreenLight) Transurethral Microwave Therapy (TUMT) Thulium Laser Resection (TmLRP) <p>As a result, these therapies were placed on ‘conditional’ reimbursement status. Clinicians and manufacturers were informed of the need for additional clinical evidence – specifically a high quality Randomized Controlled Trial (RCT) comparing to the SOC. The deadline for completion of the RCT and publication of one year results in a peer reviewed journal was set at December 31, 2016. After this time, a new HTA will be performed, and any above listed therapy that has no additional adequate evidence generated will be placed on the strict ‘unreimbursed’ list.</p>	
	8	<p>The American Urological Association (AUA) guidelines do not support the use of thulium laser systems for the treatment of BPH. The use of thulium laser is not listed as a recommended therapy solution. The following surgical therapy techniques are listed in the AUA BPH guideline:</p> <ul style="list-style-type: none"> Open prostatectomy Transurethral holmium laser ablation of the prostate (HoLAP) Transurethral holmium laser enucleation of the prostate (HoLEP) Holmium laser resection of the prostate (HoLRP) Photoselective vaporization of the prostate (PVP)* Transurethral incision of the prostate (TUIP) Transurethral vaporization of the prostate (TUVP)** Transurethral resection of the prostate (TURP) <p><i>*GreenLight, **Button TURP</i></p>	Thank you for providing this information; indeed, this guideline identified only 1 cohort study of 54 men, hence guideline developers were unable to draw conclusions about Thulium lasers.
	9	In closing, AMS supports the subcommittee’s recommendation in the current draft guidance report that strongly recommends coverage for photoselective vaporization of the prostate (PVP) based on the current clinical evidence landscape. We respectfully suggest that the subcommittee reconsider its recommendation of coverage for thulium laser resection to be consistent with global guidelines.	PVP remains a strong recommendation for coverage. Thulium has been modified to a weak recommendation.
B	1	Under strong recommendations TUVP (Electrovaporization of Prostate) is listed. Under weak recommendations you list Bipolar TUVP. These two are the same procedure. There is no electrovaporization with monopolar device--only with the bipolar. In my opinion, Bipolar TUVP should be removed from weak to strong recommendation with the parenthetical insertion reading: <i>Transurethral Bipolar Electrovaporization of Prostate.</i>	The NICE guideline reports on these interventions separately. There are up to 13 studies of monopolar TUVP included, depending on outcome, and only 2 for bipolar TUVP. They recommend that bipolar TUVP be offered only in the context of

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			<p>a clinical trial. However, in the definitions section, there is no separate definition for bipolar TUVP, and under TUVP, it states the following:</p> <p>“The current is delivered through a grooved ball or modified loop electrode with temperatures up to 300 – 400C. Further modification has allowed the use of bipolar current enabling use of physiological saline as a safer irrigant with tissue effects occurring at lower temperatures (ranging from 40-70C).”</p> <p>An additional literature review was conducted and included in the coverage guidance pertaining to bipolar TUVP. Based on this evidence, the committee has made a weak recommendation for coverage for bipolar TUVP (button procedure).</p>

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A	<ol style="list-style-type: none">(1) National Institute for Health and Clinical Excellence (NICE). (2010). <i>Management of lower urinary tract symptoms in men</i>. London: NICE. Retrieved from http://www.nice.org.uk/guidance/cg97/resources/guidance-lower-urinary-tract-symptoms-pdf(2) Lourenco, T., Armstrong, N., N'Dow, J. M. O., Nabi, G., Deverill, M., Pickard, R., et al. (2008). Systematic review and economic modelling of effectiveness and cost utility of surgical treatments for men with benign prostatic enlargement. <i>Health Technology Assessment</i>, 12(35). Retrieved from http://aura.abdn.ac.uk/bitstream/2164/266/1/Lourenco2008.pdf(3) Institute for Quality and Efficiency in Health Care (IQWiG). (2008). <i>Non-drug local procedures for treatment of benign prostatic hyperplasia</i>. Retrieved from https://www.iqwig.de/download/N04-01_Executive_summary_Non-drug_local_procedures_for_treatment_of_benign_prostatic_hyperplasia.pdf(4) American Urological Association (AUA). (2010). <i>AUA Guideline: Management of Benign Prostatic Hyperplasia (BPH)</i>. Linthicum, MD: AUA. Retrieved from http://www.auanet.org/common/pdf/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf

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Identification	Stakeholder
A	NeoTract, Inc., Pleasanton, CA <i>[submitted November 19, 2014]</i>

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Ident.	#	Comment	Disposition
A	1	<p>Please accept my formal comments on your Draft Coverage Guidance “Surgical Alternatives to Transurethral Resection of the Prostate for Lower Urinary Tract Symptoms in Men.” I applaud the HERC for recognizing that while TURP is extremely effective at reducing lower urinary tract symptoms (LUTS) due to BPH, it comes with a multitude of risks and complications, including potentially permanent side effects such as incontinence and sexual dysfunction.</p> <p>I would like to specifically address the evidence review for prostatic urethral lift (PUL). Its status as a non-destructive, surgical, outpatient BPH intervention makes PUL perfect for inclusion in this draft guidance. Prostatic urethral lift demonstrates improvements in LUTS similar to other BPH interventions with only mild to moderate risks through a strong portfolio of peer-reviewed, published clinical evidence.</p>	Thank you for taking the time to comment.
	3	The HERC subcommittee has identified the L.I.F.T. Study, a blinded, randomized, multicenter study comparing PUL and sham. The evidence summary on page 19 of the draft guidance shows this study is identified as having a 3 month follow up. While it’s true that the randomized portion of the study lasted three months, at which time the subjects were unblinded, the subjects receiving PUL were followed through two years with the data published in peer-reviewed articles in well-respected journals associated with the American Urological Association, including <i>The Journal of Urology</i> . Additionally, the patients who received sham treatment during the initial randomized period were offered PUL in a cross-over study that has also been published. The crossover study, where subjects acted as their own controls, offers additional high-level evidence regarding the efficacy of PUL.	Roehrborn 2015 reports the 2 year results of the LIFT study; results at 3 months were maintained with respect to symptoms and flow rate (42% to 58% improvement), and 7.5% required an additional procedure.
	4	All randomized studies showed remarkably similar outcomes, and a multitude of open label studies have demonstrated similarly consistent results. The consistent outcomes across all published studies and minimal risks associated with the treatment, including the unique preservation of sexual function, prompted the National Institute of Health and Clinical Excellence (NICE) to issue a guidance for PUL that states the evidence for PUL is sufficient to support its use. The NICE guidance is cited throughout HERC’s draft coverage guidance. A complete bibliography and copies of all relevant studies are enclosed with these comments.	There is only one RCT (LIFT), with multiple publications. Total N = 206. Maximum prostate size was 77 cc. It is correct that NICE guidance reports adequate evidence to support the procedure.
	5	Prostatic urethral lift is absent from the summary table on pages 20-23, although there is a footnote indicating that the HERC subcommittee did not use NICE’s evidence rating and instead graded the evidence themselves, which is inconsistent with the other interventions reviewed.	Urethral lifts has been added to the GRADE table. Quality of evidence was assessed by HTAS because NICE did not provide a strength of evidence in their document (it is HTAS’ protocol to use the primary source authors evidence rating when it

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			is available).
	6	A high-quality randomized, controlled study along with a crossover study and multiple open label studies demonstrating consistent outcomes should grant PUL a moderate to high evidence level rating, according to Appendix A of the draft coverage guidance. Not only is PUL effective at reducing LUTS but it carries risks of only mild to moderate side effects that usually resolve on their own. This large difference between the “desirable and undesirable effects” should result in a stronger recommendation for coverage according to Appendix A of the draft guidance.	There is only one RCT of this intervention (reported on in multiple articles), and 3 case series. The cross-over study is simply a case series of the sham arm of the RCT. Strength of evidence is down-graded for imprecision, observer bias, and short duration of comparative follow-up (3 months in the RCT).
	7	Safety and Effectiveness Although the draft guidance states that PUL shows significant improvement in LUTS at 3 months, studies show that PUL consistently shows a significant reduction in the American Urological Symptom Index (AUASI) score at 2 weeks, 3 months, 6 months, 1 year, and 2 years. Quality of life and flow rate improvements have also been statistically significant at all follow up points across all studies. Retreatment rates are briefly mentioned in the draft guidance, but they remain low with 5%-6.5% retreatment at 1 year and 7.5%-8% at 2 years.	The more recent publication (Roehrborn 2015) confirms these statistics.
	8	Over the first post-operative year, no additional surgical intervention has been required for complications typically associated with other BPH procedures, such as bladder neck contracture, stricture, transfusion, or stress incontinence. Notably, there has also been 0% incidence of sustained anejaculation or retrograde ejaculation and erectile function is preserved across all studies. The chart below demonstrates safety and effectiveness of several BPH procedures, including PUL delivered with the UroLift® System, through the first post-operative year. Please see the enclosed Clinical Results Summary for additional information.	These complications were not specifically reported in Roehrborn 2015 with the exception of ejaculatory or erectile dysfunction. The primary complication associated with this procedure appears to be encrustation of the implant (2% of implants). One required removal. There was one incident of clot retention requiring an overnight stay. Thank you for providing the attached graphic image.

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		<p style="text-align: center;">*ED – Erectile Dysfunction **ED – Ejaculatory Dysfunction</p> <p style="text-align: center;"><small>Roehrborn, J Urology 2013; McNicholas, Eur Urology 2013; Chin, Urology 2012; EAU Guidelines 2011; AUA Guidelines 2010 and 2003</small></p> <p style="text-align: center;"><small>1. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.</small></p>	
	9	As the subcommittee has noted, there is no study directly comparing TURP and PUL that has been published at this time. However, from the strength of the evidence for both BPH treatments, comparisons can be made regarding the relative risk/benefit ratios of each intervention. Documented rates of complications demonstrate that PUL carries fewer serious risks than TURP and other BPH interventions. Prostatic urethral lift has a 0% transfusion rate to date, and this is routinely identified as a serious risk of TURP by the HERC subcommittee throughout the draft guidance. Post-op catheterization rates are 20-32% for PUL and standard protocol for nearly all TURP patients. For patients that do require a catheter, the mean duration is only 0.9 days. Adverse effects of PUL are mostly mild to moderate transurethral side effects (e.g., dysuria, hematuria, pelvic discomfort, urgency) that usually resolve within two to four weeks.	Specific citation not provided.
	10	The truly unique feature of PUL is the preservation of sexual function. Again, there has been no incidence of sustained anejaculation or retrograde ejaculation. There has been no incidence of sustained erectile dysfunction. A sexual function analysis of the randomized study demonstrate that, while erectile function was maintained for men entering the study with no or mild ED, erectile function actually improved for men that began the study with severe ED.	McVary 2013 reports sexual function results of the LIFT study and confirms these findings.
	11	Prostatic urethral lift demonstrates similar efficacy outcomes to several of the procedures recommended for coverage in the	The committee has considered

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		draft guidance. However, as a truly minimally invasive procedure, PUL carries fewer risks than the majority of other BPH interventions. This results in a large difference between the desirable and undesirable effects that the subcommittee was looking for. The HERC subcommittee’s aim was to evaluate treatments that were less morbid than TURP that can be done in the outpatient setting. As the only surgical intervention that does not remove or destroy prostate tissue, PUL is uniquely suited to reduce the morbidities associated with BPH interventions while still having a large desired effect on lower urinary tract symptoms.	these comments and the additional information submitted. At this time the committee considers evidence insufficient to recommend coverage.
	12	As you do a final review of the evidence, I encourage you to take a broad look at all PUL studies, noting that the net health outcomes in the open label studies are similar to the net health outcomes demonstrated in the scientifically rigorous randomized, controlled trial and crossover study. The results consistently show a statistically and clinically significant improvement in LUTS, as measured by the AUA symptoms score and flow rate, with very few side effects, most of which are mild to moderate and resolve on their own.	Thus far there is only one RCT of PUL with a 2-year follow up. The committee considers evidence insufficient to recommend coverage.
	13	I encourage you to contact me for any additional information you require for your review. I would also be happy to provide the contact information for an Oregon urologist currently performing prostatic urethral lift in the outpatient setting, who would be happy to comment on the real-world use and outcomes of PUL. I sincerely appreciate the opportunity to submit comments on this draft coverage guidance, and I look forward to the outcome of your evidence review.	Thank you for your comment.

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A10	<ol style="list-style-type: none"> 4. McVary KT, Gange SN, Shore ND, Bolton DM, Cowan BE, Brown BT, Te AE, Chin PT, Rukstalis DB, Roehrborn CG. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of the prostatic urethral lift. <i>J Sex Med</i> 2014; 11: 279-287.

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Committer	References
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