

**EUnetHTA JA3 WP4 - Other technologies, OTCA17**  
**Comments by external experts on the 2<sup>nd</sup> draft rapid assessment on LBO laser for PVP in the treatment of BPH**

Comments should be submitted not later than **Thursday 31/10/2019**



Please use this form for submitting your comments and please return to [migliore@agenas.it](mailto:migliore@agenas.it) and [vicari@agenas.it](mailto:vicari@agenas.it)

Please use the *checklist* for external experts as guidance for your review.

1. Please put each new comment in a new row.
2. Please insert the page number and section number on which your comment applies. If your comment relates to the document as a whole, please put **'general'** in this column.
3. Please provide a description of your comment as specific as possible and preferably also provide a suggestion for rewording. If you wish to draw our attention to published literature, please supply the full reference.
4. Please do not address grammar or language issues as long as they do not affect comprehensibility/readability of the document. The assessment will undergo medical editing prior to its publication.

**All comments will be formally responded to in a combined document that will be published on the EUnetHTA website; individual names of the reviewers will be disclosed if reviewers gave their consent.**

The 2<sup>nd</sup> version of the Rapid Assessment on LBO laser for PVP in the treatment of BPH is open to review by external reviewers between 16/10/2019 and 31/10/2019.

Please add extra rows as needed.

<sup>1</sup> a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author

b "minor": the comment does not necessarily have to be answered in a detailed manner

c "linguistic": grammar, wording, spelling that affect comprehensibility of the document

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Comment from <i>Insert your name, title and affiliation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/ section number	Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i>	Character of comment • 'major' <sup>a</sup> =1 • 'minor' <sup>b</sup> = 2 • 'linguistic' <sup>c</sup> =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	Author's reply
Michele Colicchia Clinica Urologica Dipartimento di Scienze Chirurgiche, Oncologiche e Gastroenterologiche Azienda Ospedaliera - Università di Padova (Italy)	General		Tables layout: some tables may benefit of a change in page orientation (e.g. table on page 86) or column wideness (e.g. pages 83-84) to improve readability	2	Tables editing and formal will be checked during the finalisation of the final document to guarantee readability.
<b>Summary</b>					
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	8	139	BPH is a condition that consist in an adeseve impact on lthe lower urinary tract function due to the hyperplasia and enlargement of the central.transitional zone of the prostate	2	Amended accordingly. The term "benign (not cancer) condition" has been left for clarity.
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS	8	141	Apoptosis instead of cell death	2	Amended accordingly. The term "cell death" has been left for clarify.

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**eunetha**  
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

<b>Comment from</b> <i>Insert your name, title and affiliation</i>	<b>Page number</b> <i>Insert 'general' if your comment relates to the whole document</i>	<b>Line/ section number</b>	<b>Comment and suggestion for rewording</b> <i>Please insert each new comment in a new row.</i>	<b>Character of comment</b> <ul style="list-style-type: none"> <li>• 'major'<sup>a</sup> =1</li> <li>• 'minor'<sup>b</sup> = 2</li> <li>• 'linguistic'<sup>c</sup> =3</li> </ul> <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	<b>Author's reply</b>
Reggio Emilia (Italy)					
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	8	143	And progressively increasing of LUTS until AUR	2	Amended accordingly.
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	9	174	searches	3	Amended accordingly.
Michele Colicchia Clinica Urologica Dipartimento di Scienze Chirurgiche, Oncologiche e Gastroenterologiche Azienda Ospedaliera - Università di	30	-	"Study design Randomised controlled trials and comparative prospective nonrandomised studies." the authors might add "multicenter" if it is appropriate.	2	No changes (probably a misunderstanding). This part of the table describes the criteria for inclusion of the studies. The studies were considered of interest even if not multicenter.

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Padova (Italy)					
<b>Description and technical characteristics of the technology</b>					
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	40	659	Considering is a side firing laser with 70 ° angle	1	Amended accordingly.
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	41	676	BIPOLAR TURP IS WOKING IN SALINE SOLUTION THAT MEANS LESS LIQUID ABSORBABLE PROBLEMS FOR THE PATIENT	1	Amended accordingly. The sentence has been rephrased as follows: "Moreover, bipolar TURP uses isotonic saline as irrigation fluid (monopolar TURP typically uses glycine) and hence transurethral resection syndrome which occur in monopolar TURP can be avoided in bipolar TURP."
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	42	727	The power of generators has been increased form 120 watts to 180 watts	2	No changes (probably a misunderstanding). The paragraph describes the GreenLight XPS system which was launched with power of 180 W from the start.

Please add extra rows as needed.

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<b>Health problem and current use</b>					
-	-	-	-	-	-
<b>Clinical effectiveness</b>					
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	56	1195	Ejaculation after laser or TURP is important issue: is reported in the articles? In my opinion yes or not and eventually the results must be reported.	1	Amended accordingly. Only one article (Bachman 2014, from the GOLIATH study) reported about retrograde ejaculation: 88 patients from the GL-XPS group and 84 from the TURP group. No further analyses or comments were made by the authors of the study. The following sentence has been added to the Discussion chapter: "Even if retrograde ejaculation was not included among the outcomes of interest of the present assessment, we acknowledged its relevance and looked at it within the studies. Retrograde ejaculation was reported only for the GOLIATH study [Bachmann 2014] and was similar between the two groups (88 patients from the GL-XPS group and 84 from the TURP group). No further analyses or comments were made

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					by the study's authors."
<b>Safety</b>					
Franco Bergamaschi Director of the Urology Unit at Santa Maria Hospital-IRCCS Reggio Emilia (Italy)	60	1303	Concerning the retreatment rate after TURP reported in the GOLIATH study: in the last decades the retreatment rate after turp remains the same and the literature is still reporting from 13 to 15 % reoperation rate for obstruction. In my opinion a comment in the bias issue might be done.	2	No changes. The paragraph describes results of the included studies without making direct comparisons with previously published data.
<b>Appendix</b>					
-	-	-	-	-	-

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