



October 2018

EXTERNAL EXPERTS REVIEW

Comments were received from:

Name	Affiliation
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Franco Bergamaschi	Director of the Urology Unit at Santa Maria Hospital IRCCS, Reggio Emilia (ITALY)
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Rafael Medina	Director of the Urologist and Nephrologist Clinical Unit in Hospital Virgen del Rocío, Sevilla (SPAIN)

Comment from	Page number	Line/section number	Comment and suggestion for rewording	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3	Author's reply
Bergamaschi	12	TAB2.5	MALE DIAGNOSED WITH VOIDING OBSTRUCTION DUE TO BPH	2	Amended accordingly.
Bergamaschi	12	TAB2.5	iv) men with indwelling catheter might be considered		No changes. We acknowledge that patients with indwelling catheter may be analysed in a second step, if data from studies allow. However, the presence of an indwelling catheter alone does not represent an indication for the treatment choice and then we will not consider this group per se.
Bergamaschi	12	TAB2.5	TUIP IN GROUP i) might be considered		Amended accordingly. According to the latest European guidelines (2017), TUIP is indicated (standard of choice) for patients with low volume prostate (<30 ml) while, for the same group, the LBO laser PVO does not represent an option. However, as clarified by the clinical expert, clinical practice may differ,

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

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

^c"linguistic": grammar, wording, spelling or comprehensibility



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					and LBO laser PVP may be offered as alternative to TUIP in young patients with low volume prostate with the aim of limiting side effects.
Colicchia/Beltrami	13	166 - population	Benign prostatic hyperplasia is an histological diagnosis, benign prostatic obstruction is more appropriate in this setting	1	Partially amended. We acknowledge the issue as a semantic one. The term " <i>benign prostatic hyperplasia</i> " is mentioned in the ICD-10 code N40.1. However, we added a clarification following a previous comment to improve clarity. As indicated by ICD-9 code 600.01, the diagnosis is " <i>hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)</i> ".
Colicchia/Beltrami	13	166 - population	The 3 considered subpopulations need different comparators. The author might need to detail better their aims and study plan according to this limitation	1	Amended. The comparisons were already defined within the table. However, the text at page 8 has been reworded for clarity.
Beltrami	13	166 comparison	Laser enucleation may be considered as comparator for men at risk of bleeding sequelae	1	Amended accordingly.
Colicchia//Beltrami	13	166 outcomes	Critical: IPSS, IPSS-QoL, PVR, Qmax We would consider all the others secondary/important Procedural blood loss/ blood transfusion is critical in the 3 rd subpopulation	1	Thanks.
Colicchia	15	171	The authors might consider a more appealing dissemination plan (e.g. social media)	2	The deliverables of the project will be posted on the EUnetHTA website once complete. News are managed by the Secretariat.

MANUFACTURER FACT CHECK

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05/10/2018



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Name	Affiliation
Anna Creatore	Boston Scientific
Stephan Heumann	Boston Scientific

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Boston Scientific	12	Table 2-5, Section 'Outcomes'	We suggest to add the text in red (specifying why PVP reduces bleeding) Moreover, compared to TURP, PVP claims reduced bleeding due to a specific wavelenght of 532 nm with a high affinity with oxyhaemoglobin, thus guaranteeing coagulation of obstructive tissue in a hemostatic way , and TURP syndrome.	2	Partially amended. The section is very brief and the detailed sentence proposed does not fit in. However, the description provided will be added in the assessment report.

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