

National Institute for Health and Care Excellence

Medical technologies evaluation programme

GID-MT565 Optilume for treating recurrent bulbar urethral strictures

Consultation comments table

There were 12 consultation comments from 1 consultee:

- 12 comments from a company representative

#	Consultee ID	Role	Section	Comments	NICE response FINAL
1.	1	Company	Has all of the relevant evidence been taken into account?	Yes	Thank you for your comment.
2.	1	Company	Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?	Yes	Thank you for your comment.
3.	1	Company	Are the recommendations sound and a suitable basis for guidance to the NHS?	Yes	Thank you for your comment.
4.	1	Company	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	No	Thank you for your comment.

5.	1	Company	Recommendations (Section 1.1)	'Adult males over the age of 18 only' as per the indications highlighted in the instructions for use	Thank you for your comment. Section 2.1 has been amended to include "It is indicated for managing urethral stricture disease in 'adult males'". Optilume is recommended as an option to treat recurrent bulbar strictures. Some people may not identify as men but have a penis. The clinical experts also noted that trans women, with or without gender reassignment have a bulbar urethra. If a bulbar stricture occurs, this is managed in the same way as for cisgender men. NICE is committed to use person centred and inclusive language.
6.	1	Company	The technology (Section 2.1)	'in adult males over the age of 18' as per indications highlighted in the instructions for use	Thank you for your comment. Section 2.1 has been amended to include "It is indicated for managing urethral stricture disease in 'adult males'".
7.	1	Company	The technology (Section 2.1)	'to be used as a drug coated dilation balloon' as per the products designed mechanism of action	Thank you for your comment. Section 2.1 has been amended to include 'It is designed to be used as a drug-coated dilation balloon for a urethral stricture that is 3 cm or less in length.'
8.	1	Company	The technology (Section 2.2)	'The inflated device is then kept in place for a minimum of 5 minutes, at the recommended rated burst pressure (RBP) measured in atmospheres (ATM) as per instructions for use, to dilate the urethral stricture and allow uptake of paclitaxel.'	Thank you for your comment. Section 2.2 has been amended to 'The inflated device is then kept in place for a minimum of 5 minutes, at the recommended pressure, to dilate the urethral stricture and allow uptake of paclitaxel. The pressure is measured in atmospheres, as per instructions for use.'
9.	1	Company	NHS considerations overview (Section 4.6)	'62 procedures have been completed.'	Thank you for your comment. Section 4.6 has been amended.
10.	1	Company	NHS considerations overview (Section 4.7)	Should this be 'waiting times for NON-urgent cases are more than two years'? The sentence currently states urgent.	Thank you for your comment. Section 4.7 has been amended to 'Waiting times are now more than 2 years.'
11.	1	Company	NHS considerations overview (Section 4.7)	HES data suggests not all standard endoscopic treatments are completed as day case and	Thank you for your comment.

				some, a large number, are associated with inpatient stay >24 hours. This statement requires fact check based on data available	The EAG confirmed that the HES data suggests not all standard endoscopic treatments are completed as day case. Section 4.7 has been amended to 'Standard endoscopic treatments are typically done as day cases under general anaesthesia, but some may incorporate a short inpatient stay'.
12.	1	Company	Further research (Section 4.12)	The European registry has been finalized and is beginning enrolment of patients. This registry will include NHS Trust hospitals and NHS patients	Thank you for your comment. Section 4.12 has been amended to 'The clinical experts noted that a large European registry has been set up to collect objective outcomes for stricture recurrence prospectively for several technologies, including Optilume. This registry includes NHS Trust hospitals and NHS patients.'

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."