

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Optilume for recurrent bulbar urethral strictures

1 Technology

1.1 *Description of the technology*

Optilume (Laborie Medical Technologies) is a drug-coated balloon indicated for treating bulbar urethral strictures (narrowing of the urethra) in adult males. It is designed to be used as a dilation balloon for a single, tandem or diffuse anterior urethral stricture less than or equal to 3 cm in length.

The technology combines balloon dilation, to widen the narrowed area, with locally delivered paclitaxel ($3.5 \mu\text{g}/\text{mm}^2$) to the tissue of the strictured area of the urethra. Paclitaxel inhibits cell proliferation preventing thickening and enlargement of tissue.

Optilume is available in 6 sizes (3 different diameters for both the 3 cm or 5 cm length versions). It is inserted using endoscopic vision with or without fluoroscopy and then inflated under pressure. It stays inflated along the length of the stricture for up to 10 minutes. The balloon's inflation pressure can be measured with an inflation device, and can be visualised, using radiography and contrast media, or with direct visualisation using cystoscopy.

The technology is used by trained consultants in urology, urology trainees and urology nurse specialists. It can be done using local anaesthesia as a day case or in an outpatient setting.

1.2 *Relevant diseases and conditions*

Optilume is used to treat urinary symptoms associated with recurrent bulbar urethral strictures in men aged over 18. Men are more likely to have a urethral stricture or injury because of a longer urethra. They are rare in women and children. Urethral stricture can happen at any point from the bladder to the tip of the penis. This narrowing can lead to reduced flow or blockage of urine, and other complications such as penile swelling and pain, and pain in the pelvic or lower abdominal area. Although in most cases, no cause can be found, some common causes are ([The British Association of Urological Surgeons \[BAUS\]](#)):

- trauma to the urethra
- infection such as a sexually transmitted disease
- damage from surgical tools
- conditions that cause swelling
- congenital.

It is estimated that the prevalence of urethral strictures is approximately 20 per 100,000 men in their 50s, rising to 100 per 100,000 men aged over 65. According to [Bugeja et al, 2021](#), urethral stricture disease accounted for 17,000 hospital admission in 2016-2017 in the UK. Regardless of the treatment, urethral strictures tend to reform, usually within one year, requiring repeat procedures.

1.3 *Current management*

Current treatment options for urethral stricture depend on the site and length of stricture, age and general well-being of the person undergoing treatment and include:

- Urethral dilation (widening) of the stricture using metal or plastic dilators or non-drug coated dilation balloons. This is done endoscopically under local or general anaesthesia.

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- Urethrotomy. This is done endoscopically under general anaesthesia and involves making an incision to the strictured area of the urethra to widen the urethral lumen. About 50% of people have a successful widening of their urethral stricture after this procedure.
- Urethroplasty. This is open surgery done under general anaesthesia and depending on the length and location of the stricture, different options are available: removal of the stricture and reconnection of healthy urethra, or augmentation of the urethra, with or without removal of the strictures segment. It has a higher success rate in resolving urethral strictures with no further treatment needed compared with existing standard endoscopic treatments.

Certain factors need to be taken into account when deciding how to manage a stricture including (Bugeja et al, 2021):

- the length, location aetiology and number of strictures
- type, number, and timing of previous interventions
- symptoms severity and the presence of complications
- patient factors including co-morbidities and patient preference
- the expertise available.

Treatment options are considered as part of a multi-disciplinary team, and people with urethral strictures will undergo further investigation with a urethrogram or flexible cystoscopy to confirm the stricture before a decision is made about having surgery ([NHS England, 2016](#)). Uroflowmetry will be also performed as this objectively demonstrates the severity of restriction to urinary flow (Bugeja et al, 2021).

Both urethrotomy and urethral dilation should be considered as first-line treatments for strictures shorter than 3 cm in length unless men are contraindicated or would prefer to undergo urethroplasty. Self-dilation is advised after urethrotomy or dilation when the stricture is long and complex,

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when major surgery is not possible or as a temporising measure until urethroplasty can be performed (Bugeja et al, 2021). Urethroplasty should be considered for people with short bulbar urethral strictures following at least one urethrotomy, unless after counselling about treatment options the individual would prefer to undergo primary urethroplasty and is aware of the risks and benefits of surgery ([NHS England, 2016](#)).

1.4 Regulatory status

Optilume received a CE mark in September 2020 as a class III medical device.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Rapid and sustained improvement in symptoms and urinary flow
- Effective minimally invasive treatment
- Reduces the need for retreatments or invasive surgical procedures
- Reduces the need for self-catheterisation management
- Reduced side effects and post-operative complications (e.g., UTI) compared with urethroplasty
- Rapid return to normal daily living and improved quality of life

The benefits to the healthcare system claimed by the company are:

- Reduced burden of repeat procedures
- Reduced re-admission rates (elective or non-elective)
- Improved bed capacity
- Improved theatre capacity
- Reduced burden on community care by reducing post-operative complications such as infection, incontinence, discomfort, sexual dysfunction
- Capacity improvements and cost/resource savings
- Easy and rapidly deployable. No capital investment on behalf of the Trust is required.

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2 Decision problem

Population	Men 18 years of age and over with recurrent bulbar urethral strictures equal to or less than 3 cm in length	
Intervention	Optilume	
Comparator(s)	<ul style="list-style-type: none"> • Urethral dilation <ul style="list-style-type: none"> ○ S-Curve Dilators ○ Rigid rod (metal or plastic) dilation • Urethrotomy (Steel blade mounted on a urethroscope) • Urethroplasty 	
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> • Stricture free rate • Rate of reintervention procedures • Time to treatment failure (time until additional stricture treatment is required) • Qmax (Peak Flow Rate) as measured by uroflowmetry • International Prostate Symptom Score • Post-void residual (PVR) urine volume • Device-related adverse events 	
Cost analysis	<p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters.</p>	
Subgroups to be considered	<ul style="list-style-type: none"> • None identified 	
Special considerations, including those related to equality	<p>Optilume is intended for men with recurrent bulbar urethral strictures. These can be caused by injury to the penis, surgery or infection. Some people may not identify as men but have a penis. Urethral strictures become more common in people over 55. Sex, gender reassignment and age are protected characteristics under the Equality Act (2010).</p>	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No

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Any other special considerations	None
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3 Related NICE guidance

Published

- [Lower urinary tract symptoms in men: management](#) (2015) NICE guideline CG97.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Urological Nurses
- British Association of Urological Surgeons
- British Urological Foundation
- British Uro-Oncology Group
- North of England Urological Society
- Urology Foundation

4.2 Patient

NICE's [Public Involvement Programme](#) contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Bladder and Bowel Foundation
- Bladder and Bowel UK
- Everyman
- Kidney Care UK
- Men's Health Forum (MHF)
- Prostate Cancer Network (PCaSO)
- Prostate Cancer UK
- Prostate Help Association (PHA)
- Prostate Scotland

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- Tackle Prostate Cancer