NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

FINAL SCOPE

Rezum for treating benign prostatic hyperplasia

1 Technology

1.1 Description of the technology

Rezum (Boston Scientific) is water vapour therapy for treating lower urinary tract symptoms (LUTS) presumed to be secondary to benign prostatic hyperplasia (BPH). The technology uses the heat from radiofrequency-generated water vapour to ablate excess prostate tissue with the aim of relieving symptoms associated with prostatic obstruction.

The Rezum system uses radiofrequency current to generate wet thermal energy in the form of water vapour (at 103 degrees centigrade), which is injected into the transition zone and/or median lobe of the prostate tissue. The system comprises a portable generator and a delivery device. The water vapour is delivered through a single-use delivery device, which attaches to a urological endoscope (rod lens telescope) into the prostate. The total number of thermal ablations applied in each lobe of the prostate depends on the length of the prostatic urethra and can be customised to the configuration of the gland. The process is intended to disrupt cell membranes, leading to cell death and shrinking in the size of the prostate. The intention is to relieve obstructive symptoms without interfering with surrounding tissues that might impair sexual function.

The procedure is done under local, regional or general anaesthesia and lasts up to 20 minutes, meaning it is suitable for day-case surgery. Rezum is intended for the treatment of prostates with volumes greater than 30 cm^3 (equivalent to 30g). The Rezum system is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

1.2 Regulatory status

Rezum was CE marked as a class IIb medical device in July 2013.

1.3 Claimed benefits

The benefits to patients claimed by the company are:

- Reduction of urinary symptoms associated with BPH
- Quick return to normal activities
- Does not require inpatient hospitalisation
- Fewer procedure related adverse events as compared with TURP
- Lower surgical re-treatment rate as compared with TURP, Greenlight and other minimally invasive procedures
- Preservation of sexual function

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

- Reduction in hospital length of stay (day case procedure)
- Reduction in hospital resource use (theatre operating time, staff and resource)
- Reduction in number and cost of complications
- Minimal training needed for healthcare professionals

1.4 Relevant diseases and conditions

The Rezum is intended to be used to treat men with LUTS presumed to be secondary to benign prostatic hyperplasia (BPH). The NICE guideline on lower urinary tract symptoms defines benign prostatic hyperplasia as histopathologically confirmed hyperplastic change (i.e. abnormality or changes at the cell level) in the prostate. About half of men with BPH will develop benign prostatic enlargement (BPE), which refers to an increase in size of prostate gland.

The prevalence of BPH increases with age. BPH affects about 1 in 3 men over the age of 50. An analysis of the UK General Practice Research Database found that lower urinary tract symptoms suggestive of BPH are

present in 3.5% of men in their 40s and in 35% in their 80s (Logie et al. 2001). LUTS secondary to BPH include poor flow, frequent micturition, urgency, and nocturia. Untreated, BPH can result in urinary tract infection (UTI), acute or chronic urinary retention, and obstructive renal failure. Although LUTS secondary to BPH do not usually cause severe illness, they have a negative impact on quality of life which potentially can include reduced sexual function.

The severity of lower urinary tract symptoms can be assessed using the International Prostate Symptoms Score (IPSS). The IPSS scores patient responses on 6 questions relating to different urinary symptoms the patient might be experiencing including incomplete emptying, frequency, intermittency, urgency, weak stream, straining, and nocturia, plus 1 question related to overall quality of life. Higher scores represent worse symptoms. A symptom score of 0 to 7 is classified as mild, a score of 8 to 19 is classified as moderate, while 20 to 35 is classified as severe.

1.5 Current management

Current management for men with LUTS is outlined in the NICE pathway Lower urinary tract symptoms in men.

The NICE guideline on lower urinary tract symptoms recommends that surgery is only offered when lower urinary tract symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate.

Surgical options recommended for men with BPH include:

- monopolar or bipolar transurethral resection of the prostate (TURP)
- transurethral vapourisation of the prostate (TUVP)
- holmium laser enucleation of the prostate (HoLEP)
- transurethral incision of the prostate (TUIP; only in prostates smaller than 30 g)
- open prostatectomy (only in prostates larger than 80 g)

Minimally invasive treatments such as transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), high-intensity focused ultrasound (HIFU), transurethral ethanol ablation of the prostate (TEAP) and laser coagulation are not recommended by NICE for people with lower urinary tract obstructive symptoms.

NICE medical technologies guidance has been published on the following technologies:

- The TURis system for transurethral resection of the prostate (MTG 23) which is a bipolar electrosurgical system that is recommended in place of monopolar TURP when surgical intervention is indicated for prostatic engagement.

- The UroLift prostatic urethral lift system (MTG 26) which is recommended as an alternative day-case treatment option for LUTS caused by BPH in men aged 50 years and older, who have a prostate of less than 100 ml without an obstructing middle lobe. This can be done in a day-surgery unit.

- The GreenLight XPS (MTG 29) which is recommended for treating benign prostatic hyperplasia in non-high-risk patients, and can also be done as a day-case procedure.

NICE has published interventional procedures guidance on transurethral water vapour ablation (IPG 625) and water jet ablation (IPG 629) for lower urinary tract symptoms caused by benign prostatic hyperplasia. The IPG 625 recommends that transurethral water vapour ablation can be used with standard arrangements for clinical governance, consent and audit.

2 Statement of the decision problem

	Draft scope issued by NICE
Population	Men requiring prostatic surgery to relieve lower urinary tract symptoms due to prostatic hyperplasia with a prostatic volume of greater than 30cm^3 (equivalent to 30g)
Intervention	Rezum
Comparator(s)	• Surgical invasive interventions - monopolar or bipolar transurethral resection of the prostate (TURP); -Holmium laser enucleation of the prostate (HoLEP) - open prostatectomy -Greenlight laser • Minimally invasive interventions such as Urolift
Outcomes	The outcome measures to consider include: Patient outcomes • Relief of symptoms associated with BPH (IPSS) • Maximum flow rates (Qmax) • Residual urine volumes • Benign prostatic hyperplasia impact index (BPHII) • International Prostate Symptom Score Quality of Life (IPSS-QOL) • Quality of life • Preservation of sexual function and urinary continence (ED, erectile dysfunction; IIEF-EF, International Index of Erectile Function-Erectile Function; EF, erectile function domain; MSHQEjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction (EjD); ICS score, International Continence Society score) • Reduction in prostate volume • The need for and/or duration of catheterisation • Medication use • Time to normal daily activities • The number of hospital visits required • Rate of failure to void after initial remove of catheter System outcomes • Length of hospital stay • Rates of surgical or minimally invasive re-treatment for BPH • Healthcare associated infections • Staff time to train to perform the procedure Adverse events • Device-related adverse events. • Rate of dysuria (pain) • Rate of persistent LUTS (poor stream, frequency)

	• Rate of urinary retention • The number of patients required further treatment such as TURP, Greenlight, or a second Rezum • Rate of failure of postoperative catheter removal • Rate of postoperative urinary tract infections	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. Hospital setting should be considered. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	Men for whom surgical invasive procedures such as TURP or HoLEP is unsuitable because of the risks of blood loss or anaesthesia. Men with a prostate size greater than 80 cm^3 (equivalent 80g). Men aged <50 years.	
Special considerations, including those related to equality	The risk of having an enlarged prostate increases with age. Certain groups of men are more prone to prostate enlargement because of being overweight or underlying conditions such as diabetes. Age and disability are protected characteristics under the equality act 2010. The technology may be of particular benefit for those who wish to retain sexual function.	
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 characteristics?	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 MTAC will have relevant information to consider equality issues when developing guidance?	No
	This technology may be particularly beneficial for patients who will not accept blood transfusion.	

3 Related NICE guidance

Published

- NICE clinical guideline 97 (2010) Lower urinary tract symptoms in men: management

- NICE interventional procedure guidance 629 (2018) Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia
- NICE interventional procedure guidance 625 (2018) Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia
- NICE medical technology guidance 29 (2016) GreenLight XPS for treating benign prostatic hyperplasia
- NICE medical technology guidance 26 (2015) Urolift for treating lower urinary symptoms of benign prostatic hyperplasia
- NICE medical technology guidance 23 (2015)The TURis system for transurethral resection of the prostate

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations invited to participate in the evaluation

The following societies have been contacted for expert clinical and technical advice:

- Association for Perioperative Practice
- British Association of Day Surgery
- British Association of Urological Surgeons
- British Prostate Group
- British Urological Group (BUG)
- British Uro-oncology Group
- PSA Prostate Cancer Support Association
- Royal College of Anaesthetists
- Royal College of Surgeons of England
- The Association for Perioperative Practice
- The College of Operating Department Practitioners

4.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of British Healthcare Industries
- Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
- Boston Scientific
- Department of Health and Social Care
- Devices for Dignity
- Greater Manchester Health & Social Care Partnership
- Healthcare Improvement Scotland
- Health Tech Alliance
- Johnson & Johnson Medical Ltd.
- Medical Technology Group
- Medicines and Healthcare Products Regulatory Agency
- NHS England
- The British In Vitro Diagnostics Association (BIVDA)

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Bladder and Bowel UK
- Bladder Health UK
- Men's Health Forum
- Movember Foundation
- Age UK