



Health Technology Review	
Technology Ref.:	HTA21007
Technology Name:	REZUM transurethral water vapor therapy for benign prostatic enlargement
Approvals by International Bodies:	FDA CLEARANCE by FDA U.S. FOOD&DRUG ADMINISTRATION
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Short Description of the Technology:	The Rezūm System is a transurethral thermal therapy that uses sterile water vapor (steam) to treat BPH by delivering targeted, controlled doses of thermal energy directly to the prostate gland, targeting and reducing the obstructive tissue that causes BPH. It is a new minimally-invasive procedure to treat lower urinary tract symptoms (LUTS) associated to benign enlargement of prostate (BPE) and benign prostatic hyperplasia (BPH).
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Health Technology Assessment Team Recommendation:	Approved
Summary of Review:	
Rezum is FDA approved procedure, it's a new technology that treat lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). The procedure is safe and less invasive in comparison with other available technologies for same condition.	
Advantages	Disadvantages
Clinically Effective; Clinical studies demonstrate durable, sustained symptom improvement significantly out to two years, and studies are ongoing to determine longer term patient outcomes and Improve Patient Quality of Life	The Technology is not applicable for all Patients with BPE (Rezum should be avoided in people with prostatitis or confirmed prostate cancer, in people for whom day case treatment is impractical or unsafe, and if there's a risk of increased bleeding, for example if they're having anticoagulant treatment)
Rezum is considered a safe & minimally invasive procedure	The Urologist need specialist training to do the Rezum procedure.
International Approvals such as FDA and CE	
The procedure can be done under local anesthesia or light sedation	
The procedure is quick (<15 minutes)	

Considering Rezum as a day surgery Which reduces the cost of staying at hospital and reduce the recovery time.

We recommend an **approval of using this technology** with the following conditions:

1. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees
2. Applying the procedure on Patients with benign prostatic hyperplasia (BPH) as per the treatment guidelines.
3. To Provide the required specialist training to conduct this procedure
4. Provision of regular updates and reports about the product to DOH upon request.
5. For Insurance coverage, the applicant may address Health System Financing Division in DOH

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image





Rezum Use Criteria

Question	Answer	Comments
Which case?	for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS. Rezum relieves LUTS and improves quality of life.	
Which doctors?	Urology	
Which hospital?	Speciality Hospitals- one day surgery clinic	
Inclusion criteria	<p>Rezum is a minimally invasive procedure. It should be considered as a treatment option for people with:</p> <ul style="list-style-type: none"> • moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over) <p>And</p> <ul style="list-style-type: none"> • a moderately enlarged prostate (typically between 30 cm³ and 80 cm³). 	
Exclusion criteria	The Technology is not applicable for all Patients with BPE (Rezum should be avoided in people with prostatitis or confirmed prostate cancer, in people for whom day case treatment is impractical or unsafe, and if there's a risk of increased bleeding, for example if they're having anticoagulant treatment)	