Australian Government

Department of Health

Application Form

Transurethral water vapour ablation for benign prostatic hyperplasia

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Phone: +61 2 6289 7550
Fax: +61 2 6289 5540
Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): N/A
Corporation name: REDACTED
ABN: REDACTED
Business trading name: REDACTED

Primary contact name: REDACTED

Primary contact numbers
Business: REDACTED
Mobile: REDACTED Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☒ Yes
☐ No

(b) If yes, are you listed on the Register of Lobbyists?

☒ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Transurethral water vapour ablation (TUWA) for benign prostatic hyperplasia (BPH)

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

BPH is one of the most common diseases of the prostate, characterised by an enlargement of the prostate causing the urethra to narrow and place pressure on the base of the bladder. Narrowing of the urethra can cause problems with the passing of urine in several ways. BPH is often associated with lower urinary tract symptoms (LUTS) which in BPH may be obstructive (includes symptoms such as delay or straining when starting to pass urine, and slow flow of urine) or irritative (includes symptoms such as urgent or frequent urination during the day and night). Furthermore, LUTS associated with BPH are often accompanied by sexual dysfunction, including erectile dysfunction (ED) and ejaculatory problems. While not life-threatening, BPH can be detrimental to a patient's quality of life. When symptoms of BPH increase in severity, surgical treatment will be considered. Surgical therapy of the prostate is indicated for patients with severe or high impact symptoms.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The proposed intervention is a minimally invasive transurethral procedure for the treatment of BPH. The Rezūm System uses radiofrequency (RF) current to create and convectively deliver thermal energy to ablate, coagulate and necrose prostate tissue to treat BPH. That is, the RF current is used to create the water vapour which then ablates the prostate. This procedure is different to other minimally invasive procedures currently available on the Medicare Benefits Schedule (MBS), in the way that heat is produced (water) and transferred (convection which means tissue is uniformly heated vs conduction).

6. (a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☐ Amendment to existing MBS item(s)
☒ New MBS item(s)

In October 2018, the Australian and New Zealand Association of Urological Surgeons (ANZAUS) members received clarification on the use of MBS item numbers 37201/37202 based on correspondence the Principal Medical Advisor, Medical Benefits Division, Department of Health. ANZAUS noted the following. "Having *reviewed the item number descriptors appropriate for the usage of Rezum* [TUWA]*, it is felt that item numbers 37201 and 37202 could encompass the technology used in Rezum although it is noted that Rezum does not use radiofrequency energy to ablate the prostate. Rezum uses radiofrequency energy to create the water vapour which then ablates the prostate*. ANZAUS notes that MBS item numbers 37201/2 are restricted to patients who are not medically fit for transurethral resection of the prostate (TURP), and *"[i]f Rezum was to be used in the medically fit for TURP population, another item number would need to be utilised. In this situation consideration should be given to a new MSAC application for this device and technology"* (letter to ANZAUS members attached). This Application proposes that the TUWA procedure (performed by the REZUM system) be used in patients medically fit for TURP. Hence, consistent with the advice from the Principal Medical Advisor, the Applicant is seeking a new MBS item code for the reimbursement of the TUWA procedure.

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

i. ☐ An amendment to the way the service is clinically delivered under the existing item(s)
ii. ☐ An amendment to the patient population under the existing item(s)
iii. ☐ An amendment to the schedule fee of the existing item(s)
iv. ☐ An amendment to the time and complexity of an existing item(s)
v. ☐ Access to an existing item(s) by a different health practitioner group
vi. ☐ Minor amendments to the item descriptor that does not affect how the service is delivered
vii. ☐ An amendment to an existing specific single consultation item
viii. ☐ An amendment to an existing global consultation item(s)
ix. ☐ Other (please describe below):

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

7. What is the type of service:

☒ Therapeutic medical service
☐ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☐ Assists in establishing a diagnosis in symptomatic patients
iii. ☐ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☐ Prosthesis or device
☒ No

The procedure only relies on the Rezum device itself, not on another medical device or prosthesis.

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

☐ Yes
☐ No

(b) If yes, please list the relevant PBS item code(s):

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

☐ Yes (please provide PBAC submission item number below)
☐ No

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name:
Generic name:

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☐ Yes
☐ No

(b) If yes, please provide the following information (where relevant):

Billing code(s):
Trade name of prostheses:
Clinical name of prostheses:
Other device components delivered as part of the service:

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

☐ Yes
☐ No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☒ No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables:
Rezum Delivery Device:
• Sterile Delivery Device with cable and tubing
• Sterile Syringe
• Sterile Spike Adaptor
• 50 ml Sterile Water Vial
Multi-use consumables: N/A

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: 1) Hyperthermia system, radiofrequency and 2) hyperthermia applicator, radiofrequency, intracorporeal
Manufacturer's name: NxThera Inc
Sponsor's name: Innologic Pty Ltd

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☒ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 299127 – Hyperthermia system, radio frequency and 311560 – Hyperthermia applicator, RF, intracorporeal
TGA approved indication(s), if applicable: N/A
TGA approved purpose(s), if applicable: 299127– A transurethral Radiofrequency thermal therapy used to treat benign prostatic hyperplasia (BPH) Radiofrequency generated thermal therapy, in the form of water vapour, is applied directly to the extra prostate tissue. 311560 – a sterile, single use, delivery device, designed for transurethral insertion. Used for the treatment of Benign Prostatic Hyperplasia (BPH)when connected to a Rezum generator.

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

☐ Yes (please provide details below)
☐ No

N/A
Date of submission to TGA:
Estimated date by which TGA approval can be expected:
TGA Application ID:
TGA approved indication(s), if applicable:
TGA approved purpose(s), if applicable:

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

☐ Yes (please provide details below)
☐ No

N/A

Estimated date of submission to TGA:
Proposed indication(s), if applicable:
Proposed purpose(s), if applicable:

PART 4 – SUMMARY OF EVIDENCE

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	RCT, MC, DB	McVary 2016 Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia	The study included 197 men, ≥ 50 years old, with IPSS score of ≥ 13 and prostate size 30-80 cm^3, randomised to TUWA or sham control. After 3 months, sham control subjects crossed over. At 3 months, TUWA patients had achieved statistically significant improvements relative to control with respect to IPSS, Qmax, IPSS QOL score, OAB-q SF bother and HRQL scores. AEs were of mild to moderate severity and most resolved within 3 weeks No de novo erectile dysfunctions were observed.	https://www.ncbi.nlm.nih.gov/pubmed/26614889 NCT01912339	2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.	Long-term follow up of McVary 2016	McVary & Roehborn 2017 Three-Year Outcomes of the Prospective, Randomized Controlled Rezum System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia	The TUWA treatment effect of maximal symptom relief of at least 50% improvement in IPSS, quality of life, Qmax, and BPH Impact Index was sustained over 3 years ($p<.0001$). There was no reporting of late-related AEs and consistent with at 3 months, no de novo erectile dysfunction was observed. The rate of surgical retreatment was 4.4% over 3 years.	https://www.ncbi.nlm.nih.gov/pubmed/29122620	2017

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
	Cross-over study	Roehborn 2017 Convective Thermal Therapy: Durable 2-Year Results of Randomized Controlled and Prospective Crossover Studies for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia	This study reports on 2 years outcomes from the RCT and of the cross over to TUWA. Crossover subject IPSS scores, Qmax and QoL measures were markedly improved after TUWA compared to after the control procedure (p = 0.024 to <0.0001). No de novo erectile dysfunction was reported.	https://www.sciencedirect.com/science/article/pii/S0022534716319826	2017
	Cross-over study	McVary 2019	This abstract reports on 4 years outcomes from patients originally randomised to TUWA and for cross-over patients. The results showed durability of effect with respect to IPSS, Qmax, BPHII and QoL over 4 years. The surgical retreatment rate was 4.4% over 4 years. No late related AEs or de novo erectile dysfunction was reported.	http://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/health-conditions/Enlarged%20Prostate/rezum/PDF/URO-602901-AA-Rezum-McVary-Blue-Bar-New.pdf	2019

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Propensity score matched, cohort study	Gupta 2018 Three-Year Treatment Outcomes of Water Vapor Thermal Therapy Compared to Doxazosin, Finasteride and Combination Drug Therapy in Men with Benign Prostatic Hyperplasia: Cohort Data from the MTOPS Trial	TUWA was compared with daily medial therapy in matched patients with BPH. TUWA improved symptom scores by approximately 50% throughout 36 months ($p < 0.0001$). Symptom improvement was superior than either drug alone but similar to that of combination drugs ($p = 0.02$ and $p=0.73$, respectively). The peak flow rate improved 4- 5 ml/s after TUWA and doxazosin and was statistically superior to finasteride and combination drugs at 12 and 24 months ($p < 0.001$ and <0.01, respectively). Rate of clinical progression was approximately 5 times greater with any medical therapy vs TUWA.	https://www.jurology.com/article/S0022-5347(18)42400-7/pdf	2018

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Prospective, open-label, single arm pilot study	Dixon 2016 Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia	Men aged ≥ 45 years old with an IPSS ≥ 13 and prostate volume 20-120 cm3 were included in this study. Compared with baseline, 24 months after TUWA patients experienced significant improvement in IPSS, QOL, BPHII, Qmax, IIEF-EF and MSHQ-EJD bother scores. Most events were experienced within 30 days of procedure and were transient and mild to moderate. No late procedure related AEs were observed.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5123707/pdf/rru-8-207.pdf NCT02943070	2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	Consecutive, case series, retrospective	Darson 2017 Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezūm system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia	Men aged 47–96 years with prostates 13–183 cm^3 showed significant improvement in IPSS, QoL, and PVR through 12 months after TUWA. Patients with either moderate (IPSS 8–19) or severe (IPSS 20–35) symptoms achieved significantly improved scores. Post-procedure AEs were transient and mild–moderate in nature. No de novo erectile or ejaculatory dysfunction was reported.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5572953/	2017
	Retrospective case series, single centre	Mollengarden 2018 Convective radiofrequency water vapor thermal therapy for benign prostatic hyperplasia: a single office experience.	This study included 129 patients with BPH. IPSS improved from 18.3 at baseline to 6.9 at endpoint, and Qmax improved from 10.5 to 16.8 ml/s. The most common AE was urinary tract infection (17%) and transient urinary retention (14%).	https://www.ncbi.nlm.nih.gov/pubmed/29282358	2018

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

AE, adverse event; HRQL, health related quality of life; IIEF-EF, International Index of Erectile Function-Erectile Function; MSHQ-EJD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; *OAB-q SF, Overactive Bladder Questionnaire Short Form; Qmax=peak flow rate; IPSS, International Prostate Symptom Score; IPSS QOL, International Prostate Symptom Score quality of life score; PVR, postvoid residual volume; QoL, quality of life*

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Single group study	Rezum FIM Optimization (Rezum FIM)	The objective of the study is to evaluate the Rezum system on prostate tissue in subject with LUTS secondary to BPH.	NCT02940392	Recruitment status is unknown. Actual enrolment is 15 patients. This study is unlikely to progress as it started in February 2012.

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Australian and New Zealand Association of Urological Surgeons (ANZAUS). A letter of support will be provided as soon as possible.

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    ANZAUS

21. **List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    No relevant consumer organisations

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    No other relevant sponsors and/or manufacturers produce the Rezum water vapour system used to perform the ablative procedure

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Name of expert 2: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

BPH is a non-cancerous enlargement of the prostate gland, in which smooth muscle and epithelial cells proliferate, which occurs as a natural part of ageing. The exact aetiology is however poorly understood. The enlargement of the prostate may not necessarily constitute a problem to patients unless associated with subjective symptoms such as lower urinary tract symptoms (LUTS). BPH may cause LUTS either by directly obstructing the bladder outlet or by the increased smooth muscle tone and resistance within the enlarged gland. LUTS include symptoms such as increased frequency and urgency of urination, urinating at night, and difficulty starting or stopping urination (Roehrborn 2005). Troublesome LUTS may impact on activities of daily living, reduce patient's quality of life and interfere with sexual function (Rosen et al 2003, Girman et al 1998, Girman et al 1999).

A review of the burden of illness associated with BPH from the UK perspective conducted by Speakman et al (2015) included 33 epidemiological, humanist or economic burden of LUTSA/BPH published between 2001 and 2013. The qualitative review reported major impact of LUTS on the quality of life of patients and their partners. LUTS were found to be associated with high personal and societal costs, both direct medical costs and indirect losses in daily functioning.

The global burden of LUTS suggestive of BPH systematic review and meta-analysis reported a pooled prevalence of 26.2% (95% CI 22.8–29.6%) with estimates varying across studies due to definition of LUTS/BPH, methods, population and geographical location (Lee et al 2017). Similar to this, the prevalence of BPH estimated from the Bettering the Evaluation and Care of Health (BEACH) program in Australia was 21.2% (BEACH 2012). The prevalence of BPH is well known to increase with age peaking in those aged 70 years and older (Lee et al 2017, BEACH 2012).

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

The general practitioner (GP) is responsible for diagnosis and initial management of patients with BPH. However, when the severity of the condition increases, referral to a specialist is warranted. The Andrology Australia 2014 Clinical Summary Guideline for prostate disease, BPH and prostatitis (produced together with Monash University, referred to as Andrology Australia 2014) provide the following indications for referral to a specialist:

- the symptoms become more serious and a patient is defined as 'severely symptomatic'; the patients symptoms significantly impact a patient's quality of life (as score of 5=-unhappy or 6=terrible on the International Prostate Symptom Score [IPSS]);
- the patient has experienced urinary retention, urinary infection or haematuria;
- the patient is non-responsive to treatment;
- there is a risk of prostate cancer; or
- post void residual urine volume on ultrasound exceeds 100 ml.

Surgical therapy (including TUWA) is indicated for patients with severe or high impact symptoms (Andrology Australia 2014). These patients will be managed by a specialist (urologist) with the potential for follow-up to be conducted by the GP.

The proposed population for TUWA include:

- men with severe or high impact symptoms (LUTS) of (BPH)

Rationale

The proposed population is consistent with the PICO for the VLAP application (Application 1518) and with the TUWA evidence. Australian clinical experts advised that the proposed population for TUWA is appropriate and represents the patient who will benefit from the procedure.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

The current management pathway is illustrated in Figure 1. This reflects an amendment of the pathway included in the PICO of Application 1518 (VLAP).

Management of LUTS secondary to BPH is dependent on the severity of symptoms assessed using the IPSS score, patient age and comorbidities. When symptoms are mild or low impact, patients are managed with watchful waiting and lifestyle changes. However, upon progression to moderate symptoms patients may be managed with medical therapies. The types of medial therapy used is dependent on the symptoms and patient co-morbidities but may include alpha blockers and 5-alpha-reductase inhibitors.

Whilst, the general practitioner (GP) is responsible for diagnosis and initial management of patients with BPH, patients with severe or high impact symptoms should be referred to a specialist. Patients may be diagnosed initially with sever or high impact symptoms, or as symptoms severity increase despite management with medical treatment. Over time, as the prostate enlarges over time, it is common for LUTS of BPH to progress from mild to moderate and eventually to severe impact (illustrated by the dotted lines in Figure 1).

The EAU guidelines recommend surgical treatment for men that experience bothersome LUTS refractory to conservative or medical therapy or in cases of absolute indications for surgery. Decision making is dependent on the patient's prostate size, cardiovascular risk and ability to have anaesthesia (EAU 2016). In patients with prostates 30-80 ml, TURP is the mainstay surgical options, with open prostatectomy mostly considered for substantially enlarged glands (>80-100 ml).

The updated pathway provided in Figure 1 includes TUWA as alternate treatment option to HoLEP, VLAP and TURP in patients with enlarged prostates with severe or high impact symptoms that are suitable for the respective treatments. Prostatic urethral lift (PUL) is also included as an alternative treatment option given the minimally invasive nature of the procedure, like TUWA, and the increased utilisation of this treatment option on the MBS (refer to Part 6). The inclusion of PUL is discussed further in comparator nomination addressed in Question 38 (pg. 22).

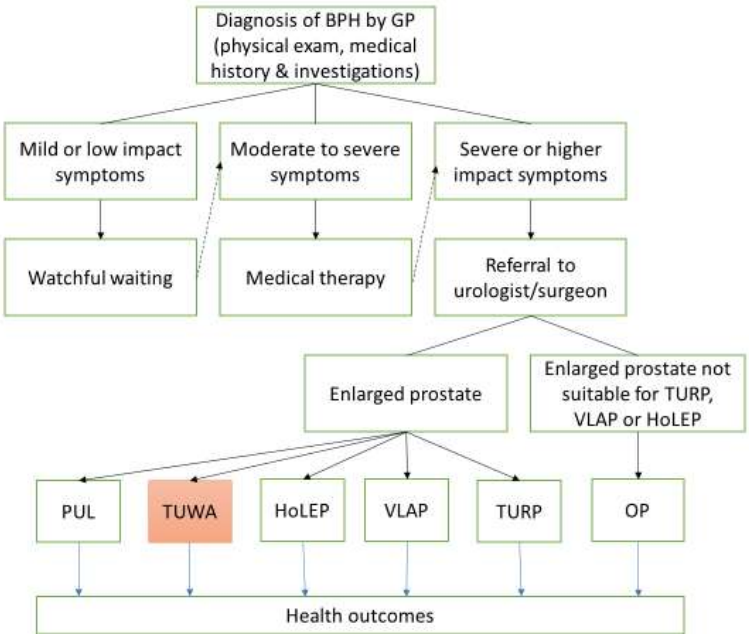

Figure 1 Current and proposed clinical management algorithm for the proposed population

Nb. The proposed change to the pathway, that is introduction of TUWA, is indicated by an orange box in the algorithm.

Abbreviations: HoLEP, holmium laser enucleation of the prostate; OP, open prostatectomy; TURP, transurethral resection of the prostate; TUWA, transurethral water ablation, VLAP, visual laser ablation of the prostate.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

The Rezūm Therapy System consists of a portable RF generator and a cystoscopic instrument (Figure 2) to deliver the ablative thermotherapy treatment created using RF current to the prostate tissue in a transurethral approach. The generator includes an RF power supply and has a number of safety features to ensure proper heating and thermal ablation of the targeted prostate tissue, whilst protecting the urothelium during treatment.

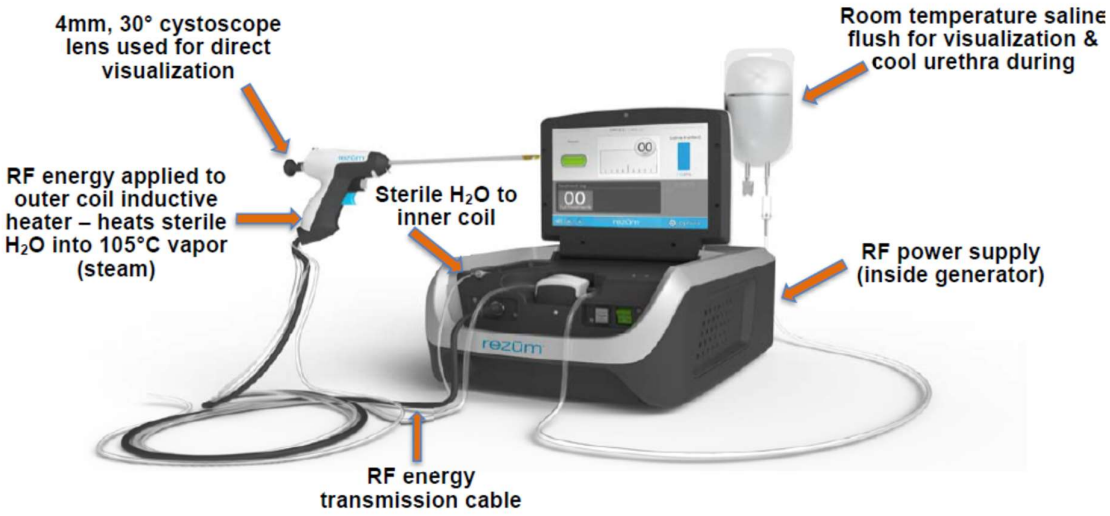

Figure 2 Rezum system for BPH

The RF power supply in the generator applies RF current to an inductive coil heater in the handle of the device and 0.45 mL of sterile water flowing through the coil is instantly heated to create thermal energy in the form of steam, or water vapour.

The sterile cystoscopic instrument portion of the Rezūm System is inserted in a transurethral approach, and the thermal energy is convectively dispersed directly into the targeted areas of the prostate tissue through twelve 0.012 vapor emitter holes that are concentrically located in rows of 4 at 120° around the distal end of the vapor treatment needle which is deployed into the prostate tissue. Each treatment convectively and circumferentially disperses the thermal energy to create a 1.5 to 2.0 cm lesion in the tissue by raising the tissue temperature in the treatment area to between 70° to 80°C, causing cell death and coagulative necrosis.

Within the prostate, the thermal energy released through condensation of the steam, or vapor, is contained by the pseudocapsules, or densified tissue membranes within the prostate which separate each of the anatomical zones or regions of the prostate (transition zone, central zone and peripheral zone). In addition, the prostate has a thick collagen outer external capsule. The density of these membranes contains the convective thermal energy within area of treatment.

Figure 3 provides an illustration of how the thermal energy of a treatment with the Rezum System is delivered directly to the prostate tissue in a transurethral approach.

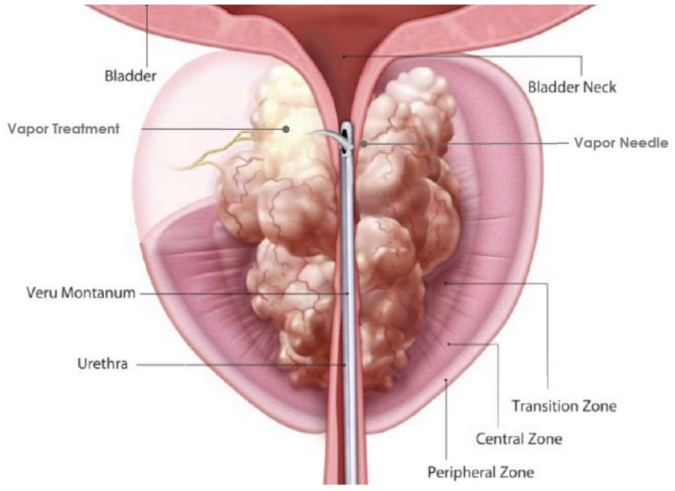

Figure 3 Rezum procedure

Each treatment takes 9 seconds and provides immediate and irreversible cell death. After each treatment, the needle is retracted 1 cm and repositioned several times so that thermoablation can be repeated in different areas of the gland, including the median lobe.

Because vapor ablation does not rely on the thermal conductivity of tissue to diffuse heat, it is not subject to the physics or biological limitations of using tissue to conduct or diffuse heat in order to cause tissue cell necrosis. Therefore, the convective transfer of thermal energy via vapor, unlike the conduction or diffusion of heat energy, is not affected by the thermal conductivity or property of tissue.

Thermocouples in the cystoscopic instrument monitor temperatures to ensure consistent delivery of thermal energy into the ablation region while preserving the prostatic urethra. The system operator deploys the treatment needle into the prostate (one centimetre - there is no variation in depth of treatment needle deployment), and views deployment of the treatment needle through a cystoscopic lens in the instrument.

TUWA is mostly performed as day-case surgery using local anaesthetic such as a peri-prostatic block, and sometimes sedation.

As a precaution, anticoagulation should be stopped prior to the procedure (continuation of aspirin is acceptable). The patient will have a catheter for a few days post procedure (on average 3 days; McVary et al 2016).

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No, the proposed medical service does not include a registered trademark component.

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

N/A

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

There are no limitations on the provision of the proposed medical service in relation to dosage, quantity, duration or frequency. Accessibility is limited by the availability of the Rezum system at the treatment centre.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

No other services need to be delivered at the same time as TUWA.

32. If applicable, advise which health professionals will primarily deliver the proposed service:

Urologists are the health professionals that will deliver the service.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not applicable

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Not applicable

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

Urologists will undergo a training program, provided by Boston Scientific, that involves education material, a Rezum simulator course and support at 10 procedures.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- ☒ Inpatient private hospital
- ☒ Inpatient public hospital
- ☐ Outpatient clinic
- ☐ Emergency Department
- ☐ Consulting rooms
- ☒ Day surgery centre
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The proposed procedure may be performed in the inpatient setting, or more commonly in the day surgery clinic setting. The procedure is generally performed under local anaesthetic and does not require the patient to stay in hospital overnight.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The nominated comparators to TUWA for the proposed patient population are TURP and PUL.

There are several surgical procedures indicated for BPH on the MBS as outlined in Table 1, including transurethral resection of the prostate (TURP), visual laser ablation of the prostate (VLAP) or photoselective vaporization of the prostate [PVP]), holmium laser enucleation of the prostate (HoLEP), transurethral needle ablation (TUNA) and transurethral microwave therapy (TUMT). The most frequently used service in 2017 was TURP procedures (11,266).

Based on the proportion of total services used for BPH, it is clear that TURP has continued to remain the most common surgical treatment for BPH in Australia with approximately 70% of BPH procedures performed in 2017 being TURP procedures. This is unsurprising given TURP has long been considered the gold standard treatment for BPH being as effective as open prostatectomy and associated with less morbidity (AUA, 2010).

VLAP, TUNA, TUMT and HoLEP are minimally invasive procedures listed on the MBS in 1995, 2002, 2006 and 2013 respectively. In 2017 only two and four TUMT and TUNA procedures were utilised on the MBS respectively, confirming these are not relevant comparators to TUWA. Of the minimally invasive procedures, VLAP is associated with the highest utilisation followed by HoLEP (15.4% and 5.8% respectively).

Another procedure, similar in level of invasiveness, duration and complexity to that of TUWA, is the PUL procedure, which involves the transurethral insertion of small, permanent UroLift implants. The UroLift implants are positioned in the prostate to retract the lateral lobes and thereby reduce the obstruction of the urethra. This procedure has not been formally evaluated by MSAC, however is listed on the Prosthesis List (billing code TX055). According to key opinion leader feedback, the PUL procedure is currently claimed using MBS item code 36811 (CYSTOSCOPY with insertion of urethral prosthesis). The utilisation of MBS item code 36811 over time shows that the utilisation has increased sharply from around 2012/2013, coinciding with UroLift being registered for used in Australia in August 2012 (ARTG 200361), with the utilisation in 2017 being 1,275 services making this procedure the third most utilised after TURP (70%) and VLAP (15%) at 8% of the market share (**Error! Reference source not found.**). It is acknowledged that MBS item code 36811 was not intended for the PUL procedure, and as such, the MBS utilisation data does not only reflect the use of PUL services. However, given the low utilisation prior to 2012/2013 it may be assumed that the vast majority of services utilised in the last few years are PUL procedures.

Table 1 Available surgical procedures on the MBS

Intervention	MBS item number and description	Current fee	Utilisation Jan 17-Dec 17 (%)
Invasive surgical interventions			
Open prostatectomy	MBS Item 37200 PROSTATECTOMY, open (Anaes.) (Assist.)	Fee: $1,016.30 Benefit: 75% = $762.25	110 (0.7)
TURP	MBS Item 37203 PROSTATECTOMY (endoscopic, using diathermy or cold punch), with or without cystoscopy and with or without urethroscopy, and including services to which item 36854, 37201, 37202, 37207, 37208, 37245, 37303, 37321 or 37324 applies (Anaes.)	Fee: $1,042.15 Benefit: 75% = $781.65	11,266 (70.1)
Minimally invasive interventions			
VLAP/PVP	MBS Item 37207 PROSTATE, endoscopic non-contact (side-firing) visual laser ablation, with or without cystoscopy and with or without urethroscopy, and including services to which items 36854, 37201, 37202, 37203, 37206, 37245, 37321 or 37324 applies	Fee: $866.45 Benefit: 75% = $649.85	2,466 (15.4)

Intervention	MBS item number and description	Current fee	Utilisation Jan 17-Dec 17 (%)
	(Anaes.)		
HoLEP	MBS Item 37245 Prostate, endoscopic enucleation of, using high-powered Holmium: YAG laser and an end-firing, non-contact fibre, with or without tissue morcellation, cystoscopy or urethroscopy, for the treatment of benign prostatic hyperplasia, and other than a service associated with a service to which item 36854, 37201, 37202, 37203, 37206, 37207, 37208, 37303, 37321, or 37324 applies. (Anaes.)	Fee: $1,262.15 Benefit: 75% = $946.65	937 (5.8)
TUNA	MBS Item 37201 PROSTATE, transurethral radio-frequency needle ablation of, with or without cystoscopy and with or without urethroscopy, in patients with moderate to severe lower urinary tract symptoms who are not medically fit for transurethral resection of the prostate (that is, prostatectomy using diathermy or cold punch) and including services to which item 36854, 37203, 37206, 37207, 37208, 37245, 37303, 37321 or 37324 applies (Anaes.)	Fee: $828.85 Benefit: 75% = $621.65	4 (0.02)
TUMT	MBS item 37230, 37233 PROSTATE, high-energy transurethral microwave thermotherapy of, with or without cystoscopy and with or without urethroscopy and including services to which item 36854, 37203, 37206, 37207, 37208, 37303, 37321 or 37324 applies	Fee: $1,042.15 Benefit: 75% = $781.65; 85% = $961.9	2 (0.01)
PUL (and other procedures)	36811 CYSTOSCOPY with insertion of urethral prosthesis	Fee: $323.40 Benefit: 75% = $242.55; 85% = $274.9	1,275 (7.9)

Abbreviations: HoLEP, Holmium Laser Enucleation of the prostate; MBS, Medicare Benefits Schedule; PVP, Photoselective Vaporization of the Prostate; TUNA, Transurethral needle ablation; TUMT, Transurethral microwave therapy; TURP, Transurethral resection of the prostate; VLAP, visual laser ablation of the prostate.

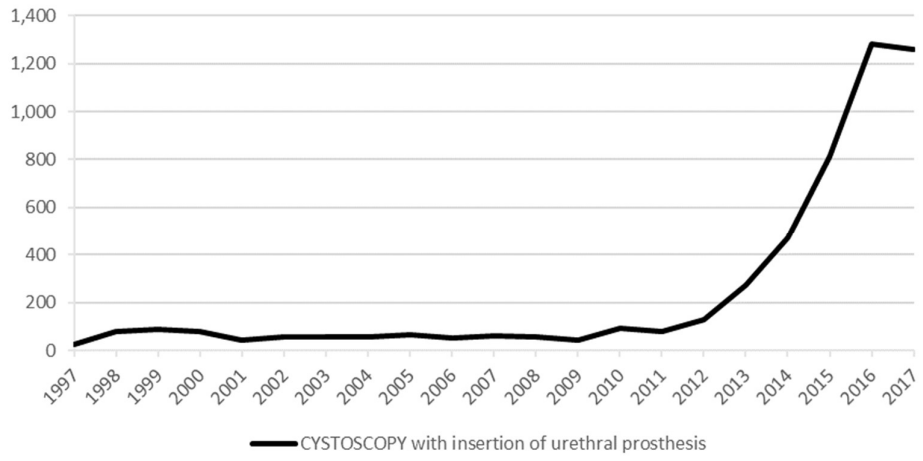

Figure 4 Utilisation of MBS item 36811 over time

It should be noted that, health funds do not routinely fund medical devices that are non-implantable but that are critical to achieving therapeutic outcomes of the procedure. For example, the TUWA procedure is dependent on the delivery device which is, by definition of not being implantable, not a prosthesis and ordinarily not eligible for listing on the Prosthesis List. In contrast, procedures that are dependent on a prosthesis, such as UroLift, may be favoured over procedures that involve a non-implantable medical device based on the funding arrangement in place for prostheses in Australia. Thus, there appears to be a need for the Australian health care system to provide appropriate funding mechanisms for medical devices that are non-implantable to ensure treatment options are determined based on clinical decisions, rather than on financial reasons.

Rationale

Given the high utilisation of TURP on the MBS, it is likely that TUWA procedures will substitute from TURP procedures should it be listed on the MBS and as such, TURP is a nominated comparator. PUL is also a nominated comparator given it represents a minimally invasive procedure that is similar in level of invasiveness and with an increasing utilisation on the MBS. Although VLAP is the minimally invasive procedure most frequently used on the MBS, and may represent an alternative comparator, this procedure is more invasive than TUWA. Furthermore, MSAC Application 1518 for VLAP supported non-inferiority to TURP. As such, an inference of relative effectiveness and safety of TUWA versus VLAP can be made based on a deductive argument utilising Application 1518.

39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

☒ Yes (please provide all relevant MBS item numbers below)
☐ No

TURP – 37203

PUL – 36811

40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

After the patient has undergone TURP or PUL, he will be followed up either by the urologist/surgeon or referred to a GP for follow-up. The Andrology Australia Clinical Summary Guide (2014) recommends follow up at 6 weeks, 12 weeks and 6 months in the first year after surgery, and annually thereafter.

Patients should be assessed for symptoms at follow up to assess effectiveness and failure to cure. Failure to cure may result in reintervention.

Roehrborn et al (2017) reported a 5-year surgical retreatment rate of 13.6% (19/140) in PUL subjects. Surgical retreatment consisted of 4.3% (6/140) receiving additional PUL implants and 9.3% (13/140) undergoing TURP or laser ablation. Based on the 12-month data from the head to head comparison of PUL versus TURP in patients with BPH, the reintervention rate for failure to cure was 6.8% (3/44) in PUL-treated subjects and 5.7% (2/35) of TURP-treated subjects.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☒ Yes
☐ No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

The proposed service will be used instead of the nominated comparators. Refer to Q49-50.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

After the patient has undergone TUWA, he will be followed up either by the urologist/surgeon or referred to a GP for follow-up. The Andrology Australia Clinical Summary Guide (2014) recommends follow up at 6 weeks, 12 weeks and 6 months in the first year after surgery, and annually thereafter.

Patients should be assessed for symptoms at follow up to assess effectiveness of the procedures. McVary et al (2017) reported a 3-year retreatment rate of 4.4% (6/135) with one subject having an open prostatectomy, three had a plasma-button transurethral vaporisation of the prostate and two were retreated with TUWA.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

It is expected that the TUWA procedure will produce similar efficacy outcomes with respect to the International Prostate Symptoms Score (IPSS) and maximum flow rate (Q_{max}) relative to TURP, with similar safety. However, TUWA is associated with reduced resource utilisation relative to TURP, given TUWA can be performed as a day procedure whereas the TURP procedure is associated with hospitalisation, benefiting both patients and treatment centres.

It is expected that the TUWA procedure will produce similar efficacy outcomes with respect to the IPSS and Q_{max} relative to PUL, with similar safety. TUWA is expected to be associated with similar resource utilisation relative to PUL.

44. Please advise if the overall clinical claim is for:

☐ Superiority
☒ Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

• Immediate complications

Bleeding

Acute urinary retention

Infection

TURP syndrome (dilutional hyponatraemia)

Mortality

• Longer term complications

Urethral stricture

Erectile dysfunction

Urinary incontinence

Clinical Effectiveness Outcomes:

• Symptom severity related to LUTS – IPSS, AUA-SI

• Peak flow (Qmax)

• Post-void residual volume

• Prostate volume

• Quality of life

• Treatment failure rate

• Re-treatment rate

Resource utilisation

• Length of hospital stay

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

A combined lifetime prevalence estimate of BPH of 26.2% (95% CI: 22.8 – 29.6%) was published by Lee et al (Lee, Chan & Lai 2017), pooled from 25 studies using objective measures. According to Lee et al prevalence increased with age, but there was no difference found between rural, urban or mixed sites; countries; respondent representativeness; sample size; or study quality.

The prevalence of diagnosed BPH estimated from the Bettering the Evaluation and Care of Health (BEACH) program in Australia was 21.2% (95%CI 17.3, 25.1) overall, with estimates varying by age (Figure 5) (BEACH 2012). The BEACH data were based on 707 male patients aged 40 years or older, of whom 150 had been diagnosed with BPH. Of the 243 symptomatic respondents in the BEACH data cohort, 44.9% (109 patients) were being treated for LUTS, and 41% of those being treated (45 patients) were taking medications (BEACH 2012).

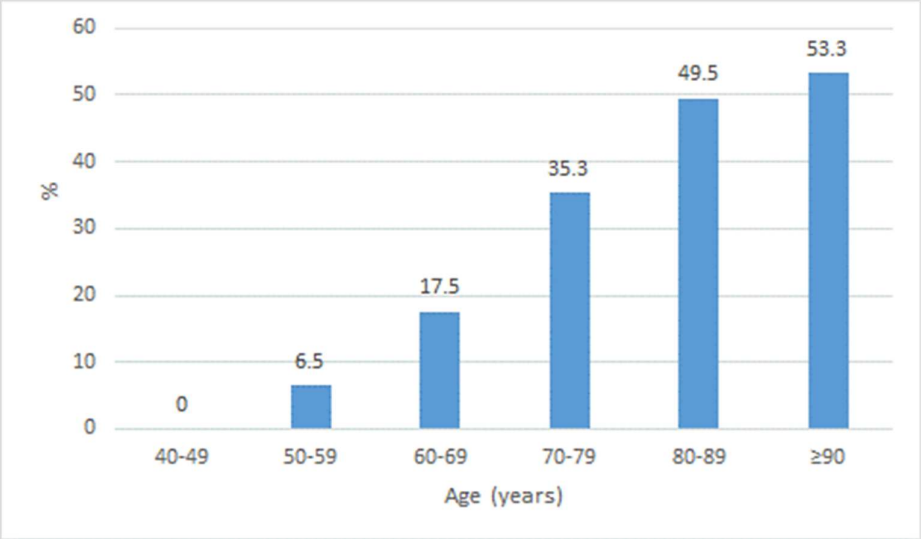

Figure 5 Prevalence of BPH by age

Source: BEACH 2012. Benign prostatic hyperplasia (BPH) among male general practice patients aged 40 years or older. SAND abstract 190 from the BEACH program: FRMC University of Sydney, 2012
BEACH = Bettering the Evaluation and Care of Health; BPH = benign prostate hyperplasia; FRMC = Family Medicine Research Centre, University of Sydney; IPSS = International Prostate Symptom score; LUTS = lower urinary tract symptoms; SAND = Supplementary Analysis of Nominated Data

Epidemiological data reported that LUTS resulting from BPH affects an estimated 70% of men aged between 61 and 70 years, and 90% of those aged 81 to 90 years (Nickel 2006). LUTS prevalence was also found to increase with age in estimates pooled across 25 studies by Lee et al. LUTS was defined as moderate or severe symptoms (IPSS or AUA-SI >7) in Lee et al's study, but authors commented on the presence of heterogeneity amongst the studies in methodology and definitions. Data can be seen in Table 2.

Table 2 Prevalence of men with moderate to severe symptoms of LUTS/BPH by age group (Lee, Chan & Lai 2017)

Age range	Prevalence of LUTS (IPSS or AUA-SI >7)
40-49 years	14.8%
50-59 years	20.2%
60-69 years	29.1%
70-79 years	36.8%
≥ 80 years	38.4%

AUA-SI = American Urological Association Symptom Index; BPH = benign prostate hyperplasia; IPSS = International Prostate Symptom score; LUTS = lower urinary tract symptoms

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

TUWA procedures are intended to be delivered once per patient. However, it is acknowledged that as with other BPH treatments TUWA is associated with a rate of reintervention. A key TUWA study, a double-blinded sham control study (McVary 2017), reports a 3-year reintervention rate of 4.4% (6/135) across 135 patients. As such, it is estimated that TUWA patients will require 0.015 (4.4%/3) reinterventions per patient per year subsequent to a single primary TUWA procedure.

For comparison, an overview of reintervention rates is reported for comparator procedures as presented in Table 3.

Table 3 Reintervention rates due to adverse events

Treatment	1 year	3 years	5 years	Source
TUWA		4.4%		McVary 2017
PUL	5.0% [6.8%]	10.7%	13.6%	Roehrborn 2017 [Sonksen 2015]
TURP	[14.3%]		5.8%-7.0%	Roehrborn 2017 [Sonksen 2015]

Abbreviations: PUL, prostatic urethral lift; TURP, transurethral resection of the prostate; TUWA, transurethral water vapour ablation

48. How many years would the proposed medical service(s) be required for the patient?

As per question 47, only one procedure per patient is expected.

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

A market share approach is employed in estimating the potential utilisation of TUWA in the first year of MBS listing (based on 2020 listing). Considering a market including MBS items 37200 (open prostatectomy - OP), 37201 (TUNA), 37203 (TURP), 37207 (PVP), 37230 (TUMT) and 37245 (HoLEP), the BPH intervention market is estimated to have included 14,785 procedures in 2017.

Table 4 Utilisation of BPH procedures listed on the MBS in 2017

	OP	TUNA	TURP	PVP	TUMT	HoLEP	Total
MBS utilisation	110	4	11,266	2,466	2	937	14,785

Applying a linear trendline and extrapolating market services, as illustrated in Figure 6, results in an estimated BPH market size of 15,333 in 2020.

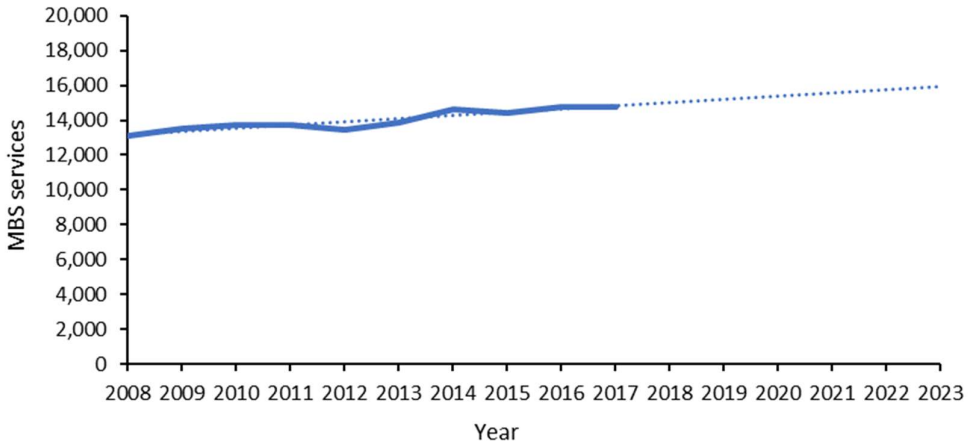

Figure 6 Linear extrapolation of historical utilisation of BPH procedures on the MBS

It is noted that this does not include PUL (UroLift) procedures as there is currently no MBS item specific to PUL in BPH. As outlined in Question 38, KoL advice indicates that current PUL utilisation is likely claimed under item 36811, for cystoscopy with insertion of urethral prosthesis. As presented in Figure 7, historically between 2000 and 2011 the number of cystoscopies accessed via the MBS had remained steady between 41 and 92 procedures per year, with an average of 61 per year. From 2012 to 2017 a pattern of market growth emerged with service numbers increasing from 78 in 2011 to 1,283 in 2016, subsequently stabilising in 2017.

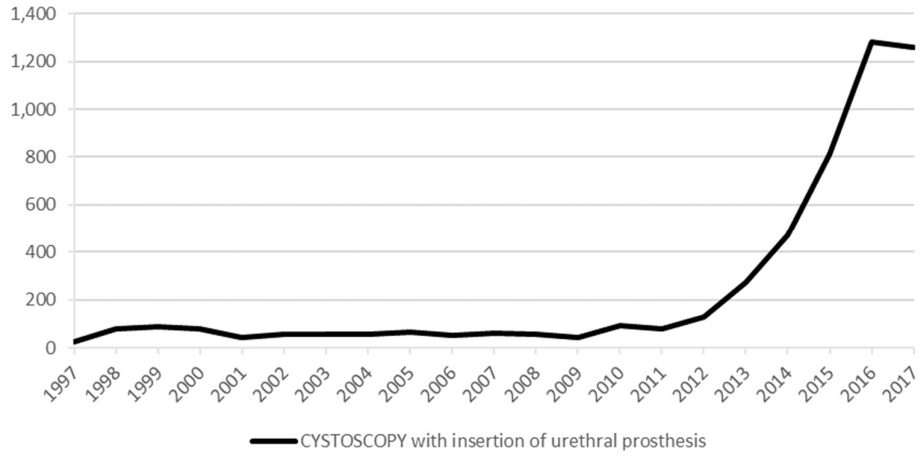

Figure 7 Historical utilisation of MBS item 36811 for cystoscopy

Based on KoL advice it is expected that this market growth, coinciding with the registering of the UroLift procedure on the ARTG in 2012, is a result of PUL procedures being claimed under MBS item 36811.

Considering the increase from an average of 61 procedures between 2000 to 2011 to 1,270 procedures across 2016 and 2017, PUL is considered to have a market size of approximately 1,200 procedures per year. Adding 1,200 PUL procedures to the previously estimated BPH market (15,333 procedures) results in a total estimated BPH market of 16,533 procedures in 2020.

MBS listing of TUWA is not expected to impact the demand for BPH interventions due to the extensive treatment options currently available. Thus, uptake of TUWA in 2020 is expected to be derived solely from substitution within the estimated 16,533 BPH procedures. Initial uptake in year 1 is expected to be

limited due to the capital costs associated with the procedure. As noted in Question 51, TUWA requires a capital investment of $ REDACTED for the purchase of a portable RF generator. These capital costs are expected to delay uptake as hospitals/practices decide whether to invest their time and capital in TUWA over alternative BPH therapies. Therefore, it is assumed that TUWA listing will result in a year 1 uptake rate of 2.5% of the total BPH market, estimated at 413 (16,533*2.5%) MBS services.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

The same methodology presented in Question 49 is used to extrapolate BPH service estimates over the next 3 years of TUWA listing (subsequent to the 1st year of listing). As presented in Table 5, total BPH services are estimated to increase from 16,533 in year 1 to 17,081 in year 4. As noted in Question 49, 2.5% uptake is expected for TUWA in the first year of MBS listing. Uptake is expected to increase linearly over the next 3 years of listing as additional hospitals/practices invest in the technology (Note: it is proposed that uptake is likely to plateau at some point outside the requested time period). Substantial uptake is considered reasonable in the long term for TUWA due to the minimally invasive nature of the procedure, namely the 15-minute procedure duration and same-day hospitalisation. Therefore, assuming increasing uptake rates of 5% (year 2), 7.5% (year 3) and 10% (year 4) results in estimated TUWA utilisation of 836, 1,267 and 1,708 services in year 2, 3 and 4 respectively (Table 5).

Table 5 Estimated TUWA services across the first 4 years of MBS listing

	2020 (Year 1)	2021 (Year 2)	2022 (Year 3)	2023 (Year 4)
Total BPH market	16,533	16,716	16,898	17,081
Uptake rate	2.5%	5.0%	7.5%	10%
Estimated TUWA services	413	836	1,267	1,708

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

An estimated cost of providing TUWA services is provided, including expected consumable, capital, anaesthesia, medical service and hospitalisation costs. It is intended to provide an understanding of the resource use involved (e.g: MBS items and hospital resources) and to a lesser extent the magnitude of the costs associated with these resources which will be fully detailed in the SBA.

TUWA procedures require the use of a disposable delivery device. Based on KoL advice a cost of $ REDACTED per procedure is estimated for this device.

TUWA procedures also require a portable RF generator incurring a capital cost to hospitals/practices that wish to perform these procedures. The Applicant estimates a cost per portable generator of $ REDACTED, which when amortised over an assumed 10-year product life results in an estimated cost of REDACTED per year. Assuming 50 services are performed per practice per year, and applying a 5% interest rate, each TUWA procedure is attributed a capital cost of $ REDACTED (Table 6).

Table 6 Capital cost calculations for TUWA

Row	Parameter	Input	Reference
A	Cost of portable generator	REDACTED	Applicant
B	Life of generator, years	10	Whitty et al. 2014
C	Applied interest rate	5%	Assumption
D	Amortised cost of capital per year	REDACTED	$\frac{A \times C}{1-(1+C)^{-B}}$
E	Estimated services per service per year	50	Assumption
F	Capital cost per TUWA procedure	REDACTED	D/E

The majority of TUWA procedures are expected to be performed under local anaesthesia. This is supported in McVary 2017 which reports oral sedation in 69% of TUWA patients, prostate block in 21% and intravenous sedation in 10%. Applying MBS costs to these anaesthesia distributions results in a total estimated cost of anaesthesia of $46.85 per procedure (Table 7).

Table 7 Anaesthesia costs for TUWA

Row	Parameter	Input	Reference
A	% nerve block	21%	McVary 2017
B	Lumbar or thoracic nerve anaesthesia (paravertebral nerve block)	$147.65	MBS 18286
C	% general anaesthesia	10%	McVary 2017
D	Time unit cost (0-15 minutes)	$19.80	MBS 23010
E	Initiation and management cost	$138.60	MBS 20914
F	Total anaesthesia costs	$46.85	A*B + C*(D+E)

TUWA is proposed to be a day procedure performed in a day hospital setting. Therefore, hospitalisation costs associated with TUWA are expected to be minimal. A day bed cost has been applied for TUWA procedures based on same day accommodation fees for privately admitted patients in NSW (NSW Health 2018). Same day fees are based on procedure bands which in turn are based on anaesthesia use and duration of procedure. For TUWA, a weighted average of Band 2 (procedures performed under local anaesthesia) and Band 3 (procedures performed under block/general anaesthesia less than 1-hour duration) costs are applied, resulting in an estimated hospitalisation cost of $299 per procedure (Table 8).

Table 8 Hospitalisation costs for TUWA

Row	Parameter	Input	Reference
A	Proportion Band 2 (local anaesthesia)	69%	Table 7
B	Day bed cost of Band 2 procedures	$290	NSW Health 2018[a]
C	Proportion Band 3 (block/general anaesthesia under 1 hour) [b]	31%	Table 7
D	Day bed cost of Band 3 procedures	$318	NSW Health 2018[a]
E	Weighted average day bed cost for TUWA	$299	A*B+C*D

[a] NSW Health. Health Services Act 1997 - Scale of Fees for Hospital and Other Services. July 2018
[b] As noted in Question 52 all TUWA procedures are expected to be performed within 15 minutes.

Combining capital, consumable, anaesthesia and hospitalisation costs, TUWA is estimated to cost REDACTED per procedure (Table 9).

The proposed fee for TUWA is based on the fee for TUNA (MBS item 37201). This is justified based on advice from the Principal Medical Advisor (Medical Benefits Division, Department of Health, Dr John Primrose) that in correspondence to UZANZ noted that "*it is felt that item numbers 37201 and 37202 could encompass the technology used in Rezum although it is noted that Rezum does not use radiofrequency energy to ablate the prostate. Rezum uses radiofrequency energy to create the water vapour which then ablates the prostate"* (Letter to ANZAUS members attached). It is acknowledged that the TUNA code is restricted to patients who are not medically fit for TURP, and the proposed TUWA code is not. The proposed fee will be further justified in the submission-based assessment in consideration of resource utilisation, complexity and clinical outcomes.

Table 9 Estimated cost of TUWA services

Row	Parameter	Cost	Reference
A	Capital	REDACTED	Table 6
B	Consumable	REDACTED	KoL advice
C	Anaesthesia	$47	Table 7
D	TUWA procedure	$829	Proposed
E	Hospitalisation	$299	Table 8
F	Total	REDACTED	A+B+C+D+E

52. Specify how long the proposed medical service typically takes to perform:

KoL advice indicates that TUWA procedures take no longer than 15 minutes, whilst NICE reported that procedures last up to 20 minutes (NICE 2018). It is noted that this is shorter than comparator treatments including PUL (25 minutes; NICE 2016) and TURP (39.3 minutes; Bachman 2014)).

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

The proposed MBS item descriptor for the TUWA procedure is provided below. As noted above, the proposed fee is based on the fee for the MBS item code for the TUNA procedure (37201).

Category 3 – THERAPEUTIC PROCEDURES
#####
PROSTATE, ablation by water vapour with or without cystoscopy and with or without urethroscopy
Fee: $828.85

REFERENCES

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