



Australian Government

Department of Health

MSAC Application 1612

**Prostatic urethral lift procedure for
men with benign prostate
hyperplasia**

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: Teleflex Medical Australia Pty Ltd.

ABN: 74 096 142 675

Business trading name: Teleflex Medical Australia Pty Ltd.

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

Prostatic urethral lift (PUL) procedure for men with benign prostate 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 non-cancerous 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 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). 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. (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)

(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:

MBS Item 36811

CYSTOSCOPY with insertion of urethral prosthesis

Multiple Operation Rule

(Anaes.) Fee: \$328.55 Benefit: 75% = \$246.45 85% = \$279.30

(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:

Prostheses List listing

6. 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

7. 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

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

- Pharmaceutical / Biological
- Prosthesis or device
- No

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

N/A

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

Insert PBS item code(s) here

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

N/A

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

N/A

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

- Yes
- No

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

Billing code(s): TX055

Trade name of prostheses: UroLift® System

Clinical name of prostheses: UroLift® System

Other device components delivered as part of the service: n/a

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

N/A

(c) 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

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

N/A

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

Single use consumables: n/a

Multi-use consumables: n/a

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

12. (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: UroLift® System

Manufacturer's name: Neotract Inc

Sponsor's name: Teleflex Medical Australia 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

13. (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: 200361

TGA approved indication(s), if applicable: Prostatic retraction implant

TGA approved purpose(s), if applicable: The UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50.

14. 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?

N/A

PART 4 – SUMMARY OF EVIDENCE

15. 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.	Prospective, multi-center, randomized, blinded sham control trial	Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study.	206 subjects ≥ 50 years old with International Prostate Symptom Score (IPSS) > 12, peak flow rate (Qmax) ≤ 12 mL/s, and prostate volume 30 cc-80 cc were randomized 2:1 to the PUL procedure or blinded sham control. In PUL permanent UroLift implants are placed to hold open the lateral lobes of the prostate to reduce urinary obstruction.	https://www.canjurol.com/html/free-articles/V24I3_08_FREE_DrRoehrborn.pdf	June 2017 Initial trial pub dated Dec 2013
2.	Prospective, multicentre, head-to-head, randomized study	Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study.	A total of 80 patients with lower urinary tract symptoms attributable to benign prostatic hyperplasia (BPH) were enrolled to compare prostatic urethral lift (PUL) with transurethral resection of the prostate (TURP) with regard to symptoms, recovery experience, sexual function, continence, safety, quality of life, sleep and overall patient perception.	https://onlinelibrary.wiley.com/doi/epdf/10.1111/bju.13714	May 2017 Initial trial pub dated Oct 2015
3.	Real-world, retrospective, multicenter study	Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study.	Outcomes within a large unconstrained multicenter data set. Retrospective chart review and analysis of 1413 consecutive patients who received PUL in North America and Australia. Compared with the randomized controlled prostatic urethral lift (L.I.F.T.) study.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6657298/pdf/end.2019.0167.pdf	July 2019

* 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.

16. 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.	n/a				

* 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

- 17. 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):**

Urological Society of Australia and New Zealand (USANZ), Australian and New Zealand Association of Urological Surgeons (ANZAUS)

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

Urological Society of Australia and New Zealand (USANZ), Australian and New Zealand Association of Urological Surgeons (ANZAUS)

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

n/a

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

n/a

- 21. 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**

Name of expert 2: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **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), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

22. 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:

The prostate gland is an organ approximately the size of a walnut that is located below the urinary bladder encircling the urethra (Leissner 1979). Benign prostatic hyperplasia (BPH) is a histological diagnosis defined as an increased number of epithelial and stromal cells in the prostate; this may cause prostatic enlargement and subsequently compression of the urethra and obstruction (Roehrborn 2008a). Therefore, BPH may develop with or without lower urinary tract symptoms (LUTS) in men over the age of 40 years (Dunphy 2015). BPH receives clinical significance when associated with bothersome LUTS (Roehrborn 2008a). Symptom bother typically correlates with the increased number and severity of symptoms, which relates to both quality of life impairment and treatment seeking (Agarwal 2014). Self-administered questionnaires, namely International Prostate Symptom Score (IPSS), include the quality of life domain to evaluate the relative degree of bother across all LUTS (Barry 1995). Chapple 2017 reported that increasing LUTS severity was associated with worsening men's overall distress using patient perception of bladder condition which is a single-item global question (ranging from 1 (causes no problems at all) to 6 (causes severe problems)). BPH is considered to be prostatic enlargement with LUTS through which to define the disease condition and potential need for intervention.

BPH can progress and cause serious consequences such as acute urinary retention, urinary tract infection, and upper urinary tract deterioration. BPH also results in a negative impact on public health and a reduction in a person's quality of life (Kozminski 2015; Martin 2014). In Europe, 30% of men over 50 years of age, equivalent to 26 million men, are affected by bothersome LUTS, including storage symptoms (such as urinary frequency, urgency, and nocturia) or voiding symptoms (such as urinary hesitancy, weak urinary stream, straining to void, and prolonged voiding), or both. The yearly reported associated number of medical prescriptions is estimated to be around 11.6 million for 74 million people at risk from 2004 to 2008 (Cornu 2010). The prevalence of LUTS, according to an international study involving 7588 men was 18% in the ages of 40s, 29% in the 50s, 40% in the 60s, and 56% in the 70s (Homma 1997). In the USA, an estimated eight million men older than 50 years of age have BPH (Roehrborn 2008b). More recent data showed that the lifetime prevalence of BPH was 26.2% (95% CI: 22.8–29.6%) (Lee 2017).

2.4 million Australian men over the aged of 50 suffer from enlarged prostate or Benign Prostatic Hyperplasia (BPH). More than 50% of men over the age of 60 are diagnosed with BPH and by 85 the number climbs to 90%.

23. 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:

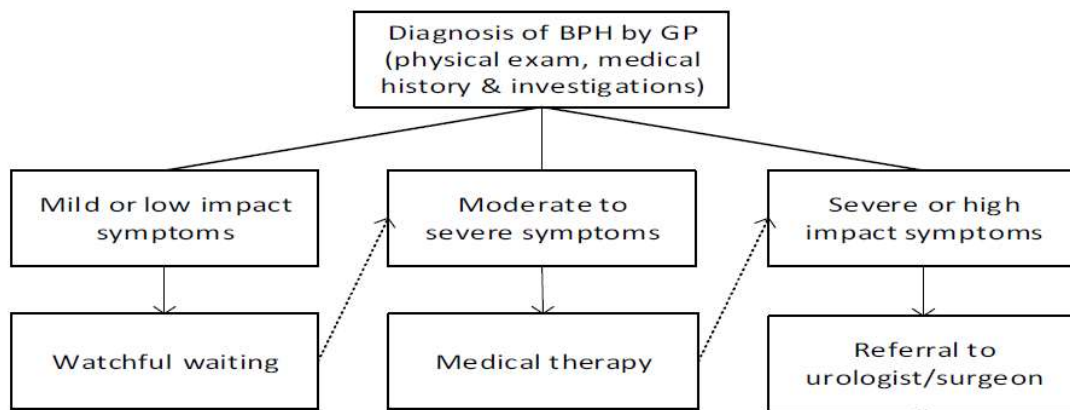
Patients proposed to be eligible for the proposed medical service would have the following:

- Age > 50 years
- Prostate volume <100mL
- International Prostate Symptom Score (IPSS) > 12

24. 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):

It is common for men to present to a general practitioner (GP) with symptoms suggestive of bladder outflow obstruction, which is often due to benign prostatic enlargement (BPE). Benign prostatic hyperplasia (BPH) is the histological cause of BPE, which often results in lower urinary tract symptoms (LUTS) related to voiding, storage or post-micturition. Not all LUTS in men are due to BPE, and other causes of voiding dysfunction require exclusion.

Management of LUTS due to BPE depends on symptom severity or complicating factors and includes observation (for men with minimal symptoms), medical therapy, minimally invasive surgical procedures, endoscopic prostatectomy and, occasionally, abdominopelvic surgery for very large prostates.



PART 6b – INFORMATION ABOUT THE INTERVENTION

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

The PUL procedure is conducted by installing small permanent implants transurethraly under endoscopic guidance to lift apart the obstructing lateral lobes and reduce urethral obstruction. The procedural objective is to create a channel through the anterior aspect of the prostatic fossa. The implant is comprised of a monofilament with a nitinol capsular tab on one end and a stainless steel urethral end-piece on the other.

After rigid cystoscopy, the implant delivery device (UroLift System), which houses a 2.9 mm telescope, is inserted into a 20F sheath and angled laterally (20-30 degrees) usually at the 10 and 2 o'clock position to compress the anterior third of the obstructive lobe. The delivery device laterally deploys a 19 gauge needle through the lobe. As the needle is withdrawn, the capsular tab of the implant engages the prostatic capsule. The monofilament is then tensioned, cut to the specific width of the compressed lobe, and secured in place by the urethral end-piece. Thus, each implant is customized in length and location in situ based on an individual's prostate anatomy. Because the fibromuscular capsule is less compliant than the periurethral tissue, the capsular tab holds firmly in place while the urethral end-piece holds the lobe apart to expand the urethral lumen. The narrow urethral end-piece invaginates into the urethral wall where epithelialization occurs.

Please see <https://www.youtube.com/watch?v=H0xchAo1GUQ>

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

Yes. The UroLift® System. This system is currently listed on the Prostheses List without a direct comparator.

27. 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?

The prostatic urethral lift procedure, which deploys adjustable implants to retract obstructing lateral prostatic lobes, was approved by the Therapeutic Goods Administration in August 2012 and has become a commonly performed procedure.^{26,27} Patients are often catheter-free on discharge, and there have been no reported de novo cases of sexual dysfunction.²⁸

28. 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):

Once only per patient per lifetime.

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

n/a

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

Urologists

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

n/a

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

Urologist

33. 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:

Same as that required to implant a pacemaker.

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

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

26. NeoTract Inc. UroLift – FAQs. Artarmon, NSW: NeoTract Inc, 2015–17. Available at <http://urolift.com.au/doctors/faqs> [Accessed 10 June 2017]. Search PubMed

27. Perera M, Roberts MJ, Doi SA, Bolton D. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: A systematic review and meta-analysis. *Eur Urol* 2015;67(4):704–13. doi: 10.1016/j.eururo.2014.10.031. Search PubMed

28. Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Can J Urol* 2017;24(3):8802–13. Search PubMed

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

The procedure is usually carried out on patients (public or private) admitted for an overnight stay.

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

- Yes
 No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

36. 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):

Transurethral resection of the prostate (TURP)

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

- Yes (please list all relevant MBS item numbers below)
 No

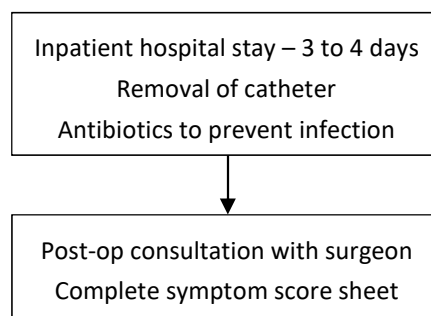
MBS Item 37203

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

Multiple Operation Rule
(Anaes.)

Fee: \$1,058.80 Benefit: 75% = \$794.10

38. Define and summarise the current clinical management pathway/s 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):



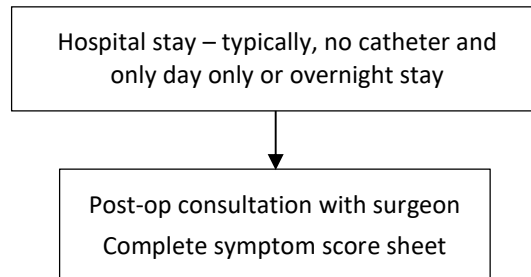
39. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

- In addition to (i.e. it is an add-on service)
 Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

One prostatic urethral lift (PUL) procedure is intended to replace one transurethral resection of the prostate (TURP). However, there is an estimated retreatment rate of 2%-3% per year.

40. 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):



PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

41. 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):

Improvements in:

- International Prostate Symptom Score (IPSS),
- Quality of life (QoL),
- BPH Impact Index (BPHII), and
- maximum urinary flow rate (Q_{max}).

Plus

- quality of recovery,
- ejaculatory function preservation,
- performance on the composite BPH6 index, and
- improvement in sleep.

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

- Superiority
 Non-inferiority

43. 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: Perioperative bleeding complications, number of complications, length of stay (LoS) and conversion to TURP.

Clinical Effectiveness Outcomes: Primary outcome, International Prostate Symptom Score (IPSS), and secondary outcomes, including maximum urinary flow rate, rate of reintervention and quality of life.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

In the 2018-19 Financial Year, there were 15,195 claims on the MBS for procedures to treat BPH (combined total of seven MBS Items).

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

Once

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

The prostatic urethral lift procedure is intended to be a permanent solution for BPH.

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

In 2018-19 there were 1,133 claims on the current MBS Item. However, the use of this procedure has been severely limited by the low MBS fee relative to the MBS fee paid for TURP.

48. 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:

It is anticipated that, if the MBS Fee for Item 36811 was increased to be on par with the fee for TURP, the uptake of the prostatic urethral lift procedure could increase as per the following.

Year 0	1,200	Current
Year 1	1,800	50% increase
Year 2	2,520	40% increase
Year 3	3,276	30% increase

PART 8 – COST INFORMATION

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

Redacted

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

46 to 60 minutes

51. 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.

Category 3 - THERAPEUTIC PROCEDURES
CYSTOSCOPY with insertion of urethral prostheses for the treatment of BPH in men: - Age > 50 years - IPSS > 12 - Prostate Volume <100 mL <i>Multiple Operation Rule</i> (Anaes.) Fee: \$1,058.80 Benefit: 75% = \$794.10 85% = \$890.00