Medica Coverage Policy

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<th>Surgical and Minimally Invasive Treatments for Benign Prostatic Hypertrophy/Hyperplasia (BPH)</th>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

The following surgical and minimally invasive approaches to the treatment of benign prostatic hypertrophy/hyperplasia (BPH) are COVERED for patients with documented urinary outflow obstruction secondary to BPH.

1. Transurethral resection of the prostate (TURP)
2. Transurethral incision of the prostate (TUIP)
3. Transurethral laser coagulation therapies, including non-contact visual laser ablation of the prostate (VLAP) and interstitial laser coagulation of the prostate (ILCP, Indigo Laser)
4. Transurethral vaporization therapies, including contact laser vaporization, electrovaporization, and photoselective vaporization (aka Green Light Laser PVP)
5. Transurethral needle ablation of the prostate (TUNA, radiofrequency thermotherapy)
6. Transurethral microwave thermotherapy (TUMT)
7. UroLift® System
8. Prostatic stent insertion
9. Water vapor thermal therapy (e.g., Rezūm® System)

All other minimally invasive approaches to the treatment of benign prostatic hypertrophy/hyperplasia (BPH) are investigative and therefore NOT COVERED, including but not limited to:

1. Bipolar plasmakinetic electrovaporization (Gyrus PlasmaKinetic™ SuperPlus System, Gyrus ACMI, subsidiary of Olympus Corp. of Japan)
2. High Intensity Focused Ultrasound (HIFU) (e.g., Sonablate®, Ablatherm®)
3. Transrectal microwave hyperthermia
4. Transurethral balloon dilatation (TUBD)
5. Transurethral laser induced prostatectomy (TULIP)
6. Water-induced thermotherapy (WIT)
7. Waterjet Tissue Ablation (e.g., AquaBeam System)
8. Prostatic arterial embolization (PAE)

There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

NOTE: This position statement does not address intraprostatic injection of chemical agents for treatment of BPH.
Description
Benign prostatic hypertrophy or hyperplasia is a noncancerous condition in which an overgrowth of prostate tissue pushes against the urethra and the bladder, blocking urine flow. The increase in the size of the prostate causes symptoms such as the frequent need to urinate and secondary complications such as urinary tract infection. BPH may or may not be accompanied by an elevated PSA reading.

Surgical and minimally invasive options for BPH are:
1. **High intensity focused ultrasound (HIFU).** During HIFU ultrasound, beams are focused on prostatic tissues and are intended to heat (up to 70 to 90 degrees Celsius) and ablate the targeted tissue without injuring adjacent healthy structures. In the case of BPH, the increased tissue temperature kills excess prostate tissue without side effects such as radiation or ionization. Two HIFU devices currently under study are the Sonablate and the Ablatherm. Although the devices are approved in Europe for marketing, they are still in U.S. clinical trials and are not currently FDA approved. The Sonablate system is currently being evaluated as an experimental therapy under an FDA investigational device exemption (IDE). Clinical trials of Sonablate are underway. The FDA has also given Ablatherm approval to conduct a clinical study in the U.S. HIFU is also under study as a treatment for other conditions, including prostate cancer.

2. **Photoselective vaporization of the prostate (PVP).** Photoselective vaporization is a laser technique for reducing prostatic tissue. The technique uses a potassium-titanyl-phosphate (KTP) laser. Unlike diode or holmium Nd:YAG lasers, the KTP laser uses a green-colored beam in the visual spectrum (523 nm). This wavelength is strongly absorbed by hemoglobin and only penetrates a few millimeters. As a result, this technique is purported to avoid deep tissue coagulation side effects. Early techniques used the KTP laser in combination with the Nd:YAG laser. Recent technology uses a high power KTP laser alone (60-80 watts), and this methodology is called PVP.

3. **Plasma kinetic vaporization.** Plasma kinetic vaporization employs the Plasma Kinetic Tissue Management System (Gyrus Medical, Ltd., Bucks, UK; Gyrus Medical, Inc., Maple Grove, MN) to apply radiofrequency energy to the enlarged prostate. The system combines vapor pulse coagulation with bipolar cutting. The technology works in electrically conductive solutions, which are used to distend and irrigate the operative site during the surgery. The system also has the capability of rapidly adjusting (in microseconds) the power delivered to the tissue.

4. **Prostatic stent insertion.** An implantable stent is a durable, hollow-chambered, tubular device that acts as internal scaffolding to hold open the area of the urethra that has become obstructed due to enlarged prostatic tissue. A delivery system is used to implant the device. After insertion, the stent fits against the wall of the urethra and is intended to create a passageway which improves urinary flow. Depending on the stent used, placement can be intended as either permanent (e.g., endourethral epithelializing stent) or temporary (nonepithelializing stent). An example of a commercially available permanent prostatic stent is the UroLume® Urethral Stent (American Medical Systems). Self-expanding temporary stents are also under development.

5. **Transrectal microwave hyperthermia.** In this technique, prostate tissue is heated by a microwave antenna inserted in the rectum. The temperatures used are higher than those applied during TUMT, and the concentrated heat is intended to shrink the enlarged prostatic tissue. This procedure has been largely replaced by TUMT.

6. **Transurethral balloon dilation (TUBD).** During TUBD a balloon is placed into the prostatic channel and then inflated, thereby stretching the prostatic channel. This is thought to produce a slight tear in the prostate gland, which results in the creation of an opening in the urinary channel. TUBD is not recommended for men with very large prostates. Due to the high recurrence rate, this technique has been abandoned in favor of alternate techniques that are associated with better long-term results.

7. **Transurethral incision of the prostate (TUIP).** A small incision is made in the prostatic tissue and is intended to result in enlarging the opening of the urethra and bladder outlet. The aim of TUIP is to eliminate the need for excision, ablation, or vaporization of prostatic tissue. TUIP is usually performed in men who have a relatively small prostate.
8. **Transurethral laser coagulation therapy.** Using non-contact visual laser ablation (VLAP) and interstitial laser coagulation approaches, tissue is destroyed and then resorbed by the body. These techniques are purported to enable the practitioner to more easily control bleeding and to result in decreased healing time.

9. **Transurethral laser induced prostatectomy (TULIP).** TULIP is an ultrasound-guided technique that results in laser energy making incisions in the circular prostatic fibers, enabling the tissue to expand outward. This eliminates pressure and allows the urethra to expand. This technique is not being performed much anymore.

10. **Transurethral microwave thermotherapy (TUMT).** In the TUMT procedure, a catheter is threaded through the urethra into the prostate. Microwaves are pulsed through the catheter which results in heating the prostate and ablating prostate tissue, which is then resorbed by the body.

11. **Transurethral needle ablation of the prostate (TUNA, radiofrequency thermotherapy).** Needles are inserted into the enlarged prostatic tissue and are heated using radiofrequency energy. Prostatic tissue is ablated and resorbed by the body.

12. **Transurethral resection of the prostate (TURP, transurethral prostatectomy).** TURP is the surgical removal of tissue from the prostate gland using a special instrument inserted through the urethra. TURP is considered the gold standard to which other surgical and minimally invasive alternatives are compared.

13. **Transurethral vaporization therapy.** These techniques use heat-producing optical lasers or electrodes to destroy prostatic tissue. In contact laser vaporization (CLVP) techniques, tissue is immediately eliminated through vaporization. In electrovaporization, a rollerball electrode rapidly heats selected prostatic tissue and turns it into steam while simultaneously cauterizing blood vessels. A constant flow of water keeps surrounding tissue cool. Both techniques are purported to enable the practitioner to more easily control bleeding and to result in decreased healing time.

14. **UroLift® System.** UroLift is a minimally invasive, permanent system comprised of a delivery device, nitinol capsular implants, sutures, and stainless steel end pieces. The system is purported to relieve obstruction and open the urethra by retracting the obstructing prostatic lobes. It eliminates the need for cutting, heating, or removing prostate tissue, while retaining the lobes in the retracted position to allow unobstructed urine flow.

15. **Water-induced thermotherapy (WIT).** WIT uses circulating hot water in a closed-loop catheter set, with temperatures controlled to ablate prostatic tissue. Conductive heat is transmitted through a specially designed treatment balloon and applied over the entire length of the targeted prostatic tissue.

16. **Water vapor thermal therapy (e.g., Rezūm® System).** Water vapor thermal therapy is a transurethral radiofrequency thermal therapy to treat benign prostatic hyperplasia (BPH) that can be performed in a clinic or out-patient setting. Using a hand-held device, Rezūm delivers radiofrequency generated thermal therapy in the form of water vapor. It is directly applied to the extra prostate tissue that is causing symptoms of BPH.

17. **Waterjet Tissue Ablation.** Waterjet tissue ablation combines real-time transrectal ultrasound image guidance and robotics for targeted removal of prostate tissue. A high-velocity saline stream (AquaBeam) is generated using water jets driven by a high-pressure pump. The stream creates a cavity in prostatic glandular tissue without the production of heat. The flow rate generated by the pump determines the depth of the stream’s penetration. To obtain hemostasis, a low-power blue laser beam is captured in a low-pressure water column to perform surface coagulation of the fossa.

18. **Prostatic arterial embolization (PAE).** PAE is a minimally invasive procedure for the treatment of BPH to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage. The procedure is performed using a percutaneous transfemoral approach with microcatheters introducing embolization agents such polyvinyl alcohol particles, coil embolizers, microspheres and other synthetic biocompatible materials which expand once delivered within the artery, causing arterial occlusion.

**FDA Approval**

These approaches are surgical procedures, and therefore not regulated by the FDA. However, multiple instruments including energy-delivery devices employing microwave, radiofrequency, electrical, laser energy, and bipolar plasmakinetic electrovaporization for ablative and vaporization applications; balloons; and stents have received FDA approval.
The Urolift Prostatic Urethral Lift System (NeoTract, Inc.) received FDA De Novo approval for the UroLift System on September 13, 2013, for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men 50 years of age or older.

Two high intensity frequency ultrasound (HIFU) devices are the Sonablate®500 (Focus Surgery, Inc.) and the Ablatherm® (EDAP TMS SA). Neither device has currently received FDA approval.

The Rezūm® System received FDA 510(k) marketing clearance in February 2018. NxThera, Inc. (Maple Grove, MN, USA) initially manufactured the system. FDA granted two previous clearances in March 2016 and August 2015. The predicate devices for the original Rezūm clearance were the Prostiva® (Medtronic, Dublin, Ireland) devices. The Rezūm System is approved for the treatment of BPH in men 50 years of age or older.

The AquaBeam® system (PROCEPT BioRobotics Corporation, Redwood Shores, CA) received FDA approval on April 17, 2017 as De Novo classification for the resection and removal of prostate tissue for males suffering from lower urinary tract symptoms (LUTS) due to BPH.

Two embolic agents have received FDA 510(k) clearance for prostatic arterial embolization (PAE), specifically for treatment of benign prostatic hyperplasia:
- Merit Medical Systems Inc. Embosphere Microspheres (April 19, 2018).

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

**Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes:**
- 52282 - Cytourethroscopy, with insertion of urethral stent
- 52450 - Transurethral incision of prostate
- 52601 - Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
- 52647 - Laser coagulation of prostate including control of postoperative bleeding, complete (vasectomy, urethral calibration and or dilation, meatotomy, cystourethroscopy, and internal urethrotomy are included if performed).
- 52648 - Laser vaporization including control of postoperative bleeding, complete (vasectomy, urethral calibration and or dilation, meatotomy, cystourethroscopy, internal urethrotomy and transurethral resection of prostate are included if performed).
- 52649 - Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
- 53850 - Transurethral destruction of prostate tissue; microwave thermotherapy
- 53852 - Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
- 53854 – Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
- 53855 - Insertion of a temporary prostatic urethral stent, including urethral measurement
- 55899 - Unlisted procedure, urinary system

**HCPCS Codes:**
- C9748 - Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy
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Original Effective Date: 11/1/2002

Re-Review Date(s):
5/24/2005
7/15/2008
7/18/2011
7/16/2014
6/21/2017
1/1/2018 – administrative update; codes added
3/2/2020 – administrative update; format
5/26/2020

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