Medica Central Coverage Policy

Policy Name:	**Surgical and Minimally Invasive Treatments for Benign Prostatic Hypertrophy/Hyperplasia (BPH) MP9361**
Effective Date:	**12/01/2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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, Medicaid, and other government programs, this policy will apply unless these 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 may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central 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. Fiber laser enucleation technologies, e.g., holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP); thulium laser (ThuLEP)
2. Transurethral resection of the prostate (TURP)
3. Transurethral incision of the prostate (TUIP)
4. Transurethral laser coagulation therapies, including non-contact visual laser ablation of the prostate (VLAP) and interstitial laser coagulation of the prostate (ILCP, Indigo Laser)
5. Transurethral vaporization of the prostate (TUVP) therapies, including contact laser vaporization, electrovaporization, and photoselective vaporization (aka Green Light Laser PVP)
6. Transurethral needle ablation of the prostate (TUNA, radiofrequency thermotherapy)
7. Transurethral microwave thermotherapy (TUMT)
8. UroLift® System
9. Prostatic stent insertion
10. Water vapor thermal therapy (WVTT) (e.g., Rezūm® System)
11. Waterjet tissue ablation (e.g., AquaBeam® Robotic System), also known as Aquablation Therapy.

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

1. Bipolar plasmakinetic electrovaporization (PlasmaKinetic™ Tissue Management Superpulse System. Gyrus ACMI, subsidiary of Olympus Corp. of Japan)
2. High intensity focused ultrasound (HIFU) (e.g., Sonablate®, Ablatherm®)
3. Transrectal microwave hyperthermia (TRMT)
4. Transurethral balloon dilatation (TUBD) also known as Endoscopic Balloon Dilation
5. Transurethral ultrasound laser induced prostatectomy (TULIP)
6. Water-induced thermotherapy (WIT)
7. 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. Fiber laser technologies (HoLAP/HoLEP/HoLRP; ThuLEP). HoLEP is a holmium:yttrium-aluminum-garnet (Ho:YAG) laser with a shallow depth of penetration, thus limiting the depth of tissue necrosis and thermal injury exposure. Holmium emits energy that is absorbed by water. HoLEP requires contact with the targeted tissue and is intended for precise incisions, dissections and enucleations. ThuLEP is a fiber laser that utilizes a thulium doped fiber rather than an ion doped YAG. Energy is channeled through the thulium doped fiber exciting the thulium electrons and generating photons that are directed to the surgical site through an outgoing laser fiber. ThuLEP is purported to generate less heat than the Ho:YAG.
2. 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.
3. 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.

4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.

12. 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.
13. 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.
14. 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.
15. 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.
16. 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.
17. 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.
18. 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.
19. 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 Uretheral 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® Robotic system (PROCEPT BioRobotics Corporation, Redwood Shores, CA) received FDA approval on April 17, 2017 as De Novo classification and in October 2021, based on its substantial equivalence to a previous device model, for the resection and removal of prostate tissue for males suffering from lower urinary tract symptoms (LUTS) due to BPH.The PlasmaKinetic Superpulse System (Gyrus, Maple Grove, MN) received 510(k) premarket notification device on July 2003. This device is substantially equivalent to the predicate devices, PlasmaKinetic Generator, the PlasmaKinetic Endourology Generator, and the Endourology Axipolar Resectoscope Electrode.

There are over 500 systems and accessories with product code GEX (i.e., laser surgical instruments) cataloged by the FDA.

Four embolic agents have received FDA 510(K) clearance for prostatic arterial embolization (PAE), specifically for treatment of benign prostatic hyperplasia:

- Boston Scientific Corp. Embozene Color-Advanced Microspheres (July 16, 2018).
- Merit Medical Systems Inc. Embosphere Microspheres (April 19, 2018).
- Biocompatibles UK Ltd. Bead Block (K203276). April 20, 2021.
- MicroVention Inc. HydroPearl Microspheres (K192684). October 22, 2020.

Prior Authorization

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:

- **0421T-** Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
- **0714T –** Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
- **0867T** - Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
- **37243** - Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

- **52282** - Cytourethroscopy, with insertion of urethral stent
- **52341**- Cystourethroscopy; with treatment of ureteral stricture (TUBD)
- **52441** - Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
- **52282**- Cystourethroscopy, with insertion of permanent urethral stent
- **52284** - Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed
- **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)
- **52630**- Transurethral resection; residual or regrowth of obstructive prostate tissue
- **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
- **53899** - Unlisted procedure, urinary system
- **55873**- Cryosurgical ablation of the prostate (HIFU)
- **55899** - Unlisted procedure, urinary system
- **75894**- Transcatheter therapy, embolization, any method

HCPC Codes:

- **C2596**- Probe, image guided, robotic, waterjet ablation
- **C9734**- Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance
- **C9739**- Cystourethroscopy, with insertion of transprostatic implant; four or more implants
- **C9740**- Cystourethroscopy, with insertion of transprostatic implant; four or more implants
- **C9748** - Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy

	Committee/Source	Date(s)
Document Created:	Utilization Management Committee/ Medical Affairs/	April 11, 2007
Revised:	Utilization Management Committee/ Medical Affairs/	August 13, 2008
	Utilization Management Committee/ Medical Affairs	August 12, 2009
	Medical Director Committee/Medical Affairs	February 19, 2014
	Medical Director Committee/Medical Affairs	March 18, 2015

	Committee/Source	Date(s)
Revised:	Medical Director Committee/Quality and Care Management Division	January 20, 2016
	Medical Policy Committee/Quality and Care Management Division	April 19, 2017
	Medical Policy Committee/Quality and Care Management Division	April 18, 2018
	Medical Policy Committee/Health Services Division	January 16, 2019
	Medical Policy Committee/Health Services Division	April 17, 2019
	Medical Policy Committee/Health Services Division	July 17, 2019
	Medical Policy Committee/Health Services Division	November 20, 2019
	Medical Policy Committee/Health Services Division	December 18, 2019
	Medical Policy Committee/Health Services Division	February 19, 2020
	Medical Policy Committee/Health Services Division	August 19, 2020
	Medical Policy Committee/Health Services Division	April 21, 2021
	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	August 17, 2022
	Medical Policy Committee/Health Services Division	June 21, 2023
	Medical Policy Committee/Health Services Division	June 20, 2024
Reviewed:	UM Committee (UMC)/Director UM/UMC Chair	March 12, 2008
	UM Committee (UMC)/Director UM/UMC Chair	April 8, 2009
	Medical Director Committee/Medical Affairs	March 24, 2011
	Medical Director Committee/Medical Affairs	March 21, 2012
	Medical Director Committee/Medical Affairs	August 15, 2012
	Medical Director Committee/Medical Affairs	January 16, 2013
	Medical Director Committee/Medical Affairs	January 15, 2014
	Medical Director Committee/Medical Affairs	February 19, 2014
	Medical Director Committee/Medical Affairs	January 21, 2015
	Medical Director Committee/Medical Affairs	March 18, 2015
	Medical Director Committee/Quality and Care Management Division	January 20 2016
	Medical Policy Committee/Quality and Care Management Division	April 19, 2017
	Medical Policy Committee/Quality and Care Management Division	April 18, 2018
	Medical Policy Committee/Health Services Division	January 16, 2019
	Medical Policy Committee/Health Services Division	April 17, 2019
	Medical Policy Committee/Health Services Division	July 17, 2019
	Medical Policy Committee/Health Services Division	November 20, 2019
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	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	August 17, 2022
	Medical Policy Committee/Health Services Division	June 21, 2023

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	Committee/Source	Date(s)
Reviewed:	Medical Policy Committee/Health Services Division	June 20, 2024

Original Effective Date:	2007
Re-Review Date(s):	7/17/2025
Administrative Update:	01/24/2025 – code added
	07/30/2025 – Codes added/removed