

Medical Coverage Policy

Effective Date: 01/28/2021 Revision Date: 01/28/2021 Review Date: 01/28/2021 Policy Number: HCS-0459-028

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Change Summary: Updated Description, Provider Claims Codes, References

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Benign prostatic hyperplasia (BPH) is caused by the abnormal growth of benign (noncancerous) prostate cells which enlarge the prostate gland. The gland may push against the bladder and urethra, causing lower urinary tract symptoms (LUTS) that include increased frequency of urination, hesitancy, nocturia (urinating at night), urgency and weak urinary stream. These symptoms typically appear slowly and progress gradually over time. The likelihood of being affected by BPH increases with age and is common in males over 50 years of age.

There is no cure for BPH; treatment focuses on reducing the symptoms. Early nonsurgical treatment options include, but may not be limited to, the following:

Avoidance of fluids prior to bedtime or before going out

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- Avoidance of medications that can exacerbate symptoms or induce urinary retention
- Double voiding to ensure complete bladder emptying
- Prescription medication
- Reducing consumption of mild diuretics such as caffeine and alcohol
- Watchful waiting

If symptoms worsen, other treatment options include, but may not be limited to, the following:

Minimally Invasive Therapies

Transurethral electrical vaporization of the prostate (TUEVP, TUVP, TVP) or transurethral vapor resection (TUVRP), is performed using a grooved roller-ball electrode with a large surface area that uses a cutting current. During the procedure, the ball is rolled over the prostate tissue multiple times to vaporize the tissue to the desired depth.

Transurethral microwave thermotherapy (TUMT) heats the prostate using a microwave antennae mounted on a urethral catheter. The catheter is inserted into the urethra where low-energy or high-energy microwave heat destroys excess prostate tissue.

Transurethral needle ablation (TUNA) or radiofrequency needle ablation (RFNA) uses low-level radiofrequency energy to treat the prostate. Using a cystoscope-like device, inserted through the urethra, twin needles are placed on either side of the prostate. Each needle emits radiofrequency energy that burns away a defined region of the prostate while shielding the urethra from heat. TUNA using water vapor (ie, Rezūm System) delivers sterile water vapor (steam) transurethrally directly into hyperplastic tissue. Heat is released as the vapor condenses, causing cell death.

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Surgical Treatments

Open or laparoscopic prostatectomy is performed when the prostate is greatly enlarged, when there are other complicating factors or if the bladder has been damaged and needs repair. In this procedure, an incision is made in the lower abdomen or perineum and the enlarged tissue is removed from the gland. Anesthesia and hospitalization are required.

Transurethral incision of the prostate (TUIP) does not remove prostate tissue. The urethra is widened by making several small cuts into the prostate and the neck of the bladder where the urethra and the bladder join. This reduces the pressure on the urethra and makes urination easier. TUIP is utilized when the prostate is not greatly enlarged.

Transurethral resection of the prostate (TURP) has long been considered the gold standard for BPH treatment. TURP requires anesthesia, but no external incision. The physician inserts a resectoscope through the urethra to deliver fluids to the prostate during the procedure. The resectoscope uses an electrical loop to cut and vaporize tissue and seal blood vessels. The excised tissue is carried to the bladder and flushed out of the body by irrigation fluids.

Laser Therapy

Laser therapy is minimally invasive and uses laser generated heat to vaporize or coagulate obstructing prostate tissue. The device is passed through the urethra to the prostate using a cystoscope to deliver bursts of energy which destroy and shrink the prostate tissue. There are several types of lasers that can be used to treat the prostate: neodymium:yttrium-aluminum-garnet (Nd:YAG), potassium-titanyl-phosphate (KTP), holmium:yttrium-aluminum-garnet (Ho:YAG), thulium:yttrium-aluminum-garnet (Tm:YAG), lithium borate:yttrium-aluminum-garnet (LBO:YAG) and diode. Laser surgery results in little blood loss. Types of laser therapy include, but may not be limited to, the following:

- Contact laser ablation of the prostate (CLAP)
- Holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP)
- Interstitial laser coagulation (ILC)
- Noncontact visual ablation (VLAP)
- Photoselective vaporization of the prostate (PVP)
- Thulium laser enucleation of the prostate (ThuLEP)

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Stents

Permanent urethral stent (ie, UroLume) placement for treating BPH is generally considered only for men who are poor surgical candidates or those who are not candidates for other types of interventions. Stents are placed into the urethra and expanded to relieve the obstruction. Complications associated with stents include bladder calculi, chronic pain, encrustation and infection.

Temporary (removable or biodegradable) prostatic urethral stents (ie, iTind) perform in a similar manner and function but do not remain in the body permanently. (Refer to Coverage Limitations section)

Additional Therapies

Absolute ethanol injection into the prostate is a technique theorized to cause coagulation necrosis (chemoablation), which destroys the tissue. (**Refer to Coverage Limitations section**)

Botulinum toxin (please refer to Botox [Botulinum Toxin] Pharmacy Coverage Policy).

Cryosurgical ablation, also known as cryotherapy or cryosurgery, proposes the use of extreme cold temperatures by liquid nitrogen or argon gas to destroy tissue. When used internally, the liquid nitrogen or argon gas is circulated through a cryoprobe which freezes the surrounding cells. After the destroyed cells thaw, they are absorbed by the body. **(Refer to Coverage Limitations section)**

High-intensity focused ultrasound (HIFU) is the use of imaging ultrasound to deliver targeted high-intensity ultrasound that rapidly elevates the temperature in a precise focal zone. The increased tissue temperature is suggested to kill excess prostate tissue. Ablatherm, Sonablate and TULSA-PRO system are examples of US Food & Drug Administration (FDA) approved high-intensity ultrasound systems. (Refer to Coverage Limitations section)

Plasma kinetic vaporization (PKVP) or **button procedure** proposes the use of two mutually isolated electrodes (active and return) to form a complete circuit with the tissue lying between them. The electrical conduction path is formed by a saline irrigant. Radiofrequency energy is used to convert the conductive medium into a

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plasma field, which vaporizes tissue upon contact. A resectoscope, an instrument that contains the electrodes and is equipped with a wide-angle telescope, is passed retrograde through the urethra to the prostate. (Refer to Coverage Limitations section)

Prostate artery embolization aims to reduce the blood supply to the prostate gland causing tissue death and subsequent shrinkage. The procedure is performed using a percutaneous transfemoral approach with microcatheters introducing embolization agents such as polyvinyl alcohol (PVA), gelatin sponge and other synthetic biocompatible materials which expand once delivered within the artery, blocking blood flow. Embosphere Microspheres and SwiftNINJA are examples of FDA approved methods. **(Refer to Coverage Limitations section)**

Prostatic Urethral Lift (PUL) is an implantable transprostatic tissue retractor system consisting of a delivery device inserted through the urethra, which then deploys an implant through the prostate. Implant increases urethral patency by providing prostate lobe tissue retraction while preserving the potential for future procedures. An example of a FDA-approved device is the UroLift System.

Transrectal thermotherapy purportedly heats the prostate using a catheter inserted into the rectum. Various types of energy, such as microwave, radiofrequency or electrothermal, are delivered via the catheter to heat and thereby destroy excess prostate tissue. (Refer to Coverage Limitations section)

Transurethral balloon dilatation involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated, theoretically pushing back prostate tissue and stretching the urethra where it has been narrowed by the prostate. An example of this includes, but may not be limited to the Optilume Basic. **(Refer to Coverage Limitations section)**

Transurethral ultrasound guided laser induced prostatectomy (TULIP) is similar to transurethral incision of the prostate (TUIP) except that cuts are made with a laser. Laser energy is delivered under ultrasound guidance, producing tissue necrosis. **(Refer to Coverage Limitations section)**

Water induced thermotherapy (WIT) purportedly combines compression and high temperature to kill and shrink prostatic tissue surrounding the urethra. A heat-

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transmitting balloon catheter full of heated water (60 degrees Celsius) is introduced into the urethra, destroying prostate tissue. (Refer to Coverage Limitations section)

Water jet tissue resection (ie, AquaBeam) is an endoscopic tissue ablation device intended to resect the prostate. The system is guided robotically using transrectal ultrasound imaging enabling the removal of the enlarged prostate tissue using a pressurized fluid jet.

Coverage Determination

Please refer to the member's applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage for medication for the treatment of BPH.

Humana members may be eligible under the Plan for BPH treatment using the following methods when nonsurgical management has failed:

- Laparoscopic or open prostatectomy; OR
- Laser therapies, including the following:
 - Contact laser ablation of the prostate (CLAP); OR
 - Holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP); OR
 - Interstitial laser coagulation (ILC); OR
 - Noncontact visual ablation (VLAP); OR
 - Photoselective vaporization of the prostate (PVP); OR
 - Thulium laser enucleation of the prostate (ThuLEP); OR
- Permanent urethral stent (ie, UroLume); OR
- Prostatic urethral lift (PUL) (ie, UroLift); OR
- Transurethral electrical vaporization of the prostate (TUEVP, TUVP, TVP) or transurethral vapor resection (TUVRP); OR
- Transurethral incision of the prostate (TUIP); OR
- Transurethral microwave thermotherapy (TUMT); OR

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- Transurethral needle ablation (TUNA) or radiofrequency needle ablation (RFNA) (including water vapor method [ie, Rezūm System]); OR
- Transurethral resection of the prostate (TURP); OR
- Water jet tissue resection (ie, AquaBeam)

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **BPH treatment** using any procedures other than those listed above including, but may not be limited to, the following:

- Absolute ethanol injection; OR
- Cryosurgical ablation; OR
- High-intensity focused ultrasound (HIFU); OR
- Plasma kinetic vaporization (PKVP); OR
- Prostate artery embolization; OR
- Temporary prostatic urethral stent (ie, iTind); OR
- Transrectal thermotherapy; OR
- Transurethral balloon dilatation (eg, Optilume Basic)*; OR
- Transurethral ultrasound guided laser induced prostatectomy (TULIP); OR
- Water induced thermotherapy (WIT)

*Optilume drug-coated balloon (0619T) has not been approved by the FDA for BPH treatment.

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Background

Additional information about **BPH** may be found from the following websites:

- American Urological Association
- National Library of Medicine

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Medical **Alternatives**

Physician consultation is advised to make an informed decision based on an individual's health needs.

Codes

Provider Claims Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	Not Covered if used to report prostate artery embolization
52282	Cystourethroscopy, with insertion of permanent urethral stent	
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	
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 including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	

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Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)	
Laser vaporization of prostate, 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)	
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)	
Transurethral destruction of prostate tissue; by microwave thermotherapy	
Transurethral destruction of prostate tissue; by radiofrequency thermotherapy	Not Covered if used to report any treatment outlined in Coverage Limitations section
Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	
Insertion of a temporary prostatic urethral stent, including urethral measurement	Not Covered
Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)	
Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages	
Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal	
	bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed) Laser vaporization of prostate, 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) 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) Transurethral destruction of prostate tissue; by microwave thermotherapy Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy Insertion of a temporary prostatic urethral stent, including urethral measurement Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy) Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages Prostatectomy, meatotomy, urethral calibration and/or dilation, vasectomy, meatotomy, urethral calibration and/or dilation,

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55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	Not Covered New Code Effective 01/01/2021
55899	Unlisted procedure, male genital system	Not Covered if used to report any treatment outlined in Coverage Limitations section
CPT® Category III Code(s)	Description	Comments
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)	
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	Not Covered New Code Effective 07/01/2020
HCPCS Code(s)	Description	Comments
C2596	Probe, image guided, robotic, waterjet ablation	Not Covered
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants	
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants	
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	Not Covered Deleted Code Effective 12/31/2020
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts	Not Covered New Code Effective 10/01/2020

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