



MASSACHUSETTS

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Medical Policy

Minimally Invasive and Surgical Treatment Options for Benign Prostatic Hyperplasia (BPH)

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Policy Number: 744

BCBSA Reference Number: 7.01.151 (For Plan internal use only)

NCD/LCD: NA

Related Policies

N/A

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Policyⁱ

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Prostatic Urethral Lift

Prostatic urethral lift may be considered **MEDICALLY NECESSARY** for the treatment of moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to Transurethral resection of the prostate (TURP) or open prostatectomy when **ALL** of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy (α 1-adrenergic antagonists maximally titrated, 5 α -reductase inhibitors, or combination medication)

therapy maximally titrated) over a trial period of no less than 6 months **OR** the individual is unable to tolerate medical therapy; **AND**

- Prostate gland volume is ≤ 80 mL; **AND**
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; **AND**
- Individual does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer; **AND**
- Individual does not have a known allergy to nickel, titanium or stainless steel.

Use of prostatic urethral lift in other situations, including repeat procedures, is considered **INVESTIGATIONAL**.

Transurethral Water Vapor Thermal Therapy (Rezum)¹

Transurethral Water Vapor Thermal Therapy (Rezum) in individuals 50 and older with or without obstructed median lobe, may be considered **MEDICALLY NECESSARY** for the treatment of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to transurethral resection of the prostate (TURP) or open prostatectomy when **ALL** of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha 1$ -adrenergic antagonists maximally titrated, 5α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months **OR** the patient is not a suitable candidate for anesthesia or is unable to tolerate medical therapy; **AND**
- IPSS score ≥ 12 , **AND**
- Prostate gland volume is ≤ 80 mL; **AND**
- Individual does not have an active urinary tract infection or prostatitis within past year; **AND**
- If individual has urinary retention, they may be a candidate for Rezum only if they cannot tolerate anesthesia or are a suboptimal candidate for anesthesia, **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer.

Waterjet Tissue Ablation (Aquablation)¹

Waterjet tissue ablation (Aquablation) in patients 45 and older may be considered **MEDICALLY NECESSARY** for the treatment of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to Transurethral resection of the prostate (TURP) or open prostatectomy when **all** of the following criteria are met:

- The Individual has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha 1$ -adrenergic antagonists maximally titrated, 5α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months **OR** the patient is not a suitable candidate for anesthesia or is unable to tolerate medical therapy; **AND**
- IPSS score ≥ 12 , **AND**
- Prostate gland volume $\geq 30 - 150$ cc; **AND**
- Individual does not have an active urinary tract infection or prostatitis within the past year; **AND**
- Individual does not have diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture, **AND**
- Individual does not have a known allergy to nickel, titanium or stainless steel, **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer.

Laser Based Procedures¹

Laser Based procedures such as photoselective vaporization of the prostate (PVP), holmium laser ablation of the prostate (HoLAP) or Holmium Laser enucleation of the prostate (HoLEP) in individuals 40 and over may be considered **MEDICALLY NECESSARY** for the treatment of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to Transurethral resection of the prostate (TURP) or open prostatectomy when **all** of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha 1$ -adrenergic antagonists maximally titrated, 5α -reductase inhibitors, or combination medication

therapy maximally titrated) over a trial period of no less than 6 months **OR** the patient is not a suitable candidate for anesthesia or is unable to tolerate medical therapy; **AND**

- IPSS score ≥ 12 , **AND**
- Individual does not have an active urinary tract infection or prostatitis within past year; **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer.

Transurethral Incision of the Prostate (TUIP)¹

Transurethral incision of the prostate (TUIP) may be considered **MEDICALLY NECESSARY** for the treatment of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to Transurethral resection of the prostate (TURP) or open prostatectomy when **all** of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha 1$ -adrenergic antagonists maximally titrated, 5α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months, **OR** the patient is not a suitable candidate for anesthesia or is unable to tolerate medical therapy; **AND**
- IPSS score ≥ 12 , **AND**
- Prostate anatomy demonstrates normal bladder neck without an obstructive median lobe; **AND**
- Prostate size ≤ 30 cc, **AND**
- Individual does not have an active urinary tract infection or prostatitis within past year; **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer.

Transurethral Microwave Therapy (TUMT)¹

Transurethral microwave therapy (TUMT) may be considered **MEDICALLY NECESSARY** for the treatment of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia as an alternative to Transurethral resection of the prostate (TURP) or open prostatectomy when **all** of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha 1$ -adrenergic antagonists maximally titrated, 5α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months **OR** is unable to tolerate medical therapy; **AND**
- IPSS score ≥ 12 , **AND**
- Individual does not have an active urinary tract infection or prostatitis within past year; **AND**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer, **AND**
- The individual is not a suitable candidate for anesthesia, **AND**
- Individual is not a suitable candidate for any of the procedures listed above.

Transurethral Needle Ablation (TUNA)¹

Transurethral Needle Ablation (TUNA) is considered **NOT MEDICALLY NECESSARY** for any indication.

Cryosurgical Ablation and Prostatic Embolization¹

The following procedures for benign prostatic hyperplasia are considered **INVESTIGATIONAL**

1. Cryosurgical ablation
2. Prostatic embolization.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
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Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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)
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
52647	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)
52648	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)
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; by microwave thermotherapy
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

HCPCS Codes

HCPCS codes:	Code Description
C2596	Probe, image guided, robotic, waterjet ablation
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

The following ICD Diagnosis Code is considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

The following CPT codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy

According to the policy statement above, the following CPT codes are considered investigational for benign prostatic hyperplasia for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue, and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

Description

Benign Prostatic Hyperplasia

BPH is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals ages 70 to 79 years.¹

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms.² Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤ 7), moderate (8-19), or severe (20-35).¹ The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."³

Many treatment options are available to help manage moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH). In most cases, medication management is used as the initial course of therapy followed by transurethral resection of the prostate (TURP). TURP is considered the GOLD standard of care however, this is a surgical procedure requiring the use of anesthesia and is associated with longer recovery times and significant side effects. Some common side effects include heavy bleeding, urinary tract infections, and erectile dysfunction or retrograde ejaculation. TURP is not indicated for individuals who are contraindicated for general anesthesia or are desiring of preserving sexual function. Rates of retreatment are lower with TURP than other treatment modalities.

Less invasive treatment options such as the Prostatic Urethral Lift (PUL) and transurethral water vapor thermal therapy (Rezum) have been evaluated for the treatment of BPH. Prostatic urethral lift (PUL) involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen. Rezum water vapor thermal therapy delivers a heated stream of water vaporizing prostate tissue and immediately reducing symptoms. Unlike other BPH treatments, Rezum allows for treatment of an obstructed median lobe which may have additional impacts on LUTS.

PUL and Rezum are indicated for men with moderate to severe LUTS with prostate sizes <80 and can be done in the outpatient setting without the use of general anesthesia. Both PUL and Rezum are safe options for men who have not responded adequately to medication therapy, are contraindicated to more invasive treatment options, and are desiring of preserving sexual function.

Aquablation therapy

Aquablation therapy has been evaluated for BPH and was recently approved by the FDA to treat enlarged prostates up to 150cc. Aquablation uses a heat free waterjet in conjunction with the AquaBeam robotic system to remove prostate tissue blocking the flow of urine. Aquablation therapy uses a cystoscope in combination with ultrasound imaging providing for direct visualization of the prostate. This provides for greater efficacy and treatment to areas of the prostate that will not result in further complications such as erectile dysfunction or incontinence. Aquablation is a surgical procedure requiring anesthesia.

Laser therapies

Laser therapies such as photoselective vaporization of the prostate (PVP), holmium laser ablation of the prostate (HoLAP) or Holmium Laser enucleation of the prostate (HoLEP) are options for individuals who may be taking blood thinners or are contraindicated to treatment options that may cause heavy bleeding. PVP and HoLAP use laser therapy to vaporize prostate tissue and allow for greater urinary flow. HoLEP is a laser-based procedure that excises prostate tissue blocking the urethra. Laser based procedures are effective for reducing prostate size and allowing for greater urinary flow while providing shorter recovery times, improvements in urinary symptoms and are not associated with increased risk of bleeding. Some of the adverse events or side effects of laser therapies include UTI, stricture of the urethra, erectile dysfunction, retrograde ejaculation, and need for retreatment.

Transurethral incision of the prostate (TUIP)

Transurethral incision of the prostate (TUIP) is done by inserting small incisions into the prostate through the urethra allowing for urine to pass through more freely. TUIP is indicated for small or moderate size prostates and is beneficial for patients who are contraindicated to medication management or other therapies. TUIP is a similarly effective procedure for reducing LUTS symptoms, providing a faster recovery period time, and lower incidences of erectile dysfunction and post op complications/bleeding. While TUIP is described as a viable alternative to TURP, the effectiveness of this procedure in larger prostates (>30) is not well documented.

Transurethral Microwave ablation (TUMT)

Transurethral Microwave ablation (TUMT) is an outpatient treatment option for benign prostatic hyperplasia. TUMT has been evaluated as an effective option for men with smaller to medium size prostates who are not candidates for alternative treatments and who are suboptimal candidates for anesthesia. During TUMT, a microwave antenna is inserted into the urethra and deliver microwave thermal energy to the prostate to heat and destroy enlarged tissue. TUMT is known as a safer alternative with no requirement for anesthesia, lower risk of bleeding and low risk of long-term side effects. The rates of retreatment for TUMT are higher than those for TURP or other minimally invasive treatment options however, the low risk of side effects or complications makes this a beneficial treatment option for certain target populations.

Transurethral needle ablation (TUNA)

Transurethral needle ablation (TUNA) has been used to treat Benign prostatic hyperplasia for many years. TUNA is done by inserting interstitial radiofrequency (RF) needles into the urethra and delivering radiofrequency ablation to the lateral lobes of the prostate. TUNA helped to reduce symptoms of LUTS due to BPH however as newer, more effective treatment options became available, TUNA has fallen out of favor. In some scenarios patients who received TUNA had a new onset or worsening of symptoms due to chronic inflammation in the areas treated. TUNA has also been associated with high rates of retreatment and long-term side effects.

Cryosurgical Ablation

Cryosurgical Ablation is the process of freezing tissue around the prostate during ultrasound or MRI ultrasound guidance. While often used to treat prostate cancer, cryosurgical ablation has been evaluated

for the treatment of Benign Prostatic Hyperplasia. During the procedure, multiple metal probes are inserted around and under the prostate via ultrasound guidance and are then cooled sufficiently enough to freeze prostate tissue resulting in cell death and reduction of prostate gland size.

Prostatic Arterial Embolization

Prostatic Arterial Embolization is a minimally invasive treatment option that works by reducing blood supply to prostatic arteries. An interventional radiologist injects microspheres through a catheter to the blood vessels around the prostate, reducing the blood supply to multiple different areas. No surgical intervention is required for this procedure and recovery times are often less than that of TURP. PAE requires significant clinician training and is associated with some common side effects such as “post-PAE syndrome, blood in urine or semen, rare cases of prostatic or bladder spasms.

Summary

For individuals who have lower urinary tract obstruction symptoms due to BPH who do not have a sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a PUL, the evidence includes systematic reviews, randomized controlled trials (RCTs), and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual health. While transurethral resection of the prostate was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. Prostatic urethral lift was further superior to transurethral resection of the prostate in preserving ejaculatory function. These findings were corroborated by another RCT (the Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia [LIFT] study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported these findings were preserved in a subset of patients over 3 to 5 years; however, a high number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs included men with a prostate volume up to 80 cm³ and excluded men with median lobe obstruction. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign prostatic hyperplasia who receive transurethral water vapor thermal therapy (Rezum), the evidence includes a randomized controlled trial with a five year follow up phase and 3 observational studies. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three months, lower urinary tract symptoms were improved compared to sham and lasted through to 5 years. No adverse effects on erectile or ejaculatory function were observed, and improvements were sustained through five years of follow-up with a retreatment rate of 4.4%, comparable to TURP. While there are no studies comparing Rezum to other treatments for LUTS, the study results demonstrate clinically meaningful improvement and similar results from clinical trials for PUL. The benefits of Rezum allow for similar improvements in reduction of symptoms for LUTS, shorter recovery period times, and limited occurrence of adverse events including catheterization, urinary tract infections and sexual dysfunction. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have benign prostatic hyperplasia who receive Aquablation, the evidence includes 2 multicenter, double-blind, randomized controlled trials with 5-year outcome measures. The initial trial included patients with prostate sizes of >30-80cc, a diagnosis of moderate to severe LUTS and IPSS scores ≥ 12 . The second RCT includes 2 year follow up data for patients with prostate sizes between 30cc-150cc. Both studies compared primary and secondary outcomes to that of TURP and demonstrated clinically significant improvement in symptoms of LUTS, comparable rates of retreatment (4.3% and 1.5%), faster recovery periods, limited adverse events and increased preservation of sexual function

(10% vs. 36%). Aquablation was recommended by AUA and NICE as an effective and safe treatment option for reducing symptoms of LUTS. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who receive TUIP, the evidence includes 10 randomized controlled trials comparing TUIP to TURP. TUIP has been established as a minimally invasive alternative to TURP with significant clinical outcomes. TUIP has demonstrated significant reductions in operative times, low rates of post procedure complications and limited long-term effects. TUIP does not require the use of anesthesia for contraindicated patients however, the benefit of the procedure is mostly found when done on smaller size prostates (<30g) and in patients where there is evidence of an obstructed median lobe. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who receive laser-based procedures for BPH, the evidence includes multiple randomized controlled trials, systematic reviews, and metaanalysis. Primary outcomes of greenlight laser, PVP, HoLEP and HoLAP laser procedures included differences in recovery times, adverse effects, lower complication rates, and reduction of symptoms compared to TURP. In all cases, laser-based procedures showed similar or significant improvement in reduction of symptoms when compared to surgical standards of care. Greenlight laser, photoselective vaporization of the prostate (PVP) and HoLEP, demonstrated shorter recovery periods and less post procedure complications (urinary tract infections, need for catheterization, postoperative bleeding, retrograde ejaculation, erectile dysfunction) when compared to TURP. Symptom reduction was comparable for laser-based procedures to TURP. The evidence is sufficient to determine the effects of the technology on health outcomes.

Transurethral Microwave ablation (TUMT) has been evaluated in multiple randomized controlled trials as a minimally invasive alternative to TURP and to SHAM groups. TUMT is associated with lower rates of post-operative bleeding, postoperative complications and is an appropriate treatment option for patients who are not suitable candidates for anesthesia or more invasive surgical approaches. While the outcomes for TUMT do not improve symptoms compared to TURP and other SHAM trials, it has been established as an appropriate and minimally invasive treatment option in specific scenarios. TUMT is an effective treatment option for patients who may be severely contracted and unable to tolerate alternative minimally invasive treatments or are poor surgical candidates. The evidence is sufficient to determine the effects of the technology on health outcomes.

Transurethral needle ablation (TUNA) has been evaluated in multiple randomized controlled trials as a minimally invasive alternative to TURP. In some studies, TUNA demonstrates clinically significant symptom reduction but also carries a high rate of adverse events and need for retreatment. Limitations in the available studies include significant differences in retreatment rates, variability in rates of postoperative complications and variability in primary outcomes. TUNA is no longer recommended as a standard of care or alternative to TURP by the American Urology Association. The evidence is insufficient to determine the effects of the technology on health outcomes.

While done primarily for the treatment of prostate cancer, cryosurgical ablation of the prostate has been evaluated in small case reviews for the treatment of benign prostatic hyperplasia. Patients undergoing cryosurgical ablation of the prostate reported reduced symptoms of lower urinary tract symptoms after treatment. Cryosurgical ablation has not been evaluated by the American Urology Association as a viable treatment options or alternative for benign prostatic hyperplasia. Due to the lack of randomized, controlled trials, comparative data or long-term safety and efficacy of cryosurgical ablation for BPH, this procedure is considered investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

Prostatic arterial embolization (PAE) has been evaluated in single arm prospective studies and one recent randomized comparative study (Insausti et al, 2020). Primary outcomes include reduction of urinary flow output symptoms, decreased IPSS scores, and increased quality of life scores from baseline. While PAE has shorter recovery times and fewer adverse events compared to TURP, clinical outcomes were on par. The available studies are limited by lack of small population sizes, lack of long-term

outcomes for randomized control arm, and unknown benefit in different size prostates. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
10/2022	Annual policy review. Description and summary updated. Policy statements unchanged.
7/2022	Clarified coding information.
6/1/2021	New references added. 6/1/2021.
4/1/2021	New medically necessary indications added. Title changed from Prostatic Urethral Lift to Minimally Invasive and Surgical Treatment Options for Benign Prostatic Hyperplasia (BPH). Effective 4/1/2021.
1/2021	Annual policy review. Repeat procedures added to the investigational policy statement. Effective 1/1/2021.
1/2020	Annual policy review. Medically necessary statement was updated to remove: Patient does not have prostate-specific antigen level ≥ 3 ng/ml. Medically necessary criterion regarding nickel allergy was expanded to include titanium and stainless steel. Effective 1/1/2020.
1/2019	Annual policy review. The medically necessary statement related to not being a surgical candidate for TURP was removed. Effective 1/1/2019.
6/2018	Annual policy review. New medically necessary indications described. Clarified coding information. Effective 6/1/2018.
10/2016	New references added from Annual medical policy.
8/2016	Local Coverage Determination (LCD): Prostatic Urethral Lift (PUL) (L36601) indicating coverage for Medicare members added. Effective 7/1/2016.
1/2016	New medical policy describing investigational indications. Effective 1/1/2016.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

Expert Opinion

1. McVary, K.T., Gittelman, M.C., Goldberg, K.A., et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of Rezūm Water Vapor Thermal Therapy for Treatment of Moderate-to-Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia, *The Journal of Urology*® (2021), doi: 10.1097/JU.0000000000001778.
2. McVary KT, Roehrborn CG, Avins AL, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). 2010 (affirmed 2014);
3. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. *J Urol.* Dec 2013; 190(6): 2161-7. PMID 23764081
4. McVary KT, Gange SN, Shore ND, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. *J Sex Med.* Jan 2014; 11(1): 279-87. PMID 24119101
5. Shore N. A Review of the Prostatic Urethral Lift for Lower Urinary Tract Symptoms: Symptom Relief, Flow Improvement, and Preservation of Sexual Function in Men With Benign Prostatic Hyperplasia. *Curr Bladder Dysfunct Rep.* NA 2015; 10(2): 186-192. PMID 25984251
6. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol.* Jun 2015; 22(3): 7772-82. PMID 26068624

7. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. *BJU Int.* Oct 2016; 118 Suppl 3: 14-22. PMID 27684483
8. Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU Int.* May 2017; 119(5): 767-775. PMID 27862831
9. Miller LE, Chughtai B, Dornbier RA, et al. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *J Urol.* May 12 2020: 101097JU00000000000001132. PMID 32396049
10. 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.* Jun 2017; 24(3): 8802-8813. PMID 28646935
11. Eure G, Gange S, Walter P, et al. Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study. *J Endourol.* Jul 2019; 33(7): 576-584. PMID 31115257
12. National Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia [IPG475]. 2014; <https://www.nice.org.uk/guidance/ipg475/chapter/1-recommendations>. Accessed July 2, 2020.
13. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [MTG26]. 2015; <https://www.nice.org.uk/guidance/mtg26>. Accessed July 2, 2020.
14. Abt D, Hechelhammer L, Müllhaupt G et al. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial. *BMJ.* 2018; 361; k23338.
15. Barry MJ, Fowler FJ Jr, O'leary MP et al. Measurement Committee of the American Urological Association. The American Urological Association Symptom Index for Benign Prostatic Hyperplasia. *J Urol.* 2017; 197(2S):S189-S197.
16. Bouza C, Lopez T, Magro A, et al. Systematic review and meta-analysis of transurethral needle ablation in symptomatic benign prostatic hyperplasia. *BMC Urol.* 2006; 6:14.
17. Cimentepe E, Unsal A, Saglam R. Randomized clinical trial comparing transurethral needle ablation with transurethral resection of the prostate for the treatment of benign prostatic hyperplasia: results at 18 months. *J Endourol.* 2003; 17(2):103-7.
18. Foster HE, Barry, MJ, Dahm P et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline. Available at: [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline). Accessed on January 15, 2020.
19. Riehmman M, Knes JM, Heisey D, et al. Transurethral resection versus incision of the prostate: a randomized, prospective study. *Urology.* 1995; 45(5):768-775.
20. Gilling, P., Barber, N., Bidair, M., et al. WATER: A double blind, randomized, controlled trial of Aquablation vs transurethral resection of the prostate in benign prostatic hyperplasia. *J Urol.* May 2018. 199(5). 1252-1261.
21. Insasti, I., Saez de Ocariz, A., Galbete, A., et al. Randomized Comparison of Prostatic Artery Embolization versus resection of the prostate for treatment of benign prostatic hyperplasia. *J Vasc Interv Radiol.* June 2020. 31(6). 882-890.
22. McVary, K.T., Gange, S.N., Gittelman, M.C., et al. Minimally invasive prostate convection water vapor energy ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *J Urol.* May 2016. 195(5). 1529-1538.
23. Mordasini, L., Di Bona, C., Klein, J., et al. 80-W GreenLight Laser Vaporization Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 5-year outcomes from a Single-center Prospective Randomized Trial. *Urology.* June 2018. 116. 144-140.
24. Zhang, J., Ou, Z., Zhang, X., et al. Holmium Laser Enucleation of the Prostate Versus thulium laser enucleation of the prostate for the treatment of large-volume prostates >80ml: 18 month follow up results. *World J. Urol.* June 2020. 38(6). 1555-1562.

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1. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med.* Jul 19 2012; 367(3): 248-57. PMID 22808960

2. Barry MJ, Fowler FJ, O'Leary MP, et al. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. *Med Care*. Apr 1995; 33(4 Suppl): AS145-55. PMID 7536866
3. O'leary MP. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. *Rev Urol*. 2005; 7(1): 1-10. PMID 16985801
4. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. *Eur Urol*. 1999; 36(1): 1-13. PMID 10364649
5. Foster HE, Barry MJ, Dahm P, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. *J Urol*. Sep 2018; 200(3): 612-619. PMID 29775639
6. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. *J Urol*. Jul 2008; 180(1): 246-9. PMID 18499179
7. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment. *J Urol*. Oct 2021; 206(4): 818-826. PMID 34384236
8. Sundaram D, Sankaran PK, Raghunath G, et al. Correlation of Prostate Gland Size and Uroflowmetry in Patients with Lower Urinary Tract Symptoms. *J Clin Diagn Res*. May 2017; 11(5): AC01-AC04. PMID 28658743
9. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. *Urology*. May 2007; 69(5): 805-9. PMID 17482908
10. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *Int J Impot Res*. Jul-Aug 2005; 17(4): 307-19. PMID 15875061
11. Sonksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *Eur Urol*. Oct 2015; 68(4): 643-52. PMID 25937539
12. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: how much change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index is perceptible to patients?. *J Urol*. Nov 1995; 154(5): 1770-4. PMID 7563343
13. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. *J Urol*. May 2012; 187(5): 1732-8. PMID 22425127
14. McVary KT, Roehrborn CG, Avins AL, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). 2010 (affirmed 2014); [http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)](http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)). Accessed July 7, 2022.
15. Perera M, Roberts MJ, Doi SA, et al. 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*. Apr 2015; 67(4): 704-13. PMID 25466940
16. Cantwell AL, Bogache WK, Richardson SF, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *BJU Int*. Apr 2014; 113(4): 615-22. PMID 24765680
17. Shore N, Freedman S, Gange S, et al. Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urol*. Feb 2014; 21(1): 7094-101. PMID 24529008
18. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol*. Aug 2013; 64(2): 292-9. PMID 23357348
19. Chin PT, Bolton DM, Jack G, et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology*. Jan 2012; 79(1): 5-11. PMID 22202539
20. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Sex Med*. Feb 2012; 9(2): 568-75. PMID 22172161

21. Woo HH, Chin PT, McNicholas TA, et al. Safety and feasibility of the prostatic urethral lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). *BJU Int.* Jul 2011; 108(1): 82-8. PMID 21554526
22. Hoffman RM, Monga M, Elliott SP, et al. Microwave thermotherapy for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* Sep 12 2012; (9): CD004135. PMID 22972068
23. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. *J Urol.* Dec 2013; 190(6): 2161-7. PMID 23764081
24. Shore N. A Review of the Prostatic Urethral Lift for Lower Urinary Tract Symptoms: Symptom Relief, Flow Improvement, and Preservation of Sexual Function in Men With Benign Prostatic Hyperplasia. *Curr Bladder Dysfunct Rep. NA* 2015; 10(2): 186-192. PMID 25984251
25. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol.* Jun 2015; 22(3): 7772-82. PMID 26068624
26. McVary KT, Gange SN, Shore ND, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. *J Sex Med.* Jan 2014; 11(1): 279-87. PMID 24119101
27. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, et al. [Urolift(R), a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results]. *Arch Esp Urol.* Jul-Aug 2013; 66(6): 584-91. PMID 23985459
28. Jones P, Rajkumar GN, Rai BP, et al. Medium-term Outcomes of Urolift (Minimum 12 Months Follow-up): Evidence From a Systematic Review. *Urology.* Nov 2016; 97: 20-24. PMID 27208817
29. Bozkurt A, Karabakan M, Keskin E, et al. Prostatic Urethral Lift: A New Minimally Invasive Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urol Int.* 2016; 96(2): 202-6. PMID 26613256
30. Ray A, Morgan H, Wilkes A, et al. The Urolift System for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A NICE Medical Technology Guidance. *Appl Health Econ Health Policy.* Oct 2016; 14(5): 515-26. PMID 26832146
31. Tanneru K, Gautam S, Norez D, et al. Meta-analysis and systematic review of intermediate-term follow-up of prostatic urethral lift for benign prostatic hyperplasia. *Int Urol Nephrol.* Jun 2020; 52(6): 999-1008. PMID 32065331
32. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. *BJU Int.* Oct 2016; 118 Suppl 3: 14-22. PMID 27684483
33. Sievert KD, Schonhaler M, Berges R, et al. Minimally invasive prostatic urethral lift (PUL) efficacious in TURP candidates: a multicenter German evaluation after 2 years. *World J Urol.* Jul 2019; 37(7): 1353-1360. PMID 30283994
34. Jung JH, Reddy B, McCutcheon KA, et al. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev.* May 25 2019; 5: CD012832. PMID 31128077
35. Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU Int.* May 2017; 119(5): 767-775. PMID 27862831
36. Franco JVA, Jung JH, Imamura M, et al. Minimally invasive treatments for benign prostatic hyperplasia: a Cochrane network meta-analysis. *BJU Int.* Aug 2022; 130(2): 142-156. PMID 34820997
37. Roehrborn CG. Prostatic Urethral Lift: A Unique Minimally Invasive Surgical Treatment of Male Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urol Clin North Am.* Aug 2016; 43(3): 357-69. PMID 27476128
38. 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.* Jun 2017; 24(3): 8802-8813. PMID 28646935
39. Rukstalis D, Grier D, Stroup SP, et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study. *Prostate Cancer Prostatic Dis.* Sep 2019; 22(3): 411-419. PMID 30542055
40. Shah BB, Tayon K, Madiraju S, et al. Prostatic Urethral Lift: Does Size Matter?. *J Endourol.* Jul 2018; 32(7): 635-638. PMID 29631445

41. Eure G, Gange S, Walter P, et al. Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study. *J Endourol.* Jul 2019; 33(7): 576-584. PMID 31115257
42. Kaplan SA. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *Letter. J Urol.* Mar 2021; 205(3): 939-940. PMID 33393811
43. Miller LE, Chughtai B, Dornbier RA, et al. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *Reply. J Urol.* Mar 2021; 205(3): 940-941. PMID 33393812
44. McVary KT, Kaplan SA. A Tower of Babel in Today's Urology: Disagreement in Concepts and Definitions of Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia Re-Treatment. *J Urol.* Aug 2020; 204(2): 213-214. PMID 32469261
45. Miller LE, Chughtai B, Dornbier RA, et al. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *J Urol.* Nov 2020; 204(5): 1019-1026. PMID 32396049
46. Gaffney CD, Basourakos SP, Al Hussein Al Awamlh B, et al. Adoption, Safety, and Retreatment Rates of Prostatic Urethral Lift for Benign Prostatic Enlargement. *J Urol.* Aug 2021; 206(2): 409-415. PMID 33793296
47. Page T, Veeratterapillay R, Keltie K, et al. Prostatic urethral lift (UroLift): a real-world analysis of outcomes using hospital episodes statistics. *BMC Urol.* Apr 07 2021; 21(1): 55. PMID 33827525
48. National Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia [IPG475]. 2014; <https://www.nice.org.uk/guidance/ipg475/chapter/1-recommendations>. Accessed July 7, 2022.
49. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [MTG58]. 2021; <https://www.nice.org.uk/guidance/MTG58>. Accessed July 7, 2022.

Endnotes

ⁱ Based on expert opinion.