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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Policy[i]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ 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 (α1-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 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 related to conditions other than benign prostatic hyperplasia, 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 (α1-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 (α1-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 **≥**30 – 150cc; **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.

Note: see LCD L38367 for Medicare HMO/PPO Blue

Laser Based Procedures[1]

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 (α1-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 (α1-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 ≤30cc, **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 (α1-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.

Cryosurgical Ablation and Prostatic Embolization[1]

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

1. Cryosurgical ablation
2. Prostatic embolization.

Temporarily Implanted Nitinol Device for Benign Prostatic Hyperplasia (iTind)

The use of a temporarily implanted nitinol device (eg, iTind) is considered **INVESTIGATIONAL** as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.

Transurethral Needle Ablation (TUNA)[1]

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

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
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	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 and HCPCS 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
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate

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.

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.

Temporarily Implanted Nitinol Device (iTind)
The use of the iTind temporarily implanted nitinol device has been investigated as a minimally invasive treatment for lower urinary tract symptoms associated with BPH. With the use of a rigid cytoscope, the device is temporarily implanted into the obstructed prostatic urethra where 3 double intertwined nitinol struts configured in a tulip shape gradually expand. The resulting circumferential force facilitates tissue reshaping via ischemic necrosis of the mucosa, resulting in urethral expansion and prostatic incisions that function as longitudinal channels to improve urine outflow. The implant is typically removed after 5 to 7 days of treatment. A distal nylon wire facilitates device retrieval which may be approached using a snare to pull the device into either a cytoscope sheath or an open-ended silicone catheter (20-22 Fr). The first-generation TIND device had one extra strut and a pointed tip covered by a soft plastic material.

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.

Summary
For individuals who have lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH) who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a prostatic urethral lift (PUL), the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized 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 (TURP) 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 TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (the 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 cm^3 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 lower urinary tract obstruction symptoms due to BPH who have had a prior PUL procedure who are treated with a repeat PUL, the evidence includes long-term follow-up data from the LIFT study, systematic reviews, and reports on care setting real world experience. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Clinical data on the occurrence of repeat PUL, and consensus on clinically relevant definitions of retreatment/reintervention and subsequent outcomes are lacking. The 5 year surgical reintervention rate in the LIFT study was reported as 13.6%, while a meta-analysis concluded that the surgical reintervention rate following PUL is 6% per year. An analysis of clinical care setting real world experience reported the overall retreatment rate at 1 and 2 years to be 5.2% (95% confidence interval [CI], 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively, following an initial PUL. A retrospective healthcare system database analysis of endoscopic procedures for BPH found that patients treated with PUL were almost twice as likely to be retreated at 2-year follow-up compared to those receiving TURP (odds ratio [OR], 1.78; $p<.01$). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS) who receive transurethral water vapor thermal therapy, the evidence includes a single 3-month, sham-controlled, randomized trial of 197 patients with a 5-year uncontrolled follow-up phase and 1 multicenter, prospective, single-arm study. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. At 3 months, LUTS improved more in the intervention group compared to the sham procedure. No adverse effects on erectile or ejaculatory function were observed, and improvements were sustained through 5 years of follow-up. While the evidence is limited by the small sample size and lack of blinding of longer-term outcomes, Rezum is recommended by the AUA and NICE as an effective and safe, minimally invasive alternative to TURP.

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 a 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 metanalysis. 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 catherization, 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.

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.

For individuals who have benign prostatic hyperplasia (BPH) with lower urinary tract symptoms who receive a temporarily implanted nitinol device (eg, iTind), the evidence includes a meta-analysis, 1 randomized controlled trial (RCT), and 2 single-arm, multicenter, international prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One network meta-analysis compared the safety and efficacy of various minimally-invasive treatments for lower urinary tract symptoms associated with BPH, finding that iTind may result in worse urologic symptoms scores compared to TURP at short-term follow-up. One RCT compared the iTind device with a sham procedure and reported an improvement of at least 3 points on the IPSS scale at 3 months in 78.6% versus 60% of participants, respectively (p=.029). However, corresponding changes in overall IPSS, IPSS QoL, Qmax, SHIM, and IIEF scores were not significantly different between groups. One single-arm study reported significant improvements in symptoms and functional outcomes through 3 years. A subsequent single-arm study enrolling men desiring to preserve ejaculatory function reported no significant change in the SHIM total score and a statistically significant improvement on the MSHQ-EjD questionnaire at 6 months. No studies have directly compared iTind to established alternatives; however, an RCT comparing iTind with the UroLift prostratic urethral lift procedure is currently ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

Policy History

Date	Action
1/2025	Clarified coding information.
11/2024	Annual policy review. No changes to policy statements. Description, summary and references reviewed. 11/1/2024.
7/2024	Clarified coding information.
2/2024	Removed LCD L37808 information from Transurethral Water Vapor Thermal Therapy. L37808 retired effective 2/15/2024.
10/2023	Annual policy review. Prostatic urethral lift criteria clarified. Individual does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year). Description and references updated. 10/2023.
5/2023	Investigational statement on temporary implantable nitinol device (iTind) added. Coding information clarified. 5/1/2023.
1/2023	Added LCD information for Transurethral Water Vapor Thermal Therapy and Waterjet Tissue Ablation.
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. UpToDate. Medical treatment of benign prostatic hyperplasia. 2023. Available at: https://www.uptodate.com/contents/medical-treatment-of-benign-prostatic-hyperplasia?search=benign%20prostatic%20hyperplasia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed July 5, 2023.
3. 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
4. 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
5. 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: 101097JU0000000000001132. PMID 32396049
6. 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
7. 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
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.
14. 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. Accessed on January 15, 2020.
15. Riehmann M, Knes JM, Heisey D, et al. Transurethral resection versus incision of the prostate: a randomized, prospective study. Urology. 1995; 45(5):768-775.
16. 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.
17. Insasti, I., Saez de Ocariz, A., Galbete, A., et al. Randomized Comparison of Prostatic Artery Embolization versus resection of the prostate for treatment of bengin prostatic hyperplasia. J Vasc Interv Radiol. June 2020. 31(6). 882-890.
18. 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.
19. 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.
20. 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.

21. Balakrishnan D, Jones P, Somani BK. iTIND: the second-generation temporary implantable nitinol device for minimally invasive treatment of benign prostatic hyperplasia. Ther Adv Urol. 2020; 12: 1756287220934355. PMID 32655690
22. Porpiglia F, Fiori C, Bertolo R, et al. Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up. BJU Int. Aug 2015; 116(2): 278-87. PMID 25382816
23. Porpiglia F, Fiori C, Bertolo R, et al. 3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction. BJU Int. Jul 2018; 122(1): 106-112. PMID 29359881
24. Franco JV, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benign prostatic hyperplasia: a network meta-analysis. Cochrane Database Syst Rev. Jul 15 2021; 7(7): CD013656. PMID 34693990
25. Chughtai B, Elterman D, Shore N, et al. The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial. Urology. Jul 2021; 153: 270-276. PMID 33373708
26. Porpiglia F, Fiori C, Amparore D, et al. Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicentre study at 1 year of follow-up. BJU Int. Jun 2019; 123(6): 1061-1069. PMID 30382600
27. Kadner G, Valerio M, Giannakis I, et al. Second generation of temporary implantable nitinol device (iTind) in men with LUTS: 2 year results of the MT-02-study. World J Urol. Dec 2020; 38(12): 3235-3244. PMID 32124019
28. Amparore D, Fiori C, Valerio M, et al. 3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction. Prostate Cancer Prostatic Dis. Jun 2021; 24(2): 349-357. PMID 33005003
29. De Nunzio C, Cantiello F, Fiori C, et al. Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study. World J Urol. Jun 2021; 39(6): 2037-2042. PMID 32851439
30. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia [IPG737]. September 21, 2022; https://www.nice.org.uk/guidance/ipg737. Accessed November 15, 2022.

Endnotes

[i] Based on expert opinion.