Clinical Guideline



Oscar Clinical Guideline: Benign Prostatic Hyperplasia Procedures (CG031, Ver. 11)

Benign Prostatic Hyperplasia Procedures

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Benign prostatic hyperplasia (BPH) is the inappropriate enlargement of the prostate gland found most frequently in older men. Because urine from the bladder must pass through the prostate, men with BPH may experience symptoms such as a feeling of incomplete emptying, decreased urinary flow, straining, or experience urinary tract infections. Treatment of BPH depends on individual risk factors and careful consideration of the risks/benefits of each therapy. Options for treatment include medications, minimally invasive procedures, and surgical interventions. The Plan utilizes benign prostatic hyperplasia treatment guidelines from the American Urological Association along with current medical literature in determining clinical criteria and exclusions. This guideline does not address the pharmaceutical treatment of BPH. Certain procedures may require prior authorization.

Indexes Used to Evaluate BPH-related Symptoms:

"The American Urological Association Symptom Index (AUA-SI)" is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUA-SI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35).

"The International Prostate Symptom Score (I-PSS)" incorporates the questions from the AUA-SI with an additional quality of life question. The first seven questions of the I-PSS are identical to the questions appearing on the AUA-SI and are scored identically. The answers to the quality of life question range from "delighted" to "terrible" or 0 to 6. Total I-PSS scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35).

Definitions

"Benign Prostatic Hyperplasia" (BPH) is a condition that causes an increase in the size of the prostate gland in men, commonly causing difficulty with urination; also referred to as benign prostatic hypertrophy although this term is technically incorrect.

"Resection" is to surgically remove or excise tissue from the body.

"Ablation" is the surgical destruction or vaporization of tissue.

"Cryosurgery" is a treatment performed with an instrument that destroys tissue by applying very cold temperature.

"Enucleation" is to remove an intact organ or tissue without cutting into the surrounding capsule.

"Hyperplasia" is an enlargement of an organ or tissue because of an increase in the number of cells. It is contrasted by hypertrophy which is defined as an increase in the size of individual cells.

Medical Therapies

- "5-Alpha Reductase Inhibitors" are medications that block the production of a type of testosterone (dihydro-testosterone) involved in prostate development and growth.
- "Alpha Adrenergic Blockers" are medications that relax the muscles of the prostate and bladder; they can improve urine flow and reduce blockage.
- "Phosphodiesterase-5 Inhibitors" are medications that have been found to relax smooth muscle fibers of the bladder and prostate.

Surgical and Minimally Invasive Therapies:

- "Contact Laser Ablation of the Prostate (CLAP)" is a procedure where the tip of an Nd:YAG laser is placed in direct contact with prostate tissue, vaporizing it.
- "Holmium Laser Procedures of the Prostate (HoLAP, HoLEP, HoLRP)" are procedures that use a holmium laser fiber to either ablate (HoLAP), enucleate (HoLEP), or resect (HoLRP) prostate tissue.
- "Interstitial Laser Coagulation of the Prostate (ILCP)" is an outdated procedure involving laser heat treatment to reduce prostatic obstruction. It has largely been replaced by newer approaches.
- "Surgical Prostatectomy" is a surgical procedure that can be done open (e.g., with a large incision to access the prostate), laparoscopically (e.g., with small incisions through which small cameras and/or instruments can be inserted), or robotic-assisted (e.g., laparoscopically and controlled by a surgeon operating the instruments robotically).
- "Photoselective Vaporization (PVP)" is a procedure that involves using a laser to vaporize obstructive prostatic tissue.

- "Prostate Artery Embolization (PAE)" is a minimally invasive therapy used to treat urinary symptoms caused by BPH. It involves blocking blood flow to the prostate, causing the prostate to shrink and relieve pressure on the urinary tract.
- "Prostatic Urethral Lift" or "UroLift" is a procedure to lift or hold the enlarged prostate tissue apart to keep this tissue from blocking the urethra.
- "Temporary Prostatic Stenting" refers to a plastic or metal stent placed into the prostatic urethra to temporarily prevent closure due to a stricture or external compression from the surrounding prostatic tissue; it is FDA-approved for 30 days of use and is not a permanent solution.
- "Transurethral Electrovaporization of the Prostate (TUVP)" is an ablative procedure that involves utilizing heat from a high-voltage electrical current to minimize obstructive prostatic tissue.
- "Transurethral Incision of the Prostate (TUIP)" is a procedure that involves making an incision in the prostate for men with small-to-moderate sized prostates; usually limited to treating glands equal to or less than 30 grams.
- "Transurethral Microwave Thermotherapy (TUMT)" is a procedure that involves using microwave energy to heat and destroy excess prostate tissue.
- "Transurethral Needle Ablation (TUNA)" is a procedure that involves using radio frequency energy to ablate prostatic tissue with the goal of relieving symptoms associated with BPH.
- "Transurethral Resection of the Prostate (TURP)" is a procedure that involves cutting away a section of the prostate accessed through the urethra. It is the gold standard treatment for BPH when conservative therapy has failed.
- "Transurethral Ultrasound Guided Laser Induced Prostatectomy (TULIP)" is an outdated procedure that involves laser ablation delivered under ultrasound guidance. It has been supplanted by newer procedures with more reproducible outcomes and fewer adverse effects.
- "UroLume" is a metallic prostatic stent surgically inserted into the prostatic urethra to prevent closure due to a stricture or external compression from the surrounding prostatic tissue; it is meant as a more permanent solution in patients who are poor surgical candidates.
- "Visually Guided Laser Ablation of the Prostate (VLAP)" is a non-contact laser ablation procedure where a Nd:YAG laser is held a short distance (approximately 2 mm) from the prostate tissue, destroying it by coagulation and allowing it to slough away over several weeks; reserved for treating small or moderately small prostates (less than 80 grams). It has been surpassed by newer procedures with more reproducible outcomes and fewer adverse effects.
- "Water induced thermotherapy (WIT) or Transurethral Convective Water Vapor Thermal Ablation" is a minimally invasive therapy that uses hot water circulating through a urethral balloon catheter to deliver heat energy to prostate tissue to shrink the prostate.
- "Waterjet-hydrodissection, waterjet tissue-ablation, Aquablation" is a minimally invasive therapy that ablates overgrown prostatic tissue with high-velocity saline under robotic guidance in order to restore patency to the urethral passageway.
- "Water vapor thermal therapy (WVTT), convective water vapor energy ablation (WAVE)" is a minimally invasive therapy that uses water vapor (steam) therapy to create necrosis of overgrown prostatic tissue, which eventually shrinks the prostate, thereby improving urinary symptoms.

A. Clinical Indications

- 1. Medical Necessity Criteria for Clinical Review
 - a. Length of Stay
 - b. General Medical Necessity Criteria
 - c. Indication-Specific Criteria
- 2. Experimental or Investigational / Not Medically Necessary
- B. Applicable Billing Codes
- C. References

Medical Necessity Criteria for Clinical Review

Length of Stay

Most treatments and procedures for benign prostatic hyperplasia (BPH) can be safely performed in an ambulatory or outpatient (same day surgery) setting. Exceptions to this where postoperative inpatient admission may be medically necessary are as follows:

- Complications of the procedure such as, but not limited to, bleeding or acute urinary retention;
 or
- Medical comorbidities requiring further acute treatment; or
- Open Prostatectomy, which is indicated for 1 day postoperative (1 midnight).

General Medical Necessity Criteria

Benign prostatic hyperplasia (BPH) procedures are considered medically necessary when ONE of the following criteria is met:

- 1. Documented diagnosis of moderate to severe BPH (I-PSS or AUA-SI score is ≥8); or
- 2. One or more of the following urological complications as a result of BPH:
 - a. Bladder stones; or
 - b. Hydronephrosis; or
 - c. Large bladder diverticula; or
 - d. Recurrent hematuria; or
 - e. Recurrent or persistent retention refractory to medical therapy; or
 - f. Recurrent or persistent urinary tract infection; or
 - g. Renal insufficiency; or
 - h. Urosepsis.

Indication-Specific Criteria

<u>Transurethral Resection of the Prostate (TURP)</u>

Transurethral Resection of the Prostate (TURP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

1. General Medical Necessity Criteria are met; and

2. Patients who request surgery, fail medical management, or have a contraindication to medical management.

Transurethral Microwave Thermotherapy (TUMT)

Transurethral Microwave Thermotherapy (TUMT) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management; *and*
- 3. Prostate volume is between 30 mL and 100 mL, as documented by ultrasound measurement; and
- 4. There is no history of prior prostatic surgery.

Transurethral Electrovaporization of the Prostate (TUVP)

Transurethral Electrovaporization of the Prostate (TUVP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management.

<u>Transurethral Incision of the Prostate (TUIP)</u>

Transurethral Incision of the Prostate (TUIP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management; *and*
- 3. Prostate volume is less than or equal to 30 mL, as documented by ultrasound measurement.

Aquablation (robotic waterjet-hydrodissection, waterjet tissue-ablation) (e.g., AquaBeam)

Aquablation (robotic waterjet-hydrodissection, waterjet tissue-ablation) (e.g., AquaBeam) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. The member has moderate-to-severe LUTS AND a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate.

Contact Laser Ablation of the Prostate (CLAP)

Contact Laser Ablation of the Prostate (CLAP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management.

Holmium Laser Procedures of the Prostate (HoLAP, HoLEP, HoLRP)

Holmium Laser Procedures of the Prostate (HoLAP, HoLEP, HoLRP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management.

Photoselective Vaporization (PVP)

Photoselective Vaporization (PVP) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management.

Prostatic Urethral Lift (e.g., UroLift)

Prostatic Urethral Lift (e.g., UroLift) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Documented diagnosis of moderate to severe BPH (I-PSS or AUA-SI score is ≥8); and
- 3. Patients who fail or do not tolerate medical management after at least 6 months of appropriate therapy, or have a contraindication to medical management; *and*
- 4. 50 years of age or older; and
- 5. Prostate volume is less than or equal to 80 mL, as documented by ultrasound measurement; and
- 6. None of the following features are present:
 - a. Obstructive or protruding median lobe on cystoscopy; and
 - b. Active urinary tract infection; and
 - c. Anatomic urethral conditions or malformations that prevent insertion of the device; and

- d. Current gross hematuria; and
- e. Known allergy or hypersensitivity to nickel.

Surgical Prostatectomy

Surgical Prostatectomy (including simple open prostatectomy, laparoscopic prostatectomy, or robotic-assisted laparoscopic prostatectomy) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. Patients who request surgery, fail medical management, or have a contraindication to medical management; *and*
- 3. Prostate is so large (defined as *at least* 80 mL) that TURP is likely to be incomplete, result in excessive bleeding, or place the member at higher risk of developing TURP syndrome.

Temporary Prostatic Stent (e.g., Spanner Prostatic Stent)

Temporary prostatic stent (e.g., Spanner Prostatic Stent) placement is considered medically necessary after minimally invasive therapy for benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

- 1. Member has undergone a covered minimally invasive procedure for the purpose of BPH treatment meeting the appropriate General Medical Necessity Criteria; and
- 2. Initial post-treatment catheterization was performed and successful prior to placement of a stent; and
- 3. The member would otherwise require urinary catheterization; and
- 4. The expected total duration of stenting is <30 days; and
- 5. A maximum of two stents is considered necessary, with a second stent only covered within 45 days of the minimally invasive procedure in members with degradation of the first stent and who would otherwise require catheterization; *and*
- 6. The member has NONE of the following contraindications:
 - a. Positive urine culture or active urinary tract infection, including bladder or kidney infection: *or*
 - b. History of symptomatic urinary tract diseases such as urethral stricture, bladder stones, or other significant urological conditions (e.g. gross hematuria) that could affect the function of the stent; *or*
 - c. Surgery altering the normal uro-genital anatomy or abnormal urethral anatomy that affects the function of the lower urinary tract; *or*
 - d. A prostatic urethral length less than 4 cm or greater than 9 cm (combined length from the top (proximal side) of the bladder neck to the bottom (distal side) of external sphincter).

UroLume Permanent Stent

UroLume Permanent Stent is considered medically necessary to relieve prostatic obstruction due to benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

- 1. Prostate length of at least 2.5cm; and
- 2. Member has life expectancy of less than 12 months; and
- 3. The member is a poor surgical candidate due to other comorbidities or anatomical irregularities.

Water Vapor Thermal Therapy (WVTT) (e.g., The Rezūm System)

Water vapor thermal therapy (WVTT) (e.g., The Rezūm System) is considered medically necessary as a treatment option for benign prostatic hyperplasia (BPH) when the member has ALL of the following:

- 1. General Medical Necessity Criteria are met; and
- 2. The member is \geq 50 years of age as per FDA indication; and
- 3. The member has lower urinary tract symptoms (LUTS) / BPH with prostate volume 30-80 mL.

Prostate Artery Embolization (PAE)

Prostate artery embolization (PAE) is considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) as an alternative to transurethral resection of the prostate (TURP) when ALL of the following criteria are met:

- 1. General Medical Necessity Criteria are met; and
- 2. The member has failed or has a contraindication to medical management; and
- 3. The member is not a candidate for standard surgical treatments; and
- 4. Malignancy has been ruled out as a cause of symptoms or of hematuria; and
- 5. Any ONE of the following additional criteria is met:
 - a. The member has a large prostate (>80 mL by volume, or > 80g by weight); or
 - b. The member has hematuria of prostatic origin.

Experimental or Investigational / Not Medically Necessary

Any treatment for BPH for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven, and is therefore NOT covered by the Plan.

Treatment options considered experimental or investigational include, but are not limited to, the following:

- 1. Absolute ethanol injection (transurethral) (TEAP)
 - a. Rationale: Published clinical guidelines by the European Association of Urology (2013), the Canadian Urology Association (2010), and the National Institute for Clinical Excellence (NICE; 2010) all recommend against ethanol injection in the treatment of BPH. Furthermore, there is a lack of randomized, controlled clinical trials comparing TEAP to other standard therapies for BPH. Sakr et al (2009) and Magno et al (2008) are two small, prospective, nonrandomized studies without comparisons to other techniques. These studies demonstrate improved outcomes but are limited in their study

design and small number of patients (total between studies, 71 patients). In the Sakr et al study, there were high rates (100%) of acute urinary retention in the postoperative period for a mean of 6.7 days. Another trial by El-Husseiny et al (2011) demonstrated 23% failure rate in 56 men treated with TEAP. A more recent study by Arsan et al (2014) on 123 patients revealed a similar 22.2% failure rate, and concluded that "The procedure is easy, inexpensive, safe, and rapid to use. Yet, long-term and multi-centered studies with larger patient series are needed to define further benefits."

2. Bipolar plasma enucleation of the prostate (BPEP)

a. Rationale: The current literature is limited to few studies directly comparing BPEP to proven techniques of treating BPH. Geavlete et al (2013) compared BPEP to open prostatectomy in 140 patients in a randomized study and found similar outcomes in terms of symptom reduction and side effects. However, further long-term studies are needed to determine potential clinical benefit of this technique.

3. Botulinum toxin

a. Rationale: Several studies have sought to determine a potential clinical benefit of botulinum toxin in BPH. This is currently not an FDA-approved indication given a lack of sufficient evidence, and the vast majority of clinical studies have concluded that botulinum toxins for BPH are in the experimental phase. While results of some trials are promising, the level of clinical evidence is low and future large, placebo-controlled, randomized studies with long-term follow up are needed.

4. Cryosurgical ablation (i.e., cryosurgery)

- a. Rationale: Per the American Urological Association consensus guidelines for the treatment of BPH, "The level of evidence regarding the safety and utility of endoscopic balloon dilation, cryosurgical ablation, HIFU ablation, and the placement of stents, including a lack of treatment outcome analysis for temporary prostatic stents, is insufficient to draw any conclusions."
- 5. Endoscopic balloon dilation of the prostate (i.e. Transurethral balloon dilation of the prostatic urethra)
 - a. Rationale: Per the American Urological Association consensus guidelines for the treatment of BPH, "The level of evidence regarding the safety and utility of endoscopic balloon dilation, cryosurgical ablation, HIFU ablation, and the placement of stents, including a lack of treatment outcome analysis for temporary prostatic stents, is insufficient to draw any conclusions." Furthermore, the 4th International Consultation on BPH states "Balloon dilation is not recommended as a treatment option for patients with symptoms of BPH."

6. Histotripsy

- a. Rationale: The existing evidence is primarily limited to canine models. Clinical benefit in human subjects with BPH has yet to be demonstrated in large scale, randomized, controlled trials.
- 7. Interstitial Laser Coagulation of the Prostate (ILCP)

- a. Rationale: ILCP has been supplanted by newer techniques with fewer side effects and improved efficacy. Daehlin et al (2007) treated 49 men with ILCP for BPH and found that while there was a decrease in I-PSS score and increased urinary flow, 50% of the patients eventually required retreatment including 15% within the first year. The authors conclude "...long-term follow-up is necessary to determine the role of ILC."
- 8. iTind System or temporary implantable nitinol device
 - a. iTind System is a 2020 FDA-approved temporary device inserted transurethrally and deployed at the prostate for acute urinary retention due to urinary outflow obstruction caused by BPH. It is a minimally invasive process with the device creating scar tissue with longitudinal incision and is removed after 5-7 days. The device can provide long-term relief by allowing urine to flow more freely. As per Hayes, there is minimal support for use of iTind for the treatment of lower urinary tract symptoms with 6 studies (3 poor quality, 2 fair quality, and 1 RCT). Furthermore, for practice guidelines, there is weak support for iTind for LUTS.
- 9. Plasma kinetic vaporization (PlasmaKinetic Tissue Management System) (PKVP)
 - a. Rationale: Koca et al (2014) looked at 75 patients randomized to TURP vs. PKVP. Only 36 patients enrolled and completed the full 6-year follow-up period. The authors concluded, "Compared to standard TURP, PKVP was found to be unsuccessful in the treatment of BPH when long-term outcomes were considered".⁵
- 10. Temporary prostatic urethral stent for the definitive treatment of BPH, as a temporizing measure prior to surgery, or for any other indication not meeting the above criteria
 - a. Rationale: Per the 2010 American Urological Association consensus guidelines for the treatment of BPH, "The level of evidence regarding the safety and utility of endoscopic balloon dilation, cryosurgical ablation, HIFU ablation, and the placement of stents, including a lack of treatment outcome analysis for temporary prostatic stents, is insufficient to draw any conclusions." The most recent update of these guidelines (affirmed 2014) makes no mention of prostatic stents for the treatment of BPH. Furthermore, the recent evidence for temporary prostatic stents in BPH is limited. Retrospective data (Abdul-Muhsin et al, 2016) shows rates of symptomatic infection approaching 16%, with 27% of patients requiring 3 or more temporary stents to be placed. Another study by Roach (2017) showed 32 of 56 men required on average 6 stents with some requiring up to 18 stents when used as the primary treatment for BPH. These studies suggest that permanent stenting solutions or alternative therapies may be more appropriate. A recent review paper on the state of prostatic stent use by Peyton et al (2015), highlights "two major drawbacks" of temporary stents when used to treat BPH: high rates of urinary tract infection rates (41% in one study) and decreased urinary flow as the stent begins to degrade.
- 11. Transrectal thermal therapy (including transrectal microwave hyperthermia, transrectal radiofrequency hyperthermia, transrectal electrothermal hyperthermia, and transrectal high-intensity focused ultrasound, regardless of whether MRI guided or not)

a. Rationale: Per the American Urological Association consensus guidelines for the treatment of BPH, "The level of evidence regarding the safety and utility of endoscopic balloon dilation, cryosurgical ablation, HIFU ablation, and the placement of stents, including a lack of treatment outcome analysis for temporary prostatic stents, is insufficient to draw any conclusions." Furthermore, a study on long-term outcomes by Madersbacher et al (2000) revealed that 43.8% of patients undergoing HIFU had to receive TURP within 4 years of therapy. There are very few recent trials examining this technique further.

12. Transurethral Ultrasound Guided Laser Induced Prostatectomy (TULIP)

a. Rationale: TULIP is increasingly considered an outdated technique given higher rates of incontinence, difficult technical usage, delayed onset of improvement in outcomes, and loss of tissue available for histological assessment. In light of these findings, TULIP is no longer a recommended treatment option for BPH.

13. Transurethral Needle Ablation (TUNA)

a. *Rationale:* TUNA was previously used to treat BPH as a minimally invasive alternative to transurethral resection of the prostate (TURP). The 2018 AUA Clinical Guidelines now advise that "TUNA is not recommended for the treatment of LUTS attributed to BPH." As such, this treatment is considered experimental or investigational.

14. Visually Guided Laser Ablation of the Prostate (VLAP)

a. Rationale: VLAP is increasingly considered an outdated technique given higher rates of incontinence, difficult technical usage, delayed onset of improvement in outcomes, and loss of tissue available for histological assessment. In light of these findings, VLAP is no longer a recommended treatment option for BPH and has largely been replaced by laser vaporization techniques.

15. Water-induced thermotherapy (WIT), hot-water balloon thermoablation, thermourethral hot-water therapy

- a. Rationale: National or international society guidelines do not address water-induced thermotherapy (WIT), hot-water balloon thermoablation, thermourethral hot-water therapy. No RCTs for these types of procedures.
- 16. The following injectable and oral treatments have scarce published data in the peer-reviewed scientific literature demonstrating effectiveness and/or clinical benefit for BPH:
 - a. Intra-prostatic injections of vitamin D3 receptor analogs
 - b. Luteinizing hormone-releasing hormone antagonists
 - c. Beta-3 Agonist Mirabegron
 - d. Phytotherapeutic agents or phytotherapy (Serenoa repens, Pygeum africanum, hypoxis rooperi, pinus, picea, urtica dioica, and secale cereale).

Applicable Billing Codes

Table 1		
CPT/HCPCS codes considered medically necessary if criteria are met:		
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)	
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) • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for prostate artery embolization (PAE), it is considered medically necessary	
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for prostate artery embolization (PAE), it is considered medically necessary	
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,	

Table 1		
CPT/HCPCS codes considered medically necessary if criteria are met:		
Code	Description	
	cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	
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 the prostate tissue; by microwave thermotherapy	
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement	
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	

Table 2		
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:		
Code	Description	
N02.0 - N02.B9	Recurrent and persistent hematuria	
N13.0	Hydronephrosis with ureteropelvic junction obstruction	
N13.1	Hydronephrosis with ureteral stricture, not elsewhere classified	
N13.2	Hydronephrosis with renal and ureteral calculous obstruction	
N13.30 - N13.39	Other and unspecified hydronephrosis	
N18.9	Chronic kidney disease, unspecified	
N21.0	Calculus in bladder	
N32.3	Diverticulum of bladder	
N35.010- N35.016	Post-traumatic urethral stricture, male	

Table 2		
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:		
Code	Description	
N35.111- N35.119	Postinfective urethral stricture, not elsewhere classified, male	
N35.811- N35.819	Other urethral stricture, male	
N35.911- N35.919	Urethral stricture, unspecified, male	
N39.0	Urinary tract infection, site not specified	
N40.0 - N40.3	Benign prostatic hyperplasia	
N30.00 - N30.91	Cystitis	
N34.0 - N34.3	Urethritis and urethral syndrome	

Table 3		
CPT/HCPCS codes considered experimental, investigational or not medically necessary for indications in this guideline:		
Code	Description	
52281	Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female	
52647	Non-contact laser coagulation of prostate (code descriptor revised 1/1/06 - 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) • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for VLAP, ILCP, it is considered experimental or investigational.	
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) • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for TULIP, it is considered experimental or investigational.	

Table 3	Table 3	
CPT/HCPCS codes considered experimental, investigational or not medically necessary for indications in this guideline:		
Code	Description	
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) • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for TULIP, it is considered experimental or investigational.	
53000	Urethrotomy or urethrostomy, external (separate procedure); pendulous urethra	
53010	Urethrotomy or urethrostomy, external (separate procedure); perineal urethra, external	
53600	Dilation of urethral stricture by passage of sound or urethral dilator, male; initial	
53601	Dilation of urethral stricture by passage of sound or urethral dilator, male; subsequent	
53605	Dilation of urethral stricture or vesical neck by passage of sound or urethral dilator, male, general or conduction (spinal) anesthesia	
53620	Dilation of urethral stricture by passage of filiform and follower, male; initial	
53621	Dilation of urethral stricture by passage of filiform and follower, male; subsequent	
53852	 Transurethral destruction of the prostate tissue by radiofrequency thermotherapy <u>Due to multiple procedures represented by this CPT code, specific exclusions are indicated:</u> When this code is billed for TUNA, it is considered experimental or investigational. 	
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)	
53899	 Unlisted procedure, urinary system <u>Due to multiple procedures represented by this CPT code, specific exclusions are indicated:</u> The procedure-specific code should be billed when appropriate, otherwise billing this unlisted code may be considered experimental or investigational 	

Table 3		
CPT/HCPCS codes considered experimental, investigational or not medically necessary for indications in this guideline:		
Code	Description	
55899	 Unlisted procedure, male genital system Due to multiple procedures represented by this CPT code, specific exclusions are indicated: The procedure-specific code should be billed when appropriate, otherwise billing this unlisted code may be considered experimental or investigational 	
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation • Due to multiple procedures represented by this CPT code, specific exclusions are indicated: • When this code is billed for prostate artery embolization (PAE), it is considered experimental or investigational.	
J0585	Injection, onabotulinumtoxinA, 1 unit	
J0586	Injection, abobotulinumtoxinA, 5 units	
J0587	Injection, rimabotulinumtoxinB, 100 units	
J0588	Injection, incobotulinumtoxinA, 1 unit	
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg	
J3315	Injection, triptorelin pamoate, 3.75 mg	
J9155	Injection, Degarelix, 1 mg	
J9202	Goserelin acetate implant, per 3.6 mg	
J9217	Leuprolide acetate (for depot suspension), 7.5 mg	
J9218	Leuprolide acetate, per 1 mg	
J9219	Leuprolide acetate implant, 65 mg	
J9226	Histrelin implant (Supprelin LA), 50 mg	
S0090	Sildenafil citrate, 25 mg	

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