Benign Prostatic Hyperplasia (BPH) Treatment Options

Approved for: See Specific Procedures for Coverage
For Sierra Health-Care Options Members - Please review plan documents prior to making a determination.
Requires Medical Director Approval

CPT Codes:

53850	Transurethral destruction of prostate tissue by microwave thermotherapy
53852	Transurethral destruction of prostate tissue by radiofrequency thermotherapy
53853	Transurethral destruction of prostate tissue by water-induced thermotherapy
52282	Cystourethroscopy, with insertion of urethral stent
52510	Transurethral balloon dilation of the prostatic urethra
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands
52450	Transurethral incision of prostate
52647	Non-contact laser coagulation of prostate
52648	Contact laser vaporization of prostate
55821	Prostatectomy; suprapubic, subtotal, one or two stages
55831	Prostatectomy; retropubic, subtotal
55801	Prostatectomy, perineal, subtotal)

Description:

Benign prostatic hyperplasia (BPH) is defined histologically as a disease process characterized by stromal and epithelial hyperplasia beginning in the periurethral zone of the prostate. The chief complaint of patients with BPH is usually bothersome lower urinary tract symptoms typified by urinary frequency, urgency, nocturia, decreased and intermittent force of stream and a sensation of incomplete bladder emptying. The relationship between BPH and lower urinary tract symptoms is complex because not all men with histological evidence of BPH develop symptoms and not all men with symptoms have BPH or prostate enlargement. Therefore treatment recommendations are based on the degree to which lower urinary tract symptoms affect quality of life, age, degree of prostate enlargement, cost, other clinical conditions as well as patient and physician preference.

Covered Indications:

Treatment options for patients with bothersome moderate to severe lower urinary tract symptoms (AUA Symptom Score ≥ 8) of benign prostate enlargement due to BPH include watchful waiting, medical therapy consisting of alpha-adrenergic blockers (alfuzosin, doxazocin, tamsulosin, terazosin), 5 alpha-reductase inhibitors (dutasteride, finasteride) or a combination of both, minimally invasive treatments such as transurethral microwave heat treatments (TUMT), transurethral needle ablation (TUNA), and prostatic fossa stents, and surgical therapies consisting of transurethral incision of the prostate (TUIP), transurethral electrovaporization or laser vaporization, coagulation, resection / enucleation of the prostate and open techniques. A description of each treatment modality with advantages / disadvantages of each follows.

Currently at the beginning of this new century, TURP is still the benchmark therapy for BPH. Alternatives to transurethral resection of the prostate may be approved by exception requiring prior authorization from Medical Director.

Minimally Invasive Treatments:
Treatments include Balloon Dilation of the Prostate, Prostatic stents and Thermal – based therapies. Thermal based therapies use high temperatures to produce coagulation necrosis of prostate tissue, attempting to achieve results similar to TURP but at a lower cost and morbidity. Heat comes in the form of microwave, radiofrequency waves, high-intensity ultrasound and hot water. Treatment to temperatures greater than 45°C is referred to a thermotherapy and treatment to temperatures below 45°C is referred to as hyperthermia. Temperatures in excess of 45° to 50°C produce tissue coagulation. Temperatures in the hyperthermia range have no demonstrable effects on prostate tissue.

BALLOON DILATION OF THE PROSTATE

CPT code: 52510
Approved for: Medicare, Medicaid
Description: Under fluoroscopic guidance, a flexible balloon catheter is placed in the urethra at the level of the prostate. The balloon is then inflated and maintained for a period of time to distend the prostatic urethra. The widening process is intended to relieve obstruction of the urethra caused by the enlarged prostate. While short-term studies in the late 1980's were promising, follow-up studies demonstrated a significant failure rate over time.

Comments: The 4th International Consultation on BPH and the American Urological Association BPH Guideline Update Panel no longer recommend balloon dilation of the prostate as a treatment option for patients with BPH.
Considerations:
1. Not suitable for large prostates

PROSTATIC STENTS (UROLUME ENDOPROSTHESIS)

CPT code: 52282
Approved for: Medicare, Medicaid
Description: The UroLume® Endoprosthesis is a flexible metal mesh tube designed to relieve urethral obstruction due to recurrent bulbar strictures or BPH. The stent is place in the urethra at the level of the obstruction and exerts radial force to keep the urethra open. As urothelial tissue grows over the prosthesis, the mesh becomes incorporated within the urethral wall and provides a flexible, open urethral lumen.

Comments: The AUA BPH Guideline Update Panel recommends that placement of prostatic urethral stents be considered only in high-risk patients, especially those in urinary retention, who are not surgical candidates because of significant complications such as encrustation with stones, infection and chronic pain.

Considerations:
1. Contraindications include meatal or urethral strictures, active UTI's, patients with other urologic conditions who require transurethral manipulations within 8 weeks of stent placement, patients with known or suspected prostate cancer, patients with transitional cell carcinoma of the bladder, previous surgical procedures for BPH, neurogenic bladder, bladder calculi, or a prostatic urethra < 2.5 cm in length.

TRANSURETHRAL MICROWAVE HEAT TREATMENTS (TUMT®)

CPT: 53850
Approved for: Medicare, Medicaid, Commercial
Description: An alternative to TURP, microwave thermotherapy uses a urethral probe to reduce prostatic tissue through heat damage and coagulation necrosis. The remaining urethra is kept cool to avoid adverse effects. Transurethral microwave heat treatment devices include the Prostatron® (Prostasoft Versions 2.0 and 2.5) and Targis® both manufactured by Urologix, CoreTherm™ manufactured by Prostalund, and TherMatrx™ manufactured by TherMatrix / American Medical Systems.

Comments: In the average patient, TUMT was more effective than medical therapy but less effective than surgery in relieving symptoms. Durability is proven out to 12 - 24 months. Long-term durability has not been established. There are no direct comparator trials to suggest superiority of one specific device over another.
Indications:
1. Bladder Outlet Obstruction (BOO) and Lower Tract Symptoms (LUTS) of significant degree to cause an American Urological Association Symptom Score above seven. A score from 0-7 reflects mild symptoms, from 8-19 moderate, and from 20-35 severe. A patient with mild symptoms may be treated with medicine or, appropriately, receive no treatment at all. A patient with moderate symptoms may be treated with medical or surgical procedures based on the physician/patient decision.
2. A peak urine flow of 15 milliliters per second or less on a voided volume of 125 milliliters or greater.

Considerations:
1. Each device has its own indications, including the criteria for eligible prostate size indicated for the specific system being used. Patients excluded from trials included those with prior prostate surgery, diabetes or other neurologic condition causing urinary retention and bladder dysfunction, acute UTI, concomitant use of medical therapy for prostate disease.
2. Patients with prior pelvic irradiation are at increased risk for rectal fistula formation.
3. Outpatient setting, local / sedation used (general or spinal not recommended)
4. Irritative voiding symptoms persist for weeks
5. Temporary urinary retention is common.
6. Use of TUMT In the treatment of chronic prostatitis has not been proven efficacious.
7. Contraindicated in the presence of a metallic hip replacement.
8. When prostate cancer and urinary obstruction are both present, TUNA may be appropriate therapy for relief of the urinary obstruction

TRANSURETHRAL NEEDLE ABLATION (TUNA)

CPT code: 53852
Approved for: Medicare, Medicaid, Commercial

Description: TUNA used radiofrequency (RF) waves (490 KHz) to heat prostatic tissue. The RF energy is administered through two 18-guage needles at the tip of a TUNA catheter. This catheter resembles a rigid cystoscope and contains a lens that guides placement in the urethra using direct vision. The needles are advanced into the prostate by piercing the urethra then heated to about 100°C to produce coagulation necrosis. Both needles have insulating sheaths to protect the urethral mucosa from heating. The ideal patient has a small to moderate sized prostate consisting mostly of lateral lobe enlargement.

Comments: TUNA appears more effective than medical therapy but less effective than TURP. The efficacy of TUNA appears to be similar to that achieved by TUMT devices.
Indications:
1. Bladder Outlet Obstruction (BOO) and Lower Tract Symptoms (LUTS) of significant degree to cause an American Urological Association Symptom Score above seven. A score from 0-7 reflects mild symptoms, from 8-19 moderate, and from 20-35 severe. A patient with mild symptoms may be treated with medicine or, appropriately, receive no treatment at all. A patient with moderate symptoms may be treated with medical or surgical procedures based on the physician/patient decision.
2. A peak urine flow of 15 milliliters per second or less on a voided volume of 125 milliliters or greater.

Considerations:
1. Irritative urinary symptoms can persist for weeks
2. Temporary urinary retention is common.
3. Higher requirement for analgesia / sedation / anesthesia than TUMT
4. When prostate cancer and urinary obstruction are both present, TUNA may be appropriate therapy for relief of the urinary obstruction

WATER INDUCED THERMOTHERAPY

CPT code: 53853
Approved for: Medicare, Medicaid, Commercial

Description: The Thermo Flex™ Water-Induced Thermotherapy system, manufactured by ArgoMed Inc., was approved by the FDA in 8/99 following a single, international, uncontrolled, multicenter trial demonstrating symptom reduction and safety. Since that time, an additional single-center study supported the findings. Circulating hot water, delivered in a proprietary closed-loop catheter, delivers coagulating levels of heat transmitted through a specially designed treatment balloon over the entire length of the targeted prostatic tissue. The treatment catheter is removed and replaced with a foley catheter. The procedure is accomplished in about 45 minutes.

Comments: The American Urological Association BPH Guideline Update Panel characterized WIT as an emerging therapy even though FDA approved. Hayes, Inc. stated there was insufficient evidence to conclude that water-induced thermotherapy (WIT) is safe and effective for the treatment of BPH. While the limited available published data suggest that WIT can provide therapeutic results, there has been no direct comparison of WIT with other treatment options for BPH. Although it is not inappropriate to offer this option to the patient, the uncertainty of outcomes compared to recommended treatment options should be discussed.

Considerations:
1. Relative contraindications include suspected or proven prostate carcinoma, previous prostate or rectal surgery (other than hemorrhoidectomy), bladder calculi or hematuria within 3 months of anticipated procedure, large median lobe protruding into the bladder, neurogenic bladder, post-void residual > 250 ml, patient interest in future fertility and large prostate.

Surgical Therapies:
Surgical therapies for treatment of an enlarged prostate should be recommended for those patients who have renal insufficiency clearly due to BPH and in those patients with recurrent gross hematuria, or bladder stones clearly due to BPH and refractory to other therapies. The presence of a bladder diverticulum is not an absolute indication for surgery unless it is associated with recurrent UTI or progressive bladder dysfunction. Surgical therapies include transurethral electrovaporization of the prostate, transurethral incision of the prostate, laser therapies to include Transurethral ultrasound-guided laser induced prostatectomy (TULIP), visually-guided laser ablation (VLAP), contact laser ablation using visual guidance (CLAP), and interstitial laser coagulation of the prostate (ILCP).

TRANSURETHRAL ELECTROVAPORIZATION OF THE PROSTATE (TVP OR TUVP)

CPT code: 52648
Approved for: Medicare, Medicaid, Commercial

Description: This procedure is a modification of the standard TURP[i]. A roller ball is put in a resectoscope and, using a technique similar to the standard TURP, the ball is rolled over the BPH tissue with the cutting current set up to a significantly higher wattage than for a standard TURP. With multiple passes, the tissue is vaporized to the desired depth. (Another variant of this procedure using laser energy to vaporize the prostate is discussed below).

Comments: Compared to TURP, transurethral electrovaporization results in equivalent short-term improvements in symptom scores, urinary flow rates and quality of life indices. Bleeding, post-TURP syndrome, and hospital stay are much less and catheter removal is earlier than with standard TURP.

Considerations:
1. May be considered in some anticoagulated patients.
2. Post-op irritative voiding symptoms, dysuria, urinary retention may be higher as well as need for unplanned secondary catheterization.

TRANSURETHRAL INCISION OF THE PROSTATE (TUIP)

CPT code: 52540
Approved for: Medicare, Medicaid, Commercial
Description: Using similar instruments as a TURP, a Collings knife is used to make two incisions in the prostate and prostate capsule to reduce the constriction of the urethra.

Comments: Appropriate for patients with small prostates, TUIP results in degrees of symptomatic improvement equivalent to those attained after TURP.

Considerations:
1. Limited to short, small prostates
2. Associated with slightly higher rates of secondary procedures
3. Much lower rates of retrograde ejaculation than standard TURP

LASER PROSTATECTOMY

CPT code: 52647 (non-contact laser *coagulation* of the prostate)
52648 (contact *vaporization* with or without transurethral resection of the prostate)
Approved for: Medicare, Medicaid, Commercial

Description: Laser energy can be used to produce coagulation necrosis, vaporization of tissue or resection of tissue. The advantages of laser prostatectomy over TURP include technical simplicity, reduced bleeding and intraoperative fluid absorption (post-TURP syndrome), reduced retrograde ejaculation, impotence and incontinence. Patients usually have shorter hospital stays and faster postoperative recovery. There are 5 variants of laser prostatectomy which use either neodynium: yttrium-aluminum-garnet (Nd:YAG), holmium laser or Indigo laser.
1. Transurethral ultrasound-guided laser induced prostatectomy (TULIP). A free-fiber with a direct end beam used to coagulate prostate tissue. Because of inability to penetrate deeply enough into tissue and the advantage of direct visualization, this procedure is uncommonly performed in favor of more advanced techniques.
2. Visual laser ablation of the prostate (VLAP). Under direct vision, special right-angle fibers direct energy directly to prostate tissue. Because the fiber is not in direct contact, the procedure is considered to be of low-power density and coagulates but does not vaporize the tissue. The coagulated tissue eventually necroses and sloughs, relieving the obstruction.
3. Transurethral laser vaporization (TVP or TLVP) or Contact Laser ablation using visual guidance (CLAP). Similar to transurethral electrovaporization with electrocautery, the prostate tissue is vaporized using laser energy. The laser fiber is maintained in contact (in contrast to the coagulation procedure during which the fiber is kept at a distance from the tissue) with the area to be treated and a series of furrows is made until a wade channel is obtained.
4. Transurethral holmium laser resection / enucleation. This is a technique whereby the prostate tissue is resected using a holmium laser fiber and a specially designed resectoscope. Results approach those obtained after TURP but long-term data is still pending. The holmium laser has also been applied to the treatment of very large glands in the form of a laser enucleation with subsequent intravesical morcellation. The results are comparable to open surgery in experienced hands.
5. Interstitial laser coagulation of the prostate (ILCP). Several laser sources have been used to place fibers directly into prostate tissue. In the Unites States, the Indigo 830e (Ethicon Endo-Surgery) has been evaluated and approved and multicenter trials are underway.

Comments: All forms of laser prostatectomy demonstrate short-term efficacy comparable to TURP (except the older technique of TULIP which has all but been abandoned in favor of newer techniques and ILCP for which efficacy has not yet been demonstrated in multicenter trials). Holmium laser resection results in improved symptom scores, quality of life indices and flow rate approach those results obtained after TURP. Long-term durability remains to be seen. All laser treatments report decreased complication rate of bleeding, retrograde ejaculation, impotence, incontinence and post-TURP syndrome.

Considerations:
1. Laser approaches have been associated with in increased incidence of a secondary procedure and urinary retention requiring secondary catheterization.
2. Laser therapies have been associated with increased irritative symptoms persisting longer than with standard TURP.

SUMMARY TABLE OF LASER PROSTATECTOMY TECHNIQUES

Procedure	Laser	Type	Visibility	Intensity	Comments
TULIP	Nd:YAG	Non-contact	Non-visibility (ultrasound)	Coagulation	Better techniques available
VLAP	Nd:YAG	Non-contact	Direct visualization	Coagulation	
TVP	Nd:YAG	Contact	Direct visualization	Vaporization	
THLR	Holmium	Contact	Direct visualization	Resection	Closest to TURP
ILCP	Indigo	Contact	Non-visualization (ultrasound)	Coagulation	Considered emerging therapy*

*AUA Guideline on the Management of Benign Prostatic Hyperplasia, 2003.

OPEN SURGICAL PROCEDURES – typically performed on patients with prostate volumes greater than 80 – 100 ml.

Suprapubic prostatectomy:

CPT code: 55821

Approved for: Medicare, Medicaid, Commercial
Description: This is an open surgical approach utilized for large prostates with a substantial intravesical component of the prostate. A suprapubic incision gives access to the anterior surface of the bladder, which is opened to give exposure to the bladder neck and underlying tissue. From inside the bladder, the mucosa surrounding the bladder neck is incised and the adenomatous elements are removed. A foley catheter and suprapubic tube are then placed.

Comments: This is an ideal procedure for large prostates that have created a bladder diverticulum, which also must be excised.

Retropubic Prostatectomy:

CPT code: 55831

Approved for: Medicare, Medicaid, Commercial
Description: This open procedure is ideally suited to a large, high-lying gland with little, if any, intravesical component. A suprapubic incision is made to gain exposure to the anterior surface of the prostate. Under direct vision, the prostate is enucleated both sharply and bluntly. The incision may be carried onto the anterior surface of the bladder to gain exposure of the bladder neck and bladder if necessary. A foley catheter is left indwelling (as well as a suprapubic tube if the bladder was entered).

Comments: Radical retropubic prostatectomy, which includes removal of the seminal vesicles, is reserved for treatment of prostate cancer.

Perineal Prostatectomy:

CPT code: 55801

Approved for: Medicare, Medicaid, Commercial
Description: This open procedure is suitable for large, low-lying prostates. The patient is placed in the extreme lithotomy position giving access to the perineum. An inverted "u"-shaped transverse incision is made anterior to the rectum. The rectum is separated from the posterior aspect of the prostate. The prostatic capsule is incised and the

adenoma removed with sharp and blunt dissection. A foley catheter is inserted into the bladder through the urethra and the prostate capsule is closed to re-establish continuity.

Comments: Radical perineal prostatectomy, which includes removal of the entire prostate and seminal vesicles, is reserved for cancer of the prostate.

EMERGING THERAPIES

The following therapies are not recommended by the AUA Guideline on the Management of BPH.
1. Phytotherapeutic agents (e.g. *Serenoa repens*)
2. Other dietary supplements

Additional data are required before the following therapies can be considered as recommended treatment options by the AUA Guideline on the Management of BPH.
1. Interstitial laser coagulation
2. Water-induced thermotherapy
3. PlasmaKinetic™ Tissue Management System

Non-Covered Indications:
The following therapies are considered investigational at this time and should not be offered outside the framework of clinical trials.
1. Absolute ethanol injection
2. High-intensity focused ultrasound

Review History:
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