Urinary outlet obstruction is difficulty in the passage of urine from the bladder to the urethra caused by compression or resistance on the bladder outflow channel at any location from the bladder neck to the urethral meatus. In males, this can be caused by benign prostatic hyperplasia (BPH). BPH is a common age-related noncancerous condition in men that is characterized by an increase of epithelial and stromal cells in the periurethral area of the prostate. This increase in cells causes an enlargement of the prostate gland. This pathologic change is important because of the proximal anatomical relationship between the prostate and the bladder neck. The condition generally involves lower urinary tract symptoms (LUTS), which may include increased urinary frequency, urgency, incontinence, or straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying. Given the substantive symptomatic impact of urinary outlet obstruction, symptomatic appraisal of interference with activities of daily living is a crucial aspect of evaluation. In an effort to quantify the severity of symptomatic BPH, a urodynamic investigation (e.g., urine flow rate assessment) may be performed.

Treatment for BPH includes watchful waiting (e.g., active surveillance), medical management with pharmacotherapy (e.g., alpha-blockers, 5-alpha-reductase inhibitors), minimally invasive treatments (e.g., transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT]), and surgery (e.g., TURP, laser treatments). If there is minimal bother (i.e., interference with activities of daily living) and no evidence of prostate enlargement, watchful waiting may be utilized. Medical management may be indicated for individuals with uncomplicated BPH or moderate to severe symptoms, and individuals who are waiting for surgery, unwilling to undergo surgery, or are poor surgical candidates. Individuals with BPH who have complications such as acute urinary retention, recurrent urinary tract infections, hematuria, bladder stones, or renal insufficiency/failure due to BPH may be treated surgically. Untreated BPH may worsen over time and increase the risk of stones, infection, or kidney failure. The choice of treatment for urinary outlet obstruction due to BPH should be based on the individual's presentation and anatomy, the surgeon's level of training and experience, and a discussion of the potential benefit and risks for complications.

The primary goal of treatment is to alleviate bothersome symptoms (i.e., symptoms that interfere with activities of daily living) that result from prostatic enlargement. More recently, treatment has been focused on altering disease progression and preventing complications associated with BPH. Standard surgical treatments such as transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP) (in which an incision is made where the prostate meets the bladder), and open prostatectomy may be accompanied by undesirable complications such as blood loss, need for transfusion, salt imbalances from fluid absorption, and side effects such as incontinence and retrograde ejaculation. Newer surgical techniques that use lasers, as well as minimally invasive techniques that use various sources of energy such as heat, microwaves, radiofrequency, and ultrasound, have been developed.

SURGICAL TREATMENTS

STANDARD SURGICAL TREATMENTS
Transurethral resection of the prostate (TURP) is the standard treatment for BPH against which all treatments are measured. TURP involves removing the core of the prostate through the urethra using instruments and electrodissection. An electrified wire loop removes pieces of prostatic tissue and coagulated blood. TURP is performed under general or spinal anesthesia and requires a hospital stay. Other standard surgical options include TUIP and open prostatectomy.

THERMAL TREATMENT
Transurethral electrovaporization of the prostate (TUVP) vaporizes the enlarged prostate tissue, destroying it by coagulation and allowing it to slough away over several weeks. TUVP steams the tissue away using high heat, and dries out the tissue using lower heat. Advantages of TUVP have shown earlier post-treatment catheter removal and less bleeding-related complications when compared to TURP. Evidence in available published peer-reviewed literature demonstrates the safety and effectiveness of TUVP for the treatment of BPH (Poulakis 2004).

LASER TREATMENTS
These procedures involve a laser fiber that is passed into the prostatic channel under telescopic guidance. The laser is then used, through vaporization or ablation techniques, to destroy the obstructing portions of the prostate with heat. With laser vaporization, high instantaneous heat is created to vaporize or steam away prostate tissue. Lower laser energy is applied with laser ablation, which heats the tissue enough to dry it out and allows it to shrink and slough away with time. Various types of laser treatments include:

- **Visual laser ablation of the prostate (VLAP)**
  - VLAP delivers a laser energy that is focused, without direct contact with the prostate, on the enlarged prostatic tissue, and causes thermal injury or coagulation necrosis of the tissue. The primary mechanism of tissue destruction is coagulation rather than vaporization, and the coagulated tissue sloughs away over several weeks following VLAP. VLAP requires a post-treatment catheterization from several days to several weeks. Community practice suggests that VLAP is not commonly used for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH), as laser vaporization is now used.
- **Interstitial laser coagulation (ILC)**
  - ILC utilizes a fiber-optic laser probe that is inserted through a cystoscope into the prostate at fixed points. Laser energy is applied to coagulate each area of obstructing prostate tissue, producing coagulation necrosis. In contrast to other laser procedures, where coagulation necrosis occurs at the urethral surface, in interstitial laser coagulation, delivery of laser energy directly into the tissues produces coagulation necrosis inside the enlarged prostatic tissue. The treated tissue is absorbed over a period of several weeks. Community practice suggests that ILC is no longer considered a standard or an option for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH).
- **Transurethral ultrasound-guided laser-induced prostatectomy (TULIP)**
  - TULIP was one of the first laser treatments used for BPH. A laser probe is housed between two ultrasound transducers that are used for real-time scanning to position the laser while it is being used. Coagulation necrosis of the prostate tissue produces shrinking over several weeks following TULIP. TULIP has been replaced by other laser techniques that have fewer side effects, shorter post-treatment catheterization times, and fewer urinary symptoms. TULIP is not mentioned in any of the evidence-based BPH guidelines. Because this treatment appears to be outdated, results of controlled trials are no longer considered. Community practice suggests that TULIP is no longer considered a standard or an option for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH).
- **Holmium laser**
  - Holmium laser treatments of the prostate are treatments that use a holmium laser fiber and a specially adapted resectoscope to ablate, resect, or enucleate enlarged prostatic tissue. Relief of obstruction is immediate. Holmium lasers are among the most common laser technologies used to treat prostate disease. With the holmium laser, there is the ability to coagulate tissue simultaneously with tissue incision, ablation, resection or enucleation. This reduces intraoperative blood loss as well as post-operative bleeding. The American Urological Association (AUA 2010) states that holmium laser treatments are appropriate and effective treatment alternatives to TURP and open prostatectomy in individuals with moderate to severe LUTS due to BPH, and/or who are significantly bothered by these symptoms (i.e., interfere with activities of daily living). Additionally, according to AUA, these treatments have been associated with shorter post-treatment catheterization time and shorter length of hospital stay.
    - **Holmium laser ablation of the prostate (HoLAP)**
      - This technology delivers laser energy at a wavelength of infrared range which is primarily absorbed by water. HoLAP is intended to be comparable to TURP, in that the prostatic lobes may be vaporized down to a surgical capsule resulting in a TURP-like effect. HoLAP does not yield tissue for histologic analysis. A controlled trial reported that although HoLAP took longer to perform than TURP, LUTS due to BPH and physiological measures improved to a similar degree after HoLAP and TURP (Mottet 1999).
    - **Holmium laser resection of the prostate (HoLRP)**
      - This technology utilizes a specially adapted resectoscope to resect prostate tissue into pieces small enough to be removed with bladder irrigation and grasping forceps or a modified resectoscope loop. Improvements in LUTS due to BPH obtained by using HoLRP are comparable to TURP (Gilling 1999, Ruzat 2008).
    - **Holmium laser enucleation of the prostate (HoLEP)**
      - HoLEP is typically used for larger glands that previously would have been treated with an open prostatectomy. Here, an entire prostatic lobe can be
separated from connective tissue and deposited in the bladder. The tissue is then extracted from the bladder. HoLEP has been evaluated in clinical trials and compared favorably with TURP in meta-analyses and system reviews (Kuntz 2002, Elzayat 2007, Naspro 2009, Burke 2010).

- **Photoselective vaporization (PVP)**
  - PVP uses a potassium-titanyl-phosphate (KTP) laser to vaporize prostate tissue. KTP laser wavelengths penetrate only 1 to 2 mm, and the vaporization process may help avoid the perioperative side effects such as tissue sloughing. Additional reported potential advantages of PVP include virtually bloodless tissue ablation, shorter length of hospital stay, and shorter post-treatment catheterization times. As compared with TURP, surgical treatment of high-risk populations such as individuals taking anticoagulants, may be possible with PVP (Burke 2010, Ruszat 2008). PVP is an appropriate and effective treatment alternative to TURP and open prostatectomy in men who have moderate to severe LUTS due to BPH and/or who are significantly bothered by the symptoms (i.e., interfere with activities of daily living).

**MINIMALLY INVASIVE TREATMENTS**

Although TURP is the most commonly used treatment option for BPH, minimally invasive treatments have been developed that utilize various sources of energy, such as heat, radiofrequency, ultrasound, and microwaves. Minimally invasive treatments available include the following:

- **Water-induced thermotherapy (WIT)**
  - During this minimally invasive treatment, heated water is circulated through a proprietary closed-loop catheter system to produce coagulative necrosis and secondary ablation of obstructing prostate tissue. Thermal insulation of the catheter shaft along the penile, bulbous, and membranous urethra, as well as in the sphincter region, prevents unwanted incidental damage of tissue along the urinary tract. According to the Urologic Clinics of North America, along with a review of the available published peer-reviewed literature and clinical guidelines, there is insufficient evidence to support the use of WIT for the treatment of urinary outlet obstruction due to BPH.

- **Balloon dilation of the prostate**
  - This minimally invasive treatment utilizes a flexible balloon catheter, which is placed in the urethra at the level of the prostate above the external sphincter. The balloon is then inflated for a short time to distend the prostatic urethra. Currently, the AUA does not recommend the use of balloon dilation of the prostate. Furthermore, the safety and/or efficacy of this service cannot be established by review of the available published peer-reviewed literature.

- **Transurethral ethanol ablation (chemoablation) of the prostate (TEAP)**
  - This minimally invasive treatment involves injecting absolute ethanol transurethrally into the prostate tissue. The injected ethanol causes cells of the prostate to burst, killing the cells. The prostate shrinks as the necrosed cells are absorbed. Currently, the AUA does not recommend the use of transurethral ethanol ablation of the prostate. Furthermore, the safety and/or efficacy of this service cannot be established by review of the available published peer-reviewed literature.

- **High-intensity focused ultrasound (HIFU)**
  - This minimally invasive treatment uses targeted high-intensity ultrasound to create coagulation necrosis in the prostate tissue. In contrast to other treatments, the HIFU device is inserted rectally and does not contact the prostate or urethra. Post-treatment catheterization time ranges from a few days to over a week. The safety and/or efficacy of this service cannot be established by review of the available published peer-reviewed literature. Randomized controlled trials comparing HIFU to standard treatments for BPH have not been published. Furthermore, at this time, the AUA considers HIFU as investigational, with additional long-term studies being warranted.

- **Transurethral needle ablation (TUNA) of the prostate (also called transurethral radiofrequency needle ablation [RFNA])**
  - This minimally invasive treatment delivers selective thermal energy to the prostate using two 18-gauge needles at the end of a TUNA catheter. A lens inside the catheter is used to guide the placement of the catheter into the urethra, where the needles are advanced to cause heat-induced coagulation necrosis in the prostate parenchyma. The prostate shrinks as the necrosed cells are absorbed. AUA recommends the use of TUNA as an appropriate and effective treatment alternative for bothersome (i.e., interfere with activities of daily living), moderate, or severe LUTS due to BPH. TUNA has been compared favorably with TURP in clinical trials and meta-analysis (Bouza 2006, Boyle 2004, Hill 2004). Although the improvement of LUTS due to BPH does not
reach the same level as TURP; fewer adverse events (e.g., incontinence, retrograde ejaculation) are demonstrated.

- Transurethral microwave thermotherapy (TUMT)
- This minimally invasive treatment begins by introducing a coolant into the urethra through a transurethral probe, which cools the urethra, followed by a microwave emission that heats and ultimately ablates prostatic tissue. AUA recommends the use of TUMT as an appropriate and effective treatment alternative for bothersome (i.e., interfere with activities of daily living), moderate, or severe LUTS due to BPH (Hoffman 2007).

- Prostatic Urethral Lift (UroLift ®)
- The UroLift ® system is a minimally invasive implant developed to treat LUTS related to urinary outflow obstruction secondary to BPH in men 50 years of age or older. In this procedure, permanent implants (made from common implantable materials: nitinol, stainless steel, and polyethylene terephthalate) are delivered trans-prostatically to retract the enlarged lateral lobes of the prostate. This procedure dilates the prostatic urethra in individuals leading to improvement in LUTS symptoms without the need for surgical resection or the application of thermal energy to the prostate. Current evidence for this intervention includes 1 randomized sham-controlled trial (n = 206) published by Roehrborn et al. (2013) which found that at 12-month follow-up, both objective and subjective outcomes were significantly improved in individuals undergoing the UroLift procedure with no adverse impact to sexual function reported among any of the participants. An RCT directly comparing UroLift to TURP is scheduled for completion in December 2015.

**Policy**

**Coverage is subject to the terms, conditions, and limitations of the members’ contract.**

**MEDICALLY NECESSARY**

The surgical and minimally invasive treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) is considered medically necessary and, therefore, covered when all of the following criteria are met:

- One of the following surgical or minimally invasive treatments is utilized:
  - Transurethral Resection of the Prostate (TURP)
  - Holmium laser ablation of the prostate (HoLAP)
  - Holmium laser enucleation of the prostate (HoLEP)
  - Holmium laser resection of the prostate (HoLRP)
  - Photoselective vaporization (PVP)
  - Transurethral electrovaporization of the prostate (TUVP)
  - Transurethral needle ablation (TUNA)
  - Transurethral microwave thermotherapy (TUMT)
- The individual has a diagnosis of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) (e.g., increased urinary frequency, urgency, incontinence, or straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying) that interfere with activities of daily living.
- The individual has a prostate-specific antigen (PSA) blood test that meets both of the following criteria:
  - Given within 12 months of the procedure
  - Resulted in a value of 2.5 ng/mL or less for individuals who are up to and including 60 years of age and 4.0 ng/mL or less for individuals who are over 60 years of age
• The individual has a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc.
• The individual has failed a trial of satisfactory voiding with medication (alpha blocker and/or alpha-reductase inhibitor) or intolerance to medication (alpha blocker and/or 5-alpha-reductase inhibitor).
• In addition to the above criteria, if the individual has a diagnosis or history of prostate cancer and meets either of the following criteria:
  ◦ The individual is not a candidate for surgical resection of the prostate but will be treated by radiation therapy and has symptoms that are so severe that immediate relief is required.
  ◦ The individual is clinically in remission as evidenced by a PSA ≤ 1.0 ng/mL.
UroLift for the treatment of urinary outlet obstruction due to BPH is considered medically necessary and, therefore covered if the following criteria are met:
• The individual has a diagnosis of LUTS secondary to BPH (e.g., increased urinary frequency, urgency, incontinence, or straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying) that interfere with activities of daily living.
• The individual has a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc.
• The individual's symptoms are caused by enlargement of the lateral lobes of the prostate with no median lobe enlargement present.
• The individual has normal renal function.
• The individual has mild to moderate symptoms that are refractory to medication or the individual does not wish to take daily medication.
• The individual is a poor candidate for other surgical interventions for BPH, or the individual opts to undergo a minimally-invasive procedure.
• The individual has a PSA blood test that meets both of the following criteria:
  ◦ Given within 12 months of the procedure
  ◦ Resulted in a value of 2.5 ng/mL or less for individuals who are up to and including 60 years of age and 4.0 ng/mL or less for individuals who are over 60 years of age
• In addition to the above criteria, if the individual has a diagnosis or history of prostate cancer and meets either of the following criteria:
  ◦ The individual is not a candidate for surgical resection of the prostate but will be treated by radiation therapy and has symptoms that are so severe that immediate relief is required.
  ◦ The individual is clinically in remission as evidenced by a PSA ≤ 1.0 ng/mL.

**NOT MEDICALLY NECESSARY**

The use of TUNA, TUMT, HoLAP, HoLEP, HoLRP, PVP, TUVP, and UroLift to treat conditions other than those described above is considered not medically necessary and, therefore, not covered because the available published peer-reviewed literature does not support their use in the diagnosis or treatment of other conditions.

The following obsolete medical services are considered not medically necessary and, therefore, not covered because the available published peer-reviewed literature does not support their use in the treatment of illness or injury:
• Visual laser ablation of the prostate (VLAP)
• Interstitial laser coagulation (ILC)
• Transurethral ultrasound-guided laser-induced prostatectomy (TULIP)
• Water-induced thermotherapy (WIT)

**EXPERIMENTAL/INVESTIGATIONAL**

The following procedures are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness in the treatment of urinary outlet obstruction due to BPH has not been established by review of the available published peer-reviewed literature:
• Balloon dilation of the prostate
• Transurethral ethanol ablation of the prostate (TEAP)
• High-intensity focused ultrasound (HIFU)

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the health care professional's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Guidelines

Serum prostate-specific antigen (PSA) level and prostate size should not be used as the sole basis of treatment recommendations.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, surgical and minimally invasive treatments for urinary outlet obstruction due to BPH are covered under the medical benefits of the Company’s products when medical necessity criteria listed in the medical policy are met.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

The use of devices in the minimally invasive treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) should be in accordance with all of the FDA-approved labeling requirements and/or criteria.

References


Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider cont Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all fi coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-9, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

Database

CPT Procedure Code Number(s)
MEDICALLY NECESSARY

THE FOLLOWING CODES REPRESENT TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)
52601, 52630

THE FOLLOWING CODES REPRESENT TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)
52601, 52630

THE FOLLOWING CODE REPRESENTS HOLMIUM LASER ABLATION OF THE PROSTATE (HoLRP), PHOTOSELECTIVE VAPORIZATION (PVP), and TRANSURETHRAL ELECTROVAPORIZATION OF THE PROSTATE (TUVP)
52648

THE FOLLOWING CODE REPRESENTS HOLMIUM LASER ENucleATION OF THE PROSTATE (HoLEP) and HOLMIUM LASER RESECTION OF THE PROSTATE (HoLRP)
52649

THE FOLLOWING CODE REPRESENTS TRANSURETHRAL NEEDLE ABLATION OF THE PROSTATE (TUNA)
53852

NOT MEDICALLY NECESSARY

THE FOLLOWING CODE REPRESENTS VISUAL LASER ABLATION OF THE PROSTATE (VLAP) AND INTERSTITIAL LASER COAGULATION (ILC)
52647

THE FOLLOWING CODES REPRESENT TRANSURETHRAL ULTRASOUND-GUIDED LASER-INDUCED PROSTATECTOMY (TULIP)
52648, 52649

THE FOLLOWING CODE REPRESENTS WATER-INDUCED THERMOTHERAPY (WIT)
55899

THE FOLLOWING CODE REPRESENTS TRANSURETHRAL MICROWAVE THERMOTHERAPY (TUMT)
53850

THE FOLLOWING CODES REPRESENT PROSTATIC URETHRAL LIFT (UROLIFT ®)
52441, 52442

EXPERIMENTAL/INVESTIGATIONAL

THE FOLLOWING CODE REPRESENTS TRANSURETHRAL BALLOON DILATION
53899
THE FOLLOWING CODE REPRESENTS TRANSURETHRAL ETHANOL ABLATION OF THE PROSTATE (TEAP)
53899

THE FOLLOWING CODE REPRESENTS HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU)
53899

ICD - 9 Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

ICD-10-PCS codes will be in effect on the determined ICD-10 compliance date. However, they are being added to policy for informational purposes only. N/A

N/A

ICD - 9 Diagnosis Code Number(s)

185 Malignant neoplasm of prostate

600.01 Hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)

600.11 Nodular prostate with urinary obstruction

600.21 Benign localized hyperplasia of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)

600.91 Hyperplasia of prostate, unspecified with urinary obstruction

V10.46 Personal history of malignant neoplasm of prostate

ICD -10 Diagnosis Code Number(s)
ICD-10-CM codes will be in effect on the determined ICD-10 compliance date. However, they are being added to policy for informational purposes only.

C61 Malignant neoplasm of prostate

N40.1 Enlarged prostate with lower urinary tract symptoms

N40.3 Nodular prostate with lower urinary tract symptoms

Z85.46 Personal history of malignant neoplasm of prostate

**HCPCS Level II Code Number(s)**

Healthcare Common Procedure Coding System (HCPCS) C Series Codes can only be reported for outpatient facility services. Professional providers should not report HCPCS C Series Codes for professional services regardless of where those services are performed:

**THE FOLLOWING CODES REPRESENT PROSTATIC URETHRAL LIFT (UROLIFT ®)**

C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

**Revenue Code Number(s)**

N/A

**Version Effective Date:** 04/08/2015