Clinical Policy Title: Management of benign prostatic hyperplasia (BPH)

Clinical Policy Number: 13.02.03

Effective Date: October 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: July 20, 2016
Next Review Date: July 2017

Related policies:

None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the management of benign prostatic hyperplasia (BPH) to be clinically proven and, therefore, medically necessary when the following criteria are met:

A. Indications:
   1. Members age 40 years or older who present with obstructive and/or irritative voiding symptoms (i.e. frequent urination and nocturia).
   2. Acute urinary retention (i.e., the sudden inability to urinate).
   3. Common obstructive symptoms:
      • Hesitancy (difficulty initiating the urinary stream; interrupted, weak stream).
      • Straining to void.
      • Dribbling, (loss of small amounts of urine due to a poor urinary stream).
      • Sensation of incomplete voiding.
B. Pharmacotherapy is considered first-line treatment for moderate to severe symptomatic BPH in members who do not have concomitant renal insufficiency, refractory urinary retention, persistent hematuria, recurrent bladder stones, or recurrent urinary tract infections (UTIs).

C. When nonsurgical management has failed the following procedures are clinically proven and, therefore, medically necessary:
   1. Minimally Invasive Therapies
      - Transurethral electrical vaporization of the prostate (TUEVP, TUVP, TVP), transurethral vapor resection (TUVRP).
      - Transurethral microwave thermotherapy (TUMT).
      - Transurethral needle ablation (TUNA) or radiofrequency needle ablation (RFNA).
   2. Surgical Treatments
      - Open or laparoscopic prostatectomy.
      - Transurethral incision of the prostate (TUIP).
      - Transurethral resection of the prostate (TURP).
   3. Laser Therapy:
      - Contact laser ablation of the prostate (CLAP).
      - Holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP).
      - Noncontact visual ablation (VLAP).
      - Photoscopic vaporization of the prostate (PVP).
      - Laser vaporization and laser ablation/coagulation.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other treatments for BPH are not medically necessary because each is considered experimental, investigational or unproven.

A. There is limited data to demonstrate improved health outcomes for members with BPH treated with the following therapies. The treatments are (this list may not be all-inclusive):
   1. Absolute ethanol injection.
   2. Cryosurgical ablation.
   3. High-intensity focused ultrasound (HIFU).
   4. Histotrepsy.
   5. Interstitial laser coagulation (ILC).
   6. Plasma kinetic vaporization (e.g., PlasmaKinetic™ Tissue Management System).
   7. Prostate artery embolization.
   8. Prostatic urethral lift.
   9. Transrectal thermal therapy.
   10. Transurethral balloon dilation of the prostatic urethra.
12. Direct injection of botulinum toxin into the prostate gland.

Note: Transurethral water-induced thermotherapy (WIT), performed in the physician’s office, is a new procedure that has been shown in a large clinical study to significantly relieve lower urinary tract symptoms (LUTS) due to BPH; however, its long-term effectiveness has not been determined.

**Alternative covered services:**

Members with moderate to severe symptoms of BPH:
- Watchful waiting (active surveillance) with a participating provider.

Note: Watchful waiting (active surveillance) is the preferred management strategy for patients with mild symptoms. It is also an appropriate option for men with moderate-to-severe symptoms who have not yet developed complications of LUTS and BOO (e.g., renal insufficiency, urinary retention or recurrent infection). Watchful waiting patients usually are reexamined yearly, repeating the initial evaluation.

**Background**

Benign prostatic hyperplasia (BPH), also known as benign prostatic hypertrophy, is a histologic diagnosis characterized by proliferation of the cellular elements of the prostate. Chronic bladder outlet obstruction (BOO) secondary to BPH may lead to urinary retention, renal insufficiency, recurrent urinary tract infections, gross hematuria, and bladder calculi. The digital rectal examination (DRE) is an integral part of the evaluation in men with presumed BPH. During this portion of the examination, prostate size and contour can be assessed, nodules can be evaluated, and areas suggestive of malignancy can be detected. The normal prostate volume in a young man is approximately 20 grams.

The prevalence and the severity of lower urinary tract symptoms (LUTS) in the aging male can be progressive, and is an important diagnosis in the healthcare of our patients and the welfare of society. In assessing the burden of disease, the Urologic Diseases in America BPH Project examined the prevalence of moderate to severe LUTS reported in U.S. population-based studies that used the definition of an American Urological Association (AUA) Symptom Index (SI) score of ≥7. Results from the Olmsted County Study showed a progressive increase in the prevalence of moderate-to-severe LUTS, rising to nearly 50% by the eighth decade of life. The presence of moderate-to-severe LUTS was also associated with the development of acute urinary retention (AUR) as a symptom of BPH progression, increasing from a prevalence of 6.8 episodes per 1000 patient years of follow-up in the overall population to a high of 34.7 episodes in men aged 70 and older with moderate to severe LUTS. Another study has estimated that 90% of men between 45 and 80 years of age suffer some type of LUTS.

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

The International Prostate Symptom Score (I-PSS) is based on the answers to seven questions concerning urinary symptoms and one question concerning quality of life. Each question concerning urinary symptoms allows the patient to choose one out of six answers indicating increasing severity of the particular symptom. The answers are assigned points from 0 to 5. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic).

The questions refer to the following urinary symptoms:

1. Incomplete emptying.
2. Frequency.
3. Intermittency.
4. Urgency.
5. Weak stream.
6. Straining.
7. Nocturia.

Question eight refers to the patient’s perceived quality of life. The first seven questions of the I-PSS are identical to the questions appearing on the American Urological Association (AUA) Symptom Index which currently categorizes symptoms as follows:

- Mild (symptom score less than or equal to 7)
- Moderate (symptom score range 8-19)
- Severe (symptom score range 20-35)

The International Scientific Committee (SCI), under the patronage of the World Health Organization (WHO) and the International Union against Cancer (UICC), recommends the use of only a single question to assess the quality of life. The answers to this question range from “delighted” to “terrible” or 0 to 6. Although this single question may or may not capture the global impact of benign prostatic hyperplasia (BPH) symptoms or quality of life, it may serve as a valuable starting point for a doctor-patient conversation.

The SCI has agreed to use the symptom index for BPH, which has been developed by the AUA Measurement Committee, as the official worldwide symptoms assessment tool for patients suffering from prostatism.

The SCI recommends that physicians consider the following components for a basic diagnostic workup: history, physical exam, appropriate labs, such as U/A, creatine, etc., and digital rectal exam (DRE) or other evaluation to rule out prostate cancer.
Treatment Options:

A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (e.g., AUASI score ≥8), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include alpha-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, and silodosin), 5-alpha-reductase inhibitors (e.g., finasteride, dutasteride), combination alpha-adrenergic blockers and 5-alpha-reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).

The gold standard for treating BPH is transurethral resection of the prostate (TURP). Treatment of BPH should be individualized to the patient and involves evaluation of symptoms along with objective findings from examination and laboratory results. Initial treatment for BPH is usually drug therapy designed to relieve obstruction, but this often provides only modest relief and up to 30% of patients require surgical intervention. There are several surgical treatments for BPH that involve burning, cutting, or removal of prostatic tissue (Hayes, et al., 2015; Moul, et al., 2015). Transurethral resection of the prostate (TURP) is considered the gold standard for surgical treatment of BPH.

Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from prostatic enlargement. More recently, treatment has additionally been focused on the alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. A variety of pharmacologic classes are employed including alpha-adrenergic antagonists (alpha-blockers), 5-alpha-reductase inhibitors (5-ARIs), anticholinergics and phytotherapeutics. Choosing the correct medical treatment for BPH is truly complex and ever-changing.

Surgery options:

Surgical intervention is an appropriate treatment alternative for patients with moderate-to-severe LUTS and for patients who have developed AUR or other BPH-related complications. By definition, surgery is the most invasive option for BPH management and generally, patients will have failed medical therapy before proceeding with surgery. However, medical therapy may not be viewed as a requirement because some patients may wish to pursue the most effective therapy as a primary treatment if their symptoms are particularly bothersome. As with other medical treatment alternatives, the decision to elect surgery as the treatment alternative is based upon the patient’s own views of treatment risks vs. benefits. The 2003 Guideline recognized that TURP remained the benchmark for therapy. Alternative technologies such as laser-assisted TURP were reported to offer lower morbidities but were typically still performed in the operating room setting and require anesthesia.

Surgery is recommended for patients who have renal insufficiency secondary to BPH, who have recurrent UTIs, bladder stones or gross hematuria due to BPH, and those who have LUTS refractory to other therapies. The presence of a bladder diverticulum is not an absolute indication for surgery unless associated with recurrent UTI or progressive bladder dysfunction.
Open Prostatectomy:

Open prostatectomy is an appropriate and effective treatment alternative for men with moderate to severe LUTS and/or who are significantly bothered by these symptoms. The choice of approach should be based on the patient's individual presentation including anatomy, the surgeon's experience, and discussion of the potential benefit and risks for complications. The Panel noted that there is usually a longer hospital stay and a larger loss of blood associated with open procedures.

Laser Therapies:

Transurethral laser enucleation (holmium laser resection of the prostate [HoLRP], holmium laser enucleation of the prostate [HoLEP]), transurethral side firing laser ablation (holmium laser ablation of the prostate [HoLAP], and photoselective vaporization [PVP]) are appropriate and effective treatment alternatives to transurethral resection of the prostate and open prostatectomy in men with moderate to severe LUTS and/or those who are significantly bothered by these symptoms. The choice of approach should be based on the patient's presentation, anatomy, the surgeon's level of training and experience, and a discussion of the potential benefit and risks for complications. Generally, transurethral laser approaches have been associated with shorter catheterization time and length of stay, with comparable improvements in LUTS. There is a decreased risk of the perioperative complication of transurethral resection syndrome. Information concerning certain outcomes, including retreatment and urethral strictures, is limited due to short follow-up.

As with all new devices, comparison of outcomes between studies should be considered cautiously given the rapid evolution in technologies and power levels. Emerging evidence suggests a possible role of transurethral enucleation and laser vaporization as options for men with very large prostates (> 100 g). There are insufficient data on which to base comments on bleeding.

In general, laser energy can be used to produce a variety of effects within prostate tissue including coagulation necrosis or vaporization and resection of tissue. Today, the holmium and variants of the PVP laser are the most common laser technologies used to treat prostate disorders.

Transurethral Holmium Laser Ablation of the Prostate (HoLAP):

- The holmium:YAG laser may be used to treat prostatic tissue transurethrally using a 550 micron side-firing laser fiber in a noncontact mode. This technology delivers laser energy at a wavelength of 2120 nm (infrared range) which is absorbed primarily by water and results in an optical penetration depth of 0.4 mm. The HoLAP procedure is intended to be comparable to TURP in that the prostatic lobes may be vaporized down to the surgical capsule resulting in a TURP-like effect.

Transurethral Holmium Laser Enucleation of the Prostate (HoLEP):
• The holmium laser has been used to enucleate the prostate adenoma, separating the adenoma from the surgical capsule, from apex to base, after any median lobe has been freed from the bladder neck. Typically, the technology is utilized for larger glands that previously would have been treated surgically with an open prostatectomy. Generally, the results compare favorably to open prostatectomy in the hands of an experienced surgeon. In other trials, improvements in symptom scores, quality of life (QoL) indices, and flow rate, approach those obtained after TURP. Nonetheless, long-term data beyond two years are still lacking, and the procedure requires specialized training and equipment. The Panel believes that the learning curve for holmium laser enucleation of the prostate appears to be greater than that of other technologies.

Photoselective Vaporization of the Prostate (PVP):

• PVP of the prostate is a form of transurethral prostatectomy performed using a 600 micron side-firing fiber in a noncontact mode. The primary difference from HoLAP is its wavelength of 532 nm (in the green visible spectrum) which is absorbed by both the water irrigation and hemoglobin resulting in an optical penetration depth of 0.8 mm. The other acronyms for this procedure, KTP (potassium tintanyl phosphate) and LBO (lithium borate), identify the crystal used in the laser generator. Typically performed using normal saline irrigation and a continuous flow scope, the goal of PVP is to create a TURP-like cavity after ablating the various prostatic lobes down to the surgical capsule. Symptom scores improved consistently in all studies, as did Qi scores and maximum urinary flow rates.

Minimally Invasive Therapies:

Safety recommendations for the use of transurethral needle ablation of the prostate (TUNA) and transurethral microwave thermotherapy (TUMT) published by the U.S. Food and Drug Administration should be followed.

Transurethral Needle Ablation (TUNA) of the Prostate:

• TUNA of the prostate is an appropriate and effective treatment alternative for bothersome moderate or severe LUTS secondary to BPH.

There are only three prospective, randomized trials (one trial reports outcomes at two time points). Improvements in symptoms, Qi, and urinary flow rates are significant but do not generally match the result of TURP and, taken together, lack sufficient detail on comorbidity of subjects. The remainders are cohort studies from which the reporting of outcomes varies considerably. In addition, the bulk of the literature suggests a high long-term retreatment rate. TUNA is safe with low peril-operative complications (such as bleeding) and has a low to nonexistent rate of associated ED for which this
therapy is attractive. The Panel concluded that a degree of uncertainty remains regarding TUNA because of a paucity of high-quality studies.

Transurethral Microwave Thermotherapy (TUMT) is effective in partially relieving LUTS secondary to BPH and may be considered in men with moderate or severe symptoms.

- TUMT heats the prostate using a microwave antennae mounted on a urethral catheter. This interventional therapy is effective in partially relieving the symptoms and bother believed secondary to BPH. TUMT is the least operator-dependent of the BPH interventions and predicting responders is difficult and inconsistent.

A systematic review of TUMT data reveals a heterogeneous mix of studies of various sample sizes and TUMT protocols often using different outcome measures with varying durations of follow-up. This leads to conflicting results, as may be seen in studies of shorter versus longer follow-up. There is no compelling evidence from comparator trials to conclude that one device is superior to another.

Transurethral Incision of the Prostate (TUIP) is an appropriate and effective treatment alternative in men with moderate to severe LUTS and/or who are significantly bothered by these symptoms when prostate size is less than 30 mile. The choice of approach should be based on the patient's individual presentation including anatomy, the surgeon's experience and discussion of the potential benefits and risks for complications.

The Diagnosis Improvement in Primary Care Trial (D-IMPACT), a prospective, multicenter study in three European countries, identified simple tests for primary care practitioners to diagnose BPH in men who present with LUTS. D-IMPACT found that a diagnostic algorithm including only the objective variables of age, International Prostate Symptom Score (IPSS) and prostate-specific antigen level (PSA), allows accurate diagnosis of BPH in approximately three-quarters of patients who report LUTS.

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on May 19, 2016. Search terms were: “benign prostatic hypertrophy, hyperplasty of prostate.”

We included:
• **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

• **Guidelines based on systematic reviews.**

• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

A number of surgical and minimally-invasive therapies are appropriate for the treatment of benign prostatic hyperplasia (BPH). Transurethral resection of the prostate (TURP) remains the benchmark therapy for the treatment of BPH. Data in the published, peer-reviewed literature demonstrate improved outcomes, and support the safety and effectiveness of selected alternatives to TURP: contact laser ablation of the prostate, Holmium laser ablation, enucleation, and resection, laser prostatectomy, open and laparoscopic prostatectomy, photoselective vaporization of the prostate, stents, transurethral needle ablation, also known as radiofrequency needle ablation, transurethral microwave thermotherapy, transurethral electrovaporization, and transurethral incision of the prostate.

The current evidence is insufficient to determine the safety and efficacy of prostatic urethral lift compared to TURP as a treatment of lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH). The evidence consists of 2 randomized controlled trials (RCTs) and a number of noncomparative studies. One RCT reported that functional improvements were durable over 3 years of follow-up in a subset of patients, but this conclusion is limited because only treated patients were included in the longer follow-up and there was a high loss to follow-up in the treated group. The other RCT compared the prostatic urethral lift procedure with transurethral resection of the prostate (TURP) and reported that TURP was associated with greater improvements in urinary tract obstruction symptom outcomes, although it was also associated with greater declines in sexual function compared with the prostatic lift. This small trial was limited by unequal dropout rates between groups after enrollment, and uncertainty about the validity of its primary outcome measure. In addition, follow-up in the available studies is inadequate to identify longer term adverse events. Furthermore, no evidence-based clinical practice guidelines address the use of the prostatic urethral lift as a treatment of symptoms related BPH. Therefore, prostatic urethral lift is considered investigational as a treatment for any condition, including but not limited to lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH).

For other therapies, there is insufficient evidence in the published peer-reviewed scientific literature to support safety and effectiveness for the treatment of BPH. In general, the available studies were relatively small in size or lost patients over time. Some therapies such as prostatic urethral lift may be a viable alternative for men who require surgical therapy for BPH due to medically refractory symptoms,
but additional data are needed from long-term RCTs to confirm these results and to confirm improved long-term health outcomes.

**Policy updates:**

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ng et al. (2005)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>- A study to evaluate the impact of improvements in surgical techniques and patient selection of overall outcomes of interstitial coagulation (ILC) of the prostate. Over a four-year period, 66 patients ILC using the Indigo 830e.</td>
</tr>
<tr>
<td></td>
<td>- They were stratified into two groups: group one consisted of those treated during the first two years (n=47) and those treated during the latest two years (n=19) were labeled as group two.</td>
</tr>
<tr>
<td></td>
<td>- At 12 months, maximum flow rates improved by 47% in group one and 85% in group two. Subjective measures were significantly improved from baseline in both groups but did not differ between groups.</td>
</tr>
<tr>
<td></td>
<td>- The incidence of adverse events was similar in the two groups. In a prospective study of 49 men with symptomatic benign prostatic hyperplasia (BPH) who underwent ILC.</td>
</tr>
<tr>
<td>Daehlin et al. (2007)</td>
<td>- Reported a decrease in International Prostate Symptom Scores (IPSS), and an increase in peak urinary flow; however, twenty-two patients (50%) required retreatment.</td>
</tr>
<tr>
<td>Perera et al. (2015)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>- That pooled estimates from between 452 and 680 patients from ten articles comprising six independent patient cohorts were included for analysis.</td>
</tr>
<tr>
<td></td>
<td>- The results suggest that this procedure is associated with minimal perioperative morbidity, whereas meta-analysis estimates suggest improvements in symptomatic and functional outcomes that are durable through 12-month follow-up. Preservation of the bladder neck and subsequent control of sexual function following PUL provide stark contrast to the medical and surgical alternatives for treatment of BPH.</td>
</tr>
<tr>
<td></td>
<td>- Further comparative trials with longer follow-up periods are required to guide clinicians as to the suitability of PUL in routine clinical practice.</td>
</tr>
<tr>
<td>Sonksen et al., (2015)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>- Eligible patients had an International Prostate Symptom Score (IPSS) above 12, a peak urinary flow rate (Qmax) less than or equal to 15 mL/s for a 125 mL voided volume, a postvoid residual volume less than 350 mL, and prostate volume less than or equal to 60 cm³ on ultrasound.</td>
</tr>
</tbody>
</table>
|                        | - The study used a novel composite endpoint, referred to as the BPH6, which included lower urinary tract symptom relief measured by the IPSS score, recovery experience measured on a visual analog scale (VAS), erectile function measured by the Sexual Health Inventory for Men (SHIM) scale, ejaculatory function measured by the Male
Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), continence preservation measured by the Incontinence Severity Index (ISI), and safety measured by no treatment-related adverse event greater than grade 1 on the Clavien-Dindo classification system.

- Patients were considered treatment responders if they met all 6 of the composite criteria. The study used a noninferiority design with a margin of 10% for the BPH6 primary endpoint.
- The study’s authors modified 2 of the original endpoint definitions in the study’s analysis, including changing the sexual function element assessment from a single time point (12 months) to assess sustained effects during 12 months of follow-up, and lowering the threshold of quality of recovery on VAS from 80 to 70.

**Glossary**

**Benign prostatic enlargement** — Is used when there is gland enlargement and is usually a presumptive diagnosis based on the size of the prostate.

**Benign prostatic obstruction (BPO)** — Used when obstruction has been proven by pressure flow studies, or is highly suspected from flow rates and if the gland is enlarged. Bladder outlet obstruction (BOO) is the generic term for all forms of obstruction to the bladder outlet (e.g., urethral stricture) including BPO.

**Decreased force of stream** — Subjective loss of force of the urinary stream over time.

**Dribbling** — The loss of small amounts of urine due to a poor urinary stream.

**Detrusor over activity** — An urodynamic observation characterized by involuntary detrusor contractions during the filling phase. These contractions may be spontaneous or provoked.

**Hesitancy** — Difficulty initiating the urinary stream; interrupted, weak stream.

**Incomplete bladder emptying** — The feeling of persistent residual urine, regardless of the frequency of urination.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the Medical Assistance Program (MA) and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
• The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**Overactive bladder syndrome** — Urgency with or without urge incontinence, usually with frequency and nocturia.

**Straining** — The need strain or push (valsalva maneuver) to initiate and maintain urination in order to more fully evacuate the bladder.

**Urinary frequency** — The need to urinate frequently during the day or night (nocturia), usually voiding only small amounts of urine with each episode.

**Urinary urgency** — The sudden, urgent need to urinate, owing to the sensation of imminent loss of urine without control.

**Watchful waiting** — A management strategy in which the patient is monitored by his physician but currently receives no active intervention for BPH. The level of symptom distress that individual patients are able to tolerate is highly variable so watchful waiting may be a patient's treatment of choice.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Clinical trials:

Searched clinicaltrials.gov on May 20, 2016 using terms benign prostatic hyperplasia, LUTS, | Open Studies. 19 studies found, two relevant.


CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>52450</td>
<td>Transurethral incision of prostate</td>
<td></td>
</tr>
<tr>
<td>52601</td>
<td>Transurethral electrosurgical resection of prostate, including control of postoperative bleeding; complete</td>
<td></td>
</tr>
<tr>
<td>52630</td>
<td>Transurethral resection; residual or regrowth of prostatic tissue including control of postoperative bleeding; complete</td>
<td></td>
</tr>
<tr>
<td>52647</td>
<td>Laser coagulation of prostate; including control of postoperative bleeding; complete</td>
<td></td>
</tr>
<tr>
<td>52648</td>
<td>Laser vaporization of prostate; including control of postoperative bleeding; complete</td>
<td></td>
</tr>
<tr>
<td>52649</td>
<td>Laser enucleation of prostate with morcellation including control of postoperative bleeding; complete</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>N40.1</td>
<td>Enlarged prostate with lower urinary tract symptoms</td>
<td>Requires additional code for symptoms</td>
</tr>
<tr>
<td>N13.8</td>
<td>Urinary obstruction</td>
<td></td>
</tr>
<tr>
<td>R33.8</td>
<td>Urinary retention</td>
<td></td>
</tr>
<tr>
<td>R35.0</td>
<td>Urinary frequency</td>
<td></td>
</tr>
<tr>
<td>R35.1</td>
<td>Nocturia</td>
<td></td>
</tr>
<tr>
<td>R39.11</td>
<td>Urinary hesitancy</td>
<td></td>
</tr>
<tr>
<td>R39.12</td>
<td>Weak urinary stream</td>
<td></td>
</tr>
<tr>
<td>R39.14</td>
<td>Incomplete bladder emptying</td>
<td></td>
</tr>
<tr>
<td>R39.16</td>
<td>Straining on urination</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Appendix**

The American Urological Association (AUA) has issued a Guideline on the Management of Benign Prostatic Hyperplasia (BPH), which the AUA validated in 2014. The guideline includes an algorithm for the diagnosis and basic treatment of lower urinary tract symptoms (LUTS), which is presented below:
Basic Management of LUTS in Men

LUTS CAUSE LITTLE OR NO BOTHER

RECOMMENDED TESTS:
- RELEVANT MEDICAL HISTORY
- ASSESSMENT OF LUTS
- SEVERITY AND BOTHER (I.e. AUA SI)
- PHYSICAL EXAMINATION INCLUDING DRE
- URINALYSIS
- SERUM PSA
- FREQUENCY/VOLUME CHART

Complicated LUTS:
- Suspicious DRE
- HEMATURIA
- ABNORMAL PSA
- PAIN
- INFECTION
- PALPABLE BLADDER
- NEUROLOGICAL DISEASE

PREDOMINANT SIGNIFICANT NOCTURIA

FREQUENCY-VOLUME CHART

Bothersome LUTs

No Polyuria

Polyuria
- 24-hour output ≥ 3 liters
- Lifestyle and fluid intake is to be reduced
- Nocturnal polyuria
- >33% output at night
- Fluid intake to be reduced
- Consider other causes

No Polyuria

Standard Treatment
- Altermodifiable factors
- Drugs
- Fluid & food intake
- Lifestyle advice

Drug Treatment

Failure

Success in relieving bothersome LUTs:

Continue treatment

Detailed Management

1 When life expectancy is > 10 years and if the diagnosis of prostate cancer can modify the management. For the AUA PSA Best Practice Statement: 2009 Update, see: www.auanet.org.
2 When significant nocturia is a predominant symptom.
3 Assess and start treatment before referral.
4 In practice, advise patients with symptoms to aim for a urine output of about 1 liter/24 hours.
5 See Figure 2.