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 19, 2017
Next Review Date: July 2018

About this policy: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 Keystone First 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. Keystone First’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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First 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 45 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:
      a. Hesitancy (difficulty initiating the urinary stream; interrupted, weak stream).
      b. Straining to void.
      c. Dribbling, (loss of small amounts of urine due to a poor urinary stream).
      d. 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).
   - Photoselective vaporization of the prostate (PVP).
   - Laser vaporization and laser ablation/coagulation.

Limitations:

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

For 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 (Wei, 2008). Results from the Olmsted County Study showed a progressive increase in the prevalence of moderate-to-severe LUTS, rising to nearly 50 percent by the eighth decade of life (Lepor, 2003). A multinational study estimates that the prevalence of men with at least one LUTS symptom is 72.3 percent (Coyne, 2009).

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) (Barry, 2017). The International Prostate Symptoms Score (IPSS) incorporates the questions from the AUASI and a quality of life question or “bother score” (I-PSS, 2017).

The IPSS is based on the answers to seven questions concerning urinary symptoms and one question concerning quality of life, namely incomplete emptying, frequency, intermittency, urgency, weak stream, straining, and nocturia. Question eight refers to the patient’s perceived quality of life.
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 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 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 percent of patients require surgical intervention (Roehrborn, 2011). There are several surgical treatments for BPH that involve burning, cutting, or removal of prostatic tissue (Hayes, 2015; Moul, 2015).

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 AUA 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 AUA 2014 guideline (McVary, 2014) 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).

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 AUA guideline authors believe 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 QoL scores and maximum urinary flow rates.

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.

Transurethral Microwave Thermotherapy (TUMT)

TUMT is effective in partially relieving LUTS secondary to BPH and may be considered in men with moderate or severe symptoms. It 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.

**Transurethral Incision of the Prostate (TUIP)**

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 cc. 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 (Carballido, 2011).

**Searches**

Keystone First 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 26, 2017. Search terms were: “benign prostatic hypertrophy,” and “benign prostatic hyperplasia.”

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**
Numerous literature reviews have been published on treatments for benign prostatic hyperplasia. TURP, the traditional standard surgical treatment for BPH, is now used less with the development of other methods, and is generally used in cases of moderate-to-severe refractory LUTS or when complications in other procedures occur. One analysis of 67 studies (n=3470) documented that over the past three decades, patients undergoing TURP have greater average prostate tissue volume and lower morbidity rates, require fewer transfusions, experience more urinary tract infections rates, and have higher reported rates of failure to void (Mayer, 2012).

The trend to substitute minimally invasive procedures for open procedures has continued for decades. One review of 27 observational studies (n=764) documented shorter hospital stays, reduced length of catheter use, shorter duration of operations, and less estimated blood loss in minimally invasive prostatectomy versus open prostatectomy. No differences were observed in Qmax, I-PSS, and perioperative complications, leading authors to conclude that minimally invasive procedures compare favorably with open procedures (Lucca, 2015).

Laser therapies are one treatment mode increasingly used to treat BPH. A meta-analysis of six studies (n=640) compared outcomes for thulium laser prostatectomy (TmLRP) with TURP for one year after surgery. TmLRP was associated with less decrease of serum sodium salt, less blood transfused, shorter catheterization time, shorter hospital time and more operation time, while no differences between groups were noted in incidence of the TUR syndrome, recatheterization rate, transitory urge incontinence, stress incontinence, urethral stricture, and retrograde ejaculation (Jiang, 2016).

A Hayes review of laser therapy used in men with BPH reviewed evidence and found support for several types of lasers. Holmium laser resection for BPH can be used for prostate glands <100 ml in volume that cannot be controlled by medicine; noncontact/contact/hybrid laser ablation techniques were found to be effective for prostate glands <70 ml in volume with bleeding or other disorders; and photoselective vaporization have good outcomes for BPH patients who cannot be effectively managed using medicinal therapy and who wish to avoid complications more often associated with TURP (Hayes, 2014).

An analysis of nine trials (n=889) comparing the increasingly popular photoselective vaporization (PVP) with TURP found significantly lower catheterization time, length of stay, and blood transfusion rates for the PVP group, which took longer than TURP (average operating time 20 minutes greater). No significant differences were identified in complication rates (Thangasamy, 2012). Another analysis of 11 RCTs and case-controlled studies (n=1398) of men with prostate volume <70ml found PVP patients had fewer transfusions, capsular perforations, cases of TUR syndrome, and clot retentions than TURP patients (Ding, 2012). Another study of five trials comparing PVP with TURP showed fewer complications for those undergoing PVP (Zhang, 2012).

A meta-analysis of 18 randomized controlled trials (n=2433) evaluated changes in erectile function for nine approaches to BPH. Of these treatments, only photoselective vaporization of the prostate resulted in a decrease in erectile function, and a significant increase was observed post-operatively for Holmium laser enucleation of the prostate, plasmakinetic enucleation of the prostate, Thulium laser, and TURP (Li,
These findings support those from a 2010 review of 33 studies on effects of minimally invasive surgery for BPH (Frieben, 2010).

An analysis of 14 RCTs documented a 27 percent reductions in average AUA symptom score and a 13 percent increase in maximum urinary flow – both statistically significant - three months after sham endoscopic procedure for BPH, with similar results for prostate based endoscopic studies. Authors warned that future trials would be strengthened with the inclusion of a placebo group in the form of sham surgery (Welliver, 2015).

Policy updates:

A total of 6 guidelines/other and 17 peer-reviewed references were added to this policy in 2017.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Li (2016)</td>
<td>Key points:</td>
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</tbody>
</table>
| Impact on erectile function for various BPH treatments | - Review of 18 articles (n=2433) on impact on erectile function of nine treatments for BPH  
- Treatments included transurethral resection of the prostate (TURP), plasmakinetic resection of the prostate (PKRP), plasmakinetic enucleation of the prostate (PKEP), Holmium laser enucleation of the prostate (HoLEP), Holmium laser resection of the prostate (HoLRP), photoselective vaporization of the prostate (PV), Thulium laser, open prostatectomy (OP), and laparoscopic simple prostatectomy (LSP).  
- None of the nine treatments reduced erectile function, except for PVP  
- Postoperative erectile function significantly increased for those undergoing HoLEP, PKEP, Thulium laser, and TURP |
| Lucca (2015) | Key points:                       |
| Minimally invasive simple prostatectomy for BPH | - Review of 27 studies (n=764) comparing outcomes for men undergoing minimally invasive simple prostatectomy with open simple prostatectomy  
- The minimally invasive group had lower length of hospital stay, lower length of catheter use, less estimated blood loss, but average operating time was significantly higher  
- Authors conclude that minimally invasive procedures offer an effective, safe option |
| Hayes (2014) | Key points:                       |
| Laser therapy for benign prostatic hyperplasia | - Literature review of studies from 1985 to 2010, that included at least six months of follow up, included at least 50 patients with symptomatic BPH, and measured symptoms and/or objective urinary outcomes  
- Holmium laser resection of the prostate had favorable outcomes for patients with prostate sizes <100 g, who cannot be managed with medical therapy, and who wish to avoid certain complications associated with TURP  
- Non-contact, contact, and laser ablation techniques had favorable outcomes in BPH patients whose prostate sizes are less than 40-60 grams and who have conditions such as bleeding disorders, and who wish to avoid TURP complications  
- Photoselective vaporization of the prostate had favorable outcomes for BPH patients who cannot be managed with medicine and who wish to avoid TURP complications |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Thangasamy (2012)</td>
<td><strong>Key points:</strong></td>
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| Outcomes of photoselective vaporization compared to TURP | - Review of nine trials; 448 patients underwent PVP, 441 underwent TURP  
- In the PVP group, catheterization time and length of stay were significantly shorter, blood transfusion was less likely  
- In the TURP group, average operating time was 20 minutes less  
- No differences found for all other complications |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

L36109 Minimally Invasive Treatment for Benign Prostatic Hyperplasia Involving Prostatic Urethral Lift (Urolift®). Effective date October 1, 2015. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36109&ver=16&Cove rageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=benign+prostatic+h yperplasia&KeyWordLookUp>Title&KeyWordSearchType=And&bc=gAAAACAAAAAAAA%3d%3d&. Accessed May 26, 2017.

**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>
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<tbody>
<tr>
<td>52450</td>
<td>Transurethral incision of prostate</td>
<td></td>
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<tr>
<td>52601</td>
<td>Transurethral electrosurgical resection of prostate, including control of postoperative bleeding; complete</td>
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<tr>
<td>52630</td>
<td>Transurethral resection; residual or regrowth of prostatic tissue including control of postoperative bleeding; complete</td>
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<tr>
<td>52647</td>
<td>Laser coagulation of prostate; including control of postoperative bleeding; complete</td>
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<tr>
<td>52648</td>
<td>Laser vaporization of prostate; including control of postoperative bleeding; complete</td>
<td></td>
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<tr>
<td>52649</td>
<td>Laser enucleation of prostate with morcellation including control of postoperative bleeding; complete</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>N40.1</td>
<td>Enlarged prostate with lower urinary tract symptoms</td>
<td>Requires additional code for symptoms</td>
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<tr>
<td>N13.8</td>
<td>Urinary obstruction</td>
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<tr>
<td>R33.8</td>
<td>Urinary retention</td>
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<tr>
<td>R35.0</td>
<td>Urinary frequency</td>
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<td>R35.1</td>
<td>Nocturia</td>
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<tr>
<td>R39.11</td>
<td>Urinary hesitancy</td>
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<tr>
<td>R39.12</td>
<td>Weak urinary stream</td>
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<tr>
<td>R39.14</td>
<td>Incomplete bladder emptying</td>
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<tr>
<td>R39.16</td>
<td>Straining on urination</td>
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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: