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OVERVIEW

Benign prostatic hyperplasia (BPH) is a common condition in older men, affecting to some degree 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 and older. BPH is a histologic diagnosis defined as an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland. In some men, BPH results in prostate enlargement which can, in turn, lead to benign prostate obstruction and bladder outlet obstruction, which are often associated with lower urinary tract symptoms including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms is the most commonly presenting urological complaint and can have a significant impact on the quality of life.

For BlueCHiP for Medicare this policy addresses This LCD addresses use of water vapor thermal therapy for the treatment of lower urinary tract symptoms attributable to benign prostatic hyperplasia (LUTS/BPH).

MEDICAL CRITERIA

ONE treatment for LUTS/BPH treatment is covered ONCE in patients with BOTH the of the following:

1. Indications including **ALL** of the following:
 - A. Age \geq 50
 - B. Symptomatic despite maximal medical management including **ALL** of the following:
 - I. International Prostate Symptom Score (IPSS) \geq 13
 - II. Maximum urinary flow rate (Qmax) of \leq 15 mL/s (voided volume greater than 125 cc)
 - III. Failure, contraindication or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
 - C. Prostate volume of 30-80 cc,
 - D. Obstructing median lobe,
 - E. Poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.), or at high risk of bleeding
2. No contraindications including **ALL** of the following:
 - A. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) $>$ 10ng/mL
 - B. Active urinary tract infection
 - C. History of bacterial prostatitis in the past three months
 - D. Urinary retention (e.g., PVR $>$ 250-300 mL, catheterization requirement, history of being unable to void)
 - E. Prior prostate surgery
 - F. Neurogenic bladder
 - G. Active urethral stricture (i.e., the source of the current LUTS)

PRIOR AUTHORIZATION

Prior Authorization is required for BlueCHiP for Medicare only

POLICY STATEMENT

BlueCHiP for Medicare Products

Transurethral water vapor thermal therapy is medically necessary as a treatment of benign prostatic hyperplasia when all of the criteria has been met.

Commercial Products

Transurethral water vapor thermal therapy is considered not medically necessary as a treatment of benign prostatic hyperplasia as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/coverage or surgery benefit.

BACKGROUND

BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of treatment. Options for medical treatment include alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 inhibitors. Medications may be used as monotherapy or in combination.

Patients with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the prostate.

BlueCHiP for Medicare

Approximately 50 percent of men at age 50, and up to 80 percent at age 80, have LUTS/BPH (1). In 2015, it was estimated that 12.2 million men were actively managed for LUTS/BPH; accounting for almost 25% of a urology practice (2). An aging population means the impact of LUTS/BPH will only increase. BPH develops primarily in the periurethral or transitional zone of the prostate (normally only 5% of prostate volume), and its pathogenesis remains incompletely understood. The natural history is variable; about one-third will ultimately require treatment, one-third remain stable, and one-third have some spontaneous regression of symptoms.

The array of therapeutic options includes conservative approaches (watchful waiting), pharmacotherapy, and a burgeoning variety of surgical options (transurethral prostate resection or ablation). The need for surgical intervention is generally based upon the adequacy of medical therapy, the development of complications, and patient preference, rather than any specific urological parameter (3). The American Urologic Association/International Prostate Symptom Score (AUA/IPSS) (assessing for both storage (frequency, nocturia, urgency), and voiding (weak urinary stream, hesitancy, intermittence, incomplete emptying) symptoms, is useful for quantifying and monitoring BPH symptoms. Symptoms (individually ranked 0-5) are classified as mild (total score 0-7), moderate (total score 8-19), or severe (total score 20-35). Surgery is usually reserved for those with moderate to severe symptoms despite medical management (insufficient efficacy and tolerability, including drug side effects involving sexual dysfunction) (4).

Transurethral resection of the prostate (TURP) has been the standard-of-care for decades. However, despite technical refinements that have improved safety, the procedure is still associated with a perioperative morbidity rate of 20% and long-term complications like ejaculatory dysfunction (EjD) (65%), erectile dysfunction (ED) (10%), urethral strictures (7%), urinary tract infection (4%), bleeding requiring transfusion (2%), urinary incontinence (2%) and a retreatment rate of 6% (5). EjD has a significant negative impact on quality-of-life (QoL), including on fertility, considering the relatively early onset of BPH.

In recent years, an alphabet soup of minimally invasive treatment options have emerged with the main goal to be equally effective to TURP but with a more favorable safety and convenience profile. Ideally, this includes the rapid and durable relief of LUTS without compromise of sexual function, under local anesthesia in an ambulatory setting, with a short convalescence (6). Increasingly, a balance between symptomatic improvement in LUTS and preservation of sexual function is expected (7). The most apt comparators to water vapor thermal therapy include transurethral needle ablation (TUNA), and transurethral microwave thermotherapy (TUMT), both minimally invasive thermal ablative techniques.

The perception exists that utilization of TUNA and TUMT has not reached initial expectations due to insufficient long-term durability, despite advantages in more convenience and lower morbidity (30). Mid-term

results suggest that durability after water vapor thermal therapy is no better, and may even be worse, than TUNA and TUMT. The new AUA water vapor thermal therapy recommendation based on one study's two-year data seems premature, especially in light of the subsequent Qmax drop from year two to three. Conversely, unlike TUNA and TUMT, water vapor thermal therapy offers the potential for a low morbidity treatment of median lobe LUTS. NGS, therefore, will tentatively cover water vapor thermal therapy treatment for LUTS/BPH (with an obstructing median lobe) in poor surgical candidates, under criteria otherwise largely based on the RCT, pending long-term data.

Commercial Products

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. The procedure uses radiofrequency-generated water vapor (~103°C) thermal energy to ablate prostate tissue.

For individuals who have benign prostatic hyperplasia who receive transurethral water vapor thermal therapy, the evidence includes one small, short-term sham-controlled randomized controlled trial with a four-year uncontrolled follow-up phase. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three months, lower urinary tract symptoms improved more in the intervention group compared to the sham procedure. No adverse effects on erectile or ejaculatory function were observed, and improvements were sustained through four years of follow-up. The evidence is limited by the small sample size, short-term duration, lack of blinding of longer-term outcomes, and lack of comparison to alternative treatments such as transurethral resection of the prostate. The evidence is insufficient to determine the effects of the technology on health outcomes.

REGULATORY STATUS

In September 2016, the Rezum System™ (NxThera, Inc) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (K150786). The Food and Drug Administration determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum™ is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia. It is indicated for men ≥ 50 years of age with a prostate volume ≥30cm³ and ≤80cm³. The Rezum System™ is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

CODES

BlueCHiP for Medicare

The following code is covered when the medical criteria is met:

53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (new eff 1/1/19)

Commercial

The following code is not medically necessary:

53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (new effective 1/1/19)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, November 2019

REFERENCES

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hyperplasia?search=benign%20prostatic%20hyperplasia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed May 28, 2019.

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3. McVary, KK, Roehrborn, CC. Three-Year Outcomes of the Prospective, Randomized Controlled Rezum System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. *Urology*, 2017 Nov 11;111:1-9. PMID 29122620

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5. McVary, KK, Rogers, TT, Roehrborn, CC. Rezum Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. *Urology*, 2019 Jan 25;126:171-179. PMID 30677455

6. American Urological Association Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms, 2018 (amended 2019) Available at: [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline). Accessed May 28, 2019.

7. National Government Services (NGS):Local Coverage Determination (LCD): Water Vapor Thermal Therapy for LUTS/BPH (L37808): <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDID=37808&ver=12&Date=&DocID=L37808&bc=iAAAABAAAA&>

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