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Aquablation Robotic Therapy Policy

Indication/Usage:

Benign prostatic hyperplasia (BPH) is caused by the abnormal growth of benign (noncancerous) prostate cells which enlarge the prostate gland. The gland may push against the bladder and urethra, causing lower urinary tract symptoms (LUTS) that include increased frequency of urination, hesitancy, nocturia (urinating at night), urgency and weak urinary stream. These symptoms typically appear slowly and progress gradually over time. The likelihood of being affected by BPH increases with age and is common in males over 50 years of age. There is no cure for BPH; treatment focuses on reducing the symptoms.

Medical Indications for Authorization Commercial Members

Coverage of Aquablation Therapy and related services is subject to the terms, conditions and limitations of the applicable benefit plan to determine benefit availability and the terms, limitations and conditions of coverage. Prior authorization is required for this outpatient procedure. Any complications post procedure where member would need to be hospitalized would require submission for an Inpatient Authorization. SummaCare considers Aquablation Robotic Therapy medically necessary for treatment of lower urinary tract symptoms attributable to benign prostatic hypertrophy (BPH) when nonsurgical conventional therapies have failed.

Treatment for LUTS/BPH treatment will be considered reasonable and necessary when performed **ONCE** in patients with the following:

1. Indications including **ALL** of the following:
    a. Age ≤80
    b. Prostate volume of 30-150 cc by transrectal ultrasound (TRUS)
    c. Persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following:
        - International Prostate Symptom Score (IPSS) ≥12[1]
        - Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc)
        - Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

2. Non-surgical treatment options include but not limited to:
    - Avoidance of fluid prior to bedtime
    - Avoidance of medication that can exacerbate symptoms or induce urinary retention
    - Double voiding to ensure complete bladder emptying
    - Prescription medication
    - Reducing consumption of mild diuretics such as caffeine and alcohol

Medicare Members

CMS

WPS Insurance Corporation LCD ID **L38682** Transurethral Waterjet Ablation of the Prostate

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Benign prostatic hyperplasia (BPH) is a histological diagnosis characterized by an increased number of epithelial and stromal cells in the prostate. It is common in men over the age of 40, and the incidence increases with age. In the United States, 8 million men older than 50 years old suffer from BPH. In many cases BPH is asymptomatic, however, symptoms may occur with prostate enlargement and compression of the urethra leading to bothersome lower urinary tract symptoms (LUTS), including voiding symptoms such as hesitancy, weak stream, straining, prolonged voiding, and storage symptoms (frequency, urgency, and nocturia). LUTS/BPH can have a significant impact on the quality of life and can cause serious complications such as infections, bleeding, calculus formation, urinary retention and decline of renal function when untreated.[1] First line treatment generally consists of treatment with medications such as alpha blockers, PDE5 Inhibitors, or finasteride/dutasteride. If treatment with medications is not successful, surgical options may then be considered. Transurethral resection of the prostate (TURP) and open simple prostatectomy (OSP) are the standard surgical treatments for LUTS/BPH and are highly effective and provide improved outcomes in urinary functions. However, neither TURP nor OSP are without considerable perioperative complication and morbidity.[2] Recently, new minimally invasive surgeries have emerged as alternatives for the resection of the prostate to manage LUTS in men with BPH. One such surgery is transurethral waterjet ablation which is minimally invasive; water based surgical therapy that combines image guidance and robotics to remove prostatic tissue.[3] The system works by pumping high pressure saline (500 to 8000 pounds per square [PSI]) through a probe nozzle to cut and dissect tissue at predetermined system parameters.[3]

Covered Indications

Treatment for LUTS/BPH will be considered reasonable and necessary **ONCE per lifetime** in patients with:

1. **All** of the following indications:
    a. Prostate volume of 30-150 cc transrectal ultrasound (TRUS)[4,5]
    b. Persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following:
        i. International Prostate Symptom Score (IPSS) ≥ 12[4]
        ii. Maximum urinary flow rate (Qmax) of ≤ 15 mL/s[4] (voided volume greater than
        125 cc) iii. Failure, contraindication or intolerance to at least 3 months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy

manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

CPT Codes

0421T Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
C2596 Probe, image-guided robotic, waterjet ablation
53850 Transurethral destruction of the prostate tissue; by microwave thermotherapy [TUMT]
53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

Limitations

The following are considered not reasonable and necessary

- Body mass index ≥ 42kg/m2
- Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines[4]) or a prostate specific antigen (PSA) >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.
- Bladder cancer, neurogenic bladder, bladder calculus, or clinically significant bladder diverticulum
- Active urinary tract or systemic infection
- Treatment for chronic prostatitis
- Diagnosis of urethral stricture, meatal stenosis, or bladder neck Contracture
- Damaged external urinary sphincter
- Known allergy to device materials
- Inability to safely stop anticoagulants or antiplatelet agents preoperatively

The following procedures are considered investigational/experimental, as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer reviewed medical literature published in the English language

- Absolute ethanol injection
- Cryosurgical ablation
- High-intensity focused ultrasound (HIFU)
- Plasma kinetic vaporization (PKVP)
- Prostate artery embolization
- Temporary prostatic urethral stent (ie, iTind)
- Transrectal thermotherapy
- Transurethral balloon dilatation (eg, Optilume Basic)*
- Transurethral ultrasound guided laser induced prostatectomy (TULIP)
- Water induced thermotherapy (WIT) *Optilume drug-coated balloon (0619T) has not been approved by the FDA for BPH treatment

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

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