DRAFT Medical Coverage Policy | Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hyperplasia

EFFECTIVE DATE: 10|01|2021
POLICY LAST UPDATED: 06|16|2021

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 (LUTS) including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms are the most commonly presenting urological complaint and can have a significant impact on the quality of life.

This policy addresses the use of water vapor thermal therapy and transurethral waterjet ablation (aquablation) for the treatment of lower urinary tract symptoms attributable to benign prostatic hyperplasia (LUTS/BPH).

MEDICAL CRITERIA

Medicare Advantage Plans

Blue Cross & Blue Shield of Rhode Island (BCBSRI) follows the medical necessity criteria from the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations (NCD/LCD) for use of water vapor thermal therapy and transurethral waterjet ablation (aquablation). Please use the online tool for participating providers. See the Related Policies section.

PRIOR AUTHORIZATION

Medicare Advantage Plans

Prior Authorization is required for Medicare Advantage Plans only. Please use the online tool for participating providers. See the Related Policies section.

Commercial Products

Not applicable.

POLICY STATEMENT

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.

Transurethral waterjet ablation (aquablation) is considered investigational 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. TURP is generally considered the reference standard for comparisons of BPH procedures. Several minimally invasive prostate ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The prostatic urethral lift procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

Transurethral water vapor thermal therapy and aquablation have been investigated as minimally invasive alternatives to transurethral resection of the prostate. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective vs conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

For individuals who have benign prostatic hyperplasia and lower urinary tract symptoms who receive transurethral water vapor thermal therapy, the evidence includes one 3-month, sham-controlled randomized controlled trial (RCT) of 197 patients with a 5-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 5-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 (TURP). The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

For individuals who have benign prostatic hyperplasia and lower urinary tract symptoms who receive aquablation, the evidence includes one noninferiority RCT of aquablation compared to TURP in 187 patients with 3 years of followup. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. The primary efficacy endpoint was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety end point was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean I-PSS decreased from baseline by 16.9 points for aquablation and 15.1 points for TURP (mean difference 1.8 points; $p < .0001$ for noninferiority and $p = .1347$ for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% vs 42%, $p = .0149$). The rate of grade 2 and greater events was similar in the 2 groups (20% for aquablation and 23% for TURP; $p = .3038$). Over 3 years, improvements remained similar between groups. Confidence in these conclusions is reduced due to imprecision of estimates and a lack of additional supportive trials, especially with regard to comparative adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

REGULATORY STATUS

In September 2016, the Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K150786). The FDA 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.

In April 2017, the Aquabeam® System (Procept Robotics Corporation) was cleared for marketing by the FDA through the 513(f)(2) (de novo) classification process (DEN170024).4,The device is intended for the resection and removal of prostate tissue in males suffering from LUTS due to benign prostatic hyperplasia.

CODING

Commercial Products

The following code(s) is not medically necessary:

53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy)

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

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update August 2021
Provider Update July 2020
Provider Update, November 2019

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