

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



EFFECTIVE DATE: 10|01|2021

POLICY LAST UPDATED: 07|06|2022

OVERVIEW

Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate (TURP), considered the traditional standard treatment for benign prostatic hyperplasia (BPH). Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

Note: This policy is applicable for Commercial Products only. For Medicare Advantage Plans, see the applicable policy in the related policy section.

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

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.¹ Benign prostatic hyperplasia 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.

Benign prostatic hyperplasia 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). 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 1 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 TURP. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

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 BPH. 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). The device is intended for the resection and removal of prostate tissue in males suffering from LUTS due to BPH.

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, September 2022

Provider Update, August 2021

REFERENCES

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