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Medicare Advantage Policy Manual **Policy ID:** M-SUR210

Benign Prostatic Hyperplasia Surgical Treatments

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Transurethral water vapor thermal therapy and transurethral waterjet ablation are minimally invasive surgical therapies for the treatment of benign prostatic hypertrophy.

Benign prostatic hypertrophy (BPH) is a condition which describes the enlargement of the prostate and is often associated with a group of obstructive symptoms, termed lower urinary tract symptoms (LUTS). Standard management of BPH includes active surveillance for patients not bothered by their symptoms, medical management, surgery (e.g., transurethral resection of the prostate [TURP], transurethral vaporization, holmium laser enucleation or resection of the prostate, prostatic artery embolization, and prostatectomy), and a number of new minimally invasive therapies (e.g., transurethral needle ablation of the prostate [TUNA]

and transurethral microwave thermotherapy [TUMT], and transurethral water vapor thermal therapy).

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None	
National Coverage Determinations (NCDs)*	None	
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	***Transurethral Waterjet Ablation of the Prostate***	L38707
	Billing and Coding: Transurethral Waterjet Ablation of the Prostate *(Codes C2596 and 0421T)*	A58229
Medical Policy Manual	Medicare coverage guidance is not available for transurethral water vapor thermal therapy (e.g., the Rezūm System® by NxThera, Inc.) or transperineal laser ablation. Therefore, the health plan's medical policy is applicable. (CPT codes 53854, 53899, 0714T, and 0867T). Benign Prostatic Hyperplasia Surgical Treatments, Surgery, Policy No. 210 (see "NOTE" below)	

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Conservative treatment provided, if any
    - If options for more conservative management are relatively or absolutely contraindicated, those contraindications should be specified.

    - If options for more conservative management previously have been tried and have been ineffective or not tolerated, clinical information regarding those previous treatments should be provided.
    - Relevant imaging (ultrasound, etc) reports documenting prostate volume.
- Documentation of specific system that will be used (e.g., Aquabeam).

REGULATORY STATUS

In 2015, the U.S. Food and Drug Administration (FDA) approved the Rezūm System® (NxThera, Inc.) under the 510(k) process for use in relieving symptoms and obstructions, and reducing prostate tissue associated with BPH.

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 benign prostatic hyperplasia.

In May 2022, the ECHOLASER X4 laser system was cleared for marketing by the FDA under the 510(k) process. The device is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 1064 nm.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

None

CODING

Codes	Number	Description

CPT	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)
	0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
	0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
	53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
	53899	Unlisted procedure, urinary system
HCPCS	C2596	Probe, image guided, robotic, waterjet ablation

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*