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Medicare Advantage Policy Manual **Policy ID:** M-SUR230

Devices for Treatment of Benign Prostatic Hyperplasia, Urethral Stricture, and Urethral Stenosis

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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

Temporarily implanted nitinol devices (e.g., iTind) have been proposed as a minimally invasive alternative to transurethral resection of the prostate (TURP) to treat symptomatic benign prostatic hyperplasia. The device is temporarily implanted into the obstructed prostatic urethra to facilitate tissue reshaping and improve urine outflow. The implant is typically removed after five to seven days.

Drug-coated balloon catheter systems (e.g., Optilume®) have been proposed as minimally invasive alternatives to TURP, endoscopic management, and urethroplasty to treat obstructive urinary tract symptoms associated with benign prostatic hyperplasia or urethral stricture. The

devices utilize balloon catheters to dilate the urethra or prostate lobes and deliver paclitaxel indicated to prevent future obstructive urinary symptoms.

Prostatic urethral scaffold devices (e.g., Zenflow Spring®) have been proposed as a minimally invasive surgical therapy for benign prostatic hyperplasia. The urethral scaffold or "spring" nitinol device treats urinary obstruction by maintaining the patency of the urethra within the prostate. The device is placed using minimally invasive surgery and is designed to be permanent.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles *	None
Medical Policy Manual	*Medicare coverage guidance is not available for temporary implanted nitinol devices to treat benign prostatic hyperplasia. Therefore, the health plan's medical policy is applicable.* Devices for Treatment of Benign Prostatic Hyperplasia, Urethral Stricture, and Urethral Stenosis, Surgery, Policy No. 230 *(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

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).

REGULATORY STATUS

In April 2019, the iTind System (Olympus; previously, Medi-Tate Ltd., Hadera, Israel) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (DEN190020; product code: QKA). The new classification applies to this device and substantially equivalent devices of this generic type (e.g., K210138). The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 years and older.

In September 2021, the Optilume® Urethral Drug Coated Balloon (Urotronic, Inc.) received premarket approval from the U.S. FDA (P210020, product code: QRH).[13] The Optilume® Urethral Drug Coated Balloon is indicated for the treatment of obstructive urinary symptoms associated with anterior urethral stricture in adult males with urethral stricture less than or equal to three cm in length.

In June 2023, the Optilume® BPH Catheter System (Urotronic, Inc.) received premarket approval by the U.S. FDA (P220029; product code: QXB).[11] The Optilume® BPH Catheter System is indicated for the treatment of obstructive urinary symptoms associated with BPH in males aged 50 years and older.

As of November, 2024 the Zenflow Spring® System is an investigational device and not FDA approved.

CROSS REFERENCES

Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) of the Prostate, Surgery, Policy No. M-SUR210

REFERENCES

None

CODING

Codes	Number	Description
CPT	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
	0941T	Cystourethroscopy, flexible; with insertion and expansion of prostatic urethral scaffold using integrated cystoscopic visualization
	0942T	Cystourethroscopy, flexible; with removal and replacement of prostatic urethral scaffold
	0943T	Cystourethroscopy, flexible; with removal of prostatic urethral scaffold
	52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed
	53855	Insertion of a temporary urethral stent, including urethral measurement
	53865	Insertion of temporary device with cystourethroscopy for ischemic remodeling of bladder neck and prostate
	53866	Catheterization with removal of temporary device for ischemic remodeling of bladder neck and prostate

HCPCS	~~C9769~~None	~~Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Nitinol, iTind device)~~ (Deleted 01/01/2025)

***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.*