

Medicare Medical Policy

Benign Prostatic Hyperplasia Treatments

MEDICARE MEDICAL POLICY NUMBER: 421

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<i>Water Vapor Thermotherapy</i>	Water vapor thermotherapy (Rezūm System; CPT 53854) may be considered medically necessary for Medicare Plan members. See <i>Policy Guidelines</i> for information.
<i>Prostatic Urethral Lift (PUL) Procedure (i.e. UroLift®)</i>	Water vapor thermotherapy (UroLift®; CPT 52441, 52442 and HCPCS C9739, C9740) may be considered medically necessary for Medicare Plan members. See <i>Policy Guidelines</i> for information.
<i>Transurethral Waterjet Ablation (e.g., AquaBeam by Procept BioRobotics) (CPT 0421T, HCPCS C2596)</i>	Local Coverage Determination (LCD): Transurethral Waterjet Ablation of the Prostate (L38707)

Medicare Coverage Criteria: “MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs.” (§ 422.101(b)(6) – see [Policy Guidelines](#) below)

- **Medicare Coverage Manuals:** Medicare does not have criteria for benign prostatic hyperplasia (BPH) treatments in a coverage manual.
- **National Coverage Determination (NCD):** Medicare does not have an NCD for BPH treatments.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, while some Medicare Administrative Contractors (MACs) have LCDs for various treatments of benign prostatic hyperplasia, none of these MACs have jurisdiction over the plan service area. In addition, no Medicare Administrative Contractors (MACs) have LCDs for the BPH treatments listed below.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan’s service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are

considered “not fully established” as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available.

- **NOTE:** *The summary of evidence, as well as the list of citations/references used in the development of the Company’s internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

Transperineal Laser Ablation (CPT 0714T, 0867T)

Company medical policy for [Benign Prostatic Hyperplasia Treatments](#)

Temporary Prosthetic Urethral Stent (iTIND) (53865, 53866)

I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

Transurethral Ultrasound Ablation (TULSA) (CPT 51721, 53881, 53882)

Prostatic Urethral Scaffold (CPT 0941T-0943T)

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

TRANSORAL INCISIONLESS FUNDOPLICATION (TIF)

The **Urolift** system used to be addressed in Noridian LCAs for *Urolift* (A54044 and A54045). However, Noridian retired these LCAs effective 9/1/2017, and Noridian did not develop new LCDs or LCAs.¹

While there is no LCD or LCA for the Company service area, many Medicare Contractors which have had LCDs or LCAs for the **Rezūm** system, either currently or in the past, indicate use of the medical technology is appropriate when used for FDA approved indications.

Therefore, at this time, use of the Rezūm or Urolift systems may be considered medically necessary by the Company for Medicare Plan members.

MEDICARE AND MEDICAL NECESSITY

For all other treatments of BPH, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (*§ 422.101(c)(1)*)

In addition:

“MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.” (*§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5*)

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* ([MP50](#)) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for most benign prostatic hyperplasia (BPH) treatments available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the [Medicare Coverage Criteria](#) table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- Local Coverage Article (LCA): Billing and Coding: Transurethral Waterjet Ablation of the Prostate ([A58229](#))

Correct Coding for Transurethral Ultrasound Ablation (TULSA)

According to CPT Manual instructions:

- If the entirety of the procedure is performed by a single physician, the proper code to use is CPT **55882**.
- If the procedure is split between a urologist (who typically performs the work described by CPT **51721**) and a radiologist (who commonly performs the work described by PT **55881**), the respective practice only reports the code corresponding to their specialist's service.

CODES*		
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
	0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
	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
	51721	Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed
	53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate
	53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate
	55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation
	55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed
	53899	Unlisted procedure, urinary system
HCPCS	C2596	Probe, image-guided, robotic, waterjet ablation
	€9769	CODE TERMED 12/31/2024 Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Coverage Database (MCD) Archive web site.
https://localcoverage.cms.gov/mcd_archive/search.aspx. Accessed 11/10/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2025	New Medicare Advantage medical policy