

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Benign Prostatic Hyperplasia (BPH) Treatments

- Aquablation (Transuretheral Waterjet Ablation of the Prostate)
- Rezūm System for the Treatment of LUTS due to BPH
- Prostatic Urethral Lift (PUL or UroLift)
- Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Therapeutic Embolization (20.28)
Local Coverage Determinations (LCD)	Transurethral Waterjet Ablation of the Prostate (L38707)
Local Coverage Article	Urolift: Local Coverage Article: Urolift (A54044)-RETIRED Noridian retired Local Coverage Article (LCA A54044). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search.
Medicare Coverage Related to Investigational Device Exemption (IDE) Studies	Prostate Artery Embolization: This procedure is considered experimental and investigational and is <u>not recommended</u> outside of a clinical trial setting. Procedure is covered when part of an approved Investigational Device Exemption (IDE) trial. There are multiple CMS-approved IDE studies underway <u>https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-</u> <u>Studies</u> .
Kaiser Permanente Medical Policy	Rezūm: Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, " <i>Rezūm System for the Treatment of LUTS due to BPH</i> ," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Transurethral Waterjet Ablation	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
UroLift	Covers prostatic urethral lift (e.g., UroLift) as medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met: A. age 50 or above B. prostate volume < 80 cc on ultrasound imaging C. no obstructive median lobe of the prostate identified on cystoscopy D. failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
	Last 6 months of clinical notes from requesting provider &/or specialist
Rezūm System for the Treatment of LUTS due to BPH	 Water vapor thermal therapy (e.g., Rezūm System) is considered medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met: age 50 years or above estimated prostate volume ≥ 30 cm3 and ≤ 80 cm3 failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) If requesting this service, please send the following documentation to support medical necessity:
	Last 6 months of clinical notes from requesting provider &/or specialist
Prostate artery embolization for benign prostatic hyperplasia (BPH)	 Inere is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. If requesting review for these services, please send the following documentation: Last 6 months of clinical notes from requesting provider &/or specialist
High Intensity Focused Ultrasound (HIFU) for the Treatment of Localized Prostate Cancer	Please see criteria <u>here</u> . *Not covered for BPH Treatments

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Benign prostatic hyperplasia (BPH) is most common among men between 50 to 60 years old. BPH growth is associated with aging and varies from person to person. The doubling time of BPH growth is 4.5 years and 10 years between the ages of 31- 50 and 51 to 70, respectively (Vuichoud & Loughlin, 2015). Although the exact etiology is not well known, BPH is characterized by an augmentation of epithelial and stroma cells in the periurethral region of the prostate (Vuichoud & Loughlin, 2015) resulting in a compression of the wall of the urethra and a decrease in urine flow. Men with BPH present with low urinary tract symptoms (LUTS), including urinary frequency, urgency, intermittency, hesitancy, nocturia, straining, incomplete emptying, or weak urinary stream (Porst et al., 2009). These conditions compromise erectile function and result in low quality of life (QOL) and depression. BPH is generally evaluated by using one of the following scores: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptoms Score (IPSS). AUASI is a self-administered questionnaire with symptom scores ranging from 0 to 35, with higher scores (>20) equivalent to severe symptoms. The IPSS includes AUASI and QOL questions (Vuichoud & Loughlin, 2015).

The treatment of LUTS depends on the patient's symptoms and level of bother. Therapeutic options include

- Watchful waiting (active surveillance) for patients with mild symptoms of LUTS secondary to BPH and for
 patients with moderate-to-severe symptoms who are not bothered by their symptoms and are not
 experiencing complications of BPH.
- Lifestyle modification is initially recommended for patients with bothersome LUTS that begin affecting their quality of life.
- Drug therapy (e.g. alpha-blockers, 5-alpha-reductase inhibitors, muscarinic receptor antagonists and phosphodiesterase 5, inhibitors) is an appropriate and effective treatment for patients with bothersome, moderate to severe LUTS secondary to BPH.
- Surgical intervention is appropriate for patients with moderate-to-severe LUTS, acute urinary retention, or
 other complications due BPH. Surgery is the most invasive option for BPH management and is generally
 performed in patients will have failed medical therapy. However, some patients may wish to pursue the most
 effective therapy as a primary treatment if their symptoms are particularly bothersome (American Urological
 Association Guideline).

Transurethral resection of the prostate (TURP) and open simple prostatectomy are currently the gold standard surgical interventions. Both are highly effective and provide durable improvement in urinary functional outcomes. However, despite the refinements made in the operative technique, these invasive procedures are associated with perioperative complications and morbidity including bleeding, erectile and ejaculatory dysfunction, urethral stricture, urinary tract infection, and urinary incontinence (Chung 2018, Christidis 2017, Magistro 2017).

Several novel minimally invasive therapies have been developed, or are at different stages of development, with the aim of improving the patients' symptoms and avoiding the adverse outcomes of associated with the more invasive surgeries. Among these therapies are the UroLift System, intraprostatic injectables, temporary implantable nitinol device, image guided robotic waterjet ablation, transurethral microwave therapy (TUMT), convective water vapor energy (WAVE) ablation, prostatic artery embolization, and others. An ideal minimally invasive treatment would be an intervention that can be easily performed in the office or in an outpatient setting, leads to rapid and durable relief of symptoms, is associated with minimal morbidity and recovery time, and preserves the erectile and ejaculatory functions of the patient (Chung 2018, (Magistro 2017).

Rezūm System; NxThera, Inc. Maple Grove, MN) is a minimally invasive transurethral therapy that uses the stored thermal energy in water vapor (steam) to treat the extra prostate tissue that is causing symptoms. Tissue ablation with Rezūm System uses the thermodynamic principle of convection energy transfer in contrast to conductive heat transfer techniques used in the transurethral microwave therapy or transurethral needle ablation. The Rezūm system utilizes radiofrequency (RF) to generate wet thermal energy in the form of water vapor (steam). Once the vapor (103oC) is injected, it disperses through the tissue spaces and immediately changes to liquid releasing and delivering approximately 208 cal of thermal energy in 9 seconds. The target tissue temperature reaches 70o resulting in irreversible and near instantaneous cell death. No thermal effects occur outside the prostate or in the peripheral zone when a transition zone is targeted. In addition, as the vapor is wet thermal energy, there is no charring, desiccation, or carbonization of the treated tissue. The dead tissue will be © 2019, Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top

eventually absorbed by the body through its natural healing response (Dixon 2016, Christidis 2017, Woo 2017 Magistro 2017).

The Rezūm System is composed of a generator containing a radiofrequency power supply to create water vapor from sterile water, and a single use transurethral delivery device that incorporates a standard 4 mm 30o rod lens allowing the procedure to be performed under direct cystoscopic visualization. The tip of the delivery device contains an 18-guage polyether ether ketone needle which has 12 small emitter holes spaced around its tip at 1200 intervals to allow for circumferential dispersion of water vapor into the prostate tissue. (Darson 2017, Woo 2017).

The procedure is performed in the clinic or out-patient setting, under cystoscopic guidance and oral sedation. Radiofrequency energy is applied to a few drops of water (0.5ml) to create vapor inside a hand-held device. The patient is placed in the lithotomy position and the delivery device is inserted into the urethra; the total penetrating length of the vapor needle is fixed at 10.25mm. Its tip is visually positioned and inserted approximately 1cm distal to the bladder neck. Once the delivery system is within the prostate, the needle is deployed, and a 9-second burst of water vapor is injected into the prostatic tissue. This disperses rapidly and homogeneously through the tissue spaces and immediately condenses to water releasing the energy stored in the vapor into the cell membranes causing cell death and necrosis. The needle is retracted after each treatment and repositioned in 1cm increments distal from the previous site with the objective of creating adjacent overlapping lesions running parallel to the natural slope of the urethra. Usually 1-3 injections are needed for each lateral lobe and 1-2 injections for the median lobe. The total number of injections may vary according to size of the hypertrophied prostate tissue and the length of the urethra (McVary 2016, Woo 2017, Chung 2018).

Potential procedure-related side effects include acute urinary retention, failure of the procedure requiring secondary surgery, posttreatment dysuria, hematuria, frequency & urgency, hematospermia and urinary tract infection. According to the manufacturer, most of these events resolve within 3 weeks of the procedure, but there is a possibility that some may last longer.

Medical Technology Assessment Committee (MTAC)

Convection Radiofrequency Thermal Therapy with Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy 04/21/2018: MTAC REVIEW

Evidence Conclusion:

- There is no published evidence to determine the comparative efficacy and safety of convection radiofrequency thermal therapy with the Rezūm System and transurethral resection of the prostate (TURP), open simple prostatectomy, or other noninvasive intervention currently used in practice for relieving bothersome lower urinary tract symptoms secondary to benign prostatic hypertrophy.
- The published literature on Rezūm System consisted of one relatively small randomized sham- controlled trial
 with a duration of three months after which it was converted to an observational study comparing outcomes to
 baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall
 poor quality.
- The published literature only provides low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

<u>Articles:</u> The literature search for studies on the efficacy and safety of Rezūm system for the treatment LUTS secondary to BPH, identified one randomized sham-controlled trial that reported three years follow-up results in 4 publications (McVary 2015, 2016 & 2018, and Roehrborn 2017), as well as three pretest- posttest studies (one small pilot study with 2 years follow up results [Dixon 2012, and 2016] and two retrospective analyses [Darson 2017 and Mollengarden 2017]). All 4 studies were critically appraised. <u>See Evidence Table 1.</u>

The use of Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy does not meet the *Kaiser Permanente Medical Technology* Assessment Criteria.

Rezūm for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH) 03/04/2019: INTC REVIEW

Evidence Conclusion: There is insufficient evidence to draw a conclusion on use of Rezūm. The existing evidence is of insufficient quantity and quality.

© 2019, Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top <u>Articles:</u> The published literature on Rezūm System consisted of one relatively small randomized shamcontrolled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality. Two indirect comparisons of Rezūm versus other medical therapy trial data were also reviewed.

The available published literature provided low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment. https://cl.kp.org/pkc/national/cpg/intc/topics/03_04_191.html

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) 03/21/2016: MTAC REVIEW

Evidence Conclusion: Conclusion from INTC review - "Urolift may be viable alternative to TURP for patients with LUTS secondary to BPH. Short-term data from low to moderate quality, industry-funded studies conclude that Urolift is effective and safe. The overall quality of the evidence is low to moderate. However, due to concerns regarding risk of bias in these studies, a definitive conclusion regarding the long-term safety and effectiveness of UroLift cannot be made from existing evidence. Additional, high quality studies with longer follow-up are needed to confirm preliminary findings".

<u>Articles:</u> Since the search did not identify new studies, and because INTC evidence review is recent, their review can be adopted. In addition, the search did not find studies comparing PUL to medical management. <u>See Summary of RCTs</u>.

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) 06/28/2017: MTAC REVIEW

Evidence Conclusion: One study (C Roehrborn et al., 2016) (See Evidence Table 1) assessed the long term (4 vears) effectiveness and safety of PUL. PUL was compared to sham control. Characteristics of patients were similar. Patients were randomized to either PUL (N=140) or sham control (N=66) at 19 centers in North America and Australia and followed for 4 years. The authors reported that Urolift improved urinary symptoms, preserved sexual and ejaculatory function with minor adverse events. The authors indicated that durability of these effects needs to be confirmed at 5-year follow-up. The risk of bias is unclear for incomplete outcome data and the major limitation is the high attrition rate. The author of the previous study (Claus Roehrborn et al., 2017) (See Evidence Table 2) confirmed the durability of PUL effects in the 5-year follow-up study. Urinary symptoms (IPSS), BPHII, flow rate (Qmax), QoL, erectile and ejaculation functions were improved and /or preserved with minimal complications. Another abstract was reviewed (Henry Woo). Comparison was made between PUL and sham. This was a crossover study wherein 53 patients were enrolled. Patients were treated with sham, then crossover occurred, and patients were followed for 4 years. Compared to baseline, IPSS, QoL, and BPHII statistically improved at 45%, 49%, and 44% respectively (P<0.001). Flow rate (Qmax) also increased by 50% (P=0.01). Adverse events were mild. Level of evidence: In the first two studies, the risk of bias is unclear for incomplete outcome data and low in other domains of risk of bias assessment; no serious precision or directness issues were identified: findings were consistent: the quality of the study assessed by Modified Jadad Scale is high. The studies provide moderate evidence to support the use of PUL.

Conclusion:

- The long-term effectiveness and safety are based on three articles that compare PUL versus sham over 4 and 5 years. Compared to sham, moderate level of evidence indicates that PUL is effective and durable in patients with LUTS due to BPH on the long-term.
- The technology is also safe with minimal complications.

<u>Articles:</u> Three articles were reviewed: Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalis, D. (2016). Prospective, randomized, blinded study of Prostatic Urethral Lift (pul): four-year results. BJU Int, 117, 19-20. Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Te, A. (2017). PD27-01. 5 year prospective, randomized, controlled study results on the minimally invasive prostatic urethral lift (PUL). J Urol, 197(4), e511. Crossover study on the prostatic urethral lift (pul): 4-year results. Henry Woo, Sydney, Australia; Jack Barkin, Toronto, Canada; Damien Bolton, Heidelberg, Australia; Prem Rashid, Port Macquarie, Australia; Anthony Cantwell, Daytona Beach, FL; William Bogache, Myrtle Beach, SC; Stephen Richardson, Salt Lake City, UT; Ronald Tutrone, Baltimore, MD; James Fagelson, Englewood, CO; Peter Chin, Figtree, Australia

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Prostate artery embolization for benign prostatic hyperplasia (BPH) 10/14/2019: MTAC REVIEW

Evidence Conclusion:

- Low-quality evidence shows that prostatic artery embolization (PAE) may be less effective than TURP in terms of patient-reported and functional outcomes on the short-term.
- Low-quality evidence suggests that PAE may cause fewer complications than TURP, preserve erectile function, and decrease the duration of hospitalization. More RCTs with enough power and longer follow-up are warranted.
- There is insufficient evidence to compare PAE vs open prostatectomy.

<u>Articles:</u> PubMed search was conducted up to August 8, 2019 with the search terms prostate artery embolization. Other search terms included low urinary tract symptoms or LUTS, and benign prostatic hyperplasia or BPH. The search yielded 7 meta-analyses. Of these, four were retained (two meta-analyses with comparative studies and two with noncomparative studies). The other meta-analyses are included in other references because their findings are similar to that of the two meta-analyses of noncomparative studies retained.

In addition, the search yielded 8 RCTs. Of the 8 RCTs, none was retained (RCTs were either included in metaanalysis or were out of scope). Regarding nonrandomized studies, search yielded 18 studies, but none was included due to their inclusion in the meta-analyses of noncomparative studies. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Prostate artery embolization for benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Transurethral Waterjet Ablation (Aquablation, Hydroblation) 04/10/2023: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence, to date, to determine that Aquablation therapy is safer and more
 effective than TURP, robotic simple prostatectomy, or other minimally invasive procedures in improving lower
 urinary tract symptoms attributed to BPH, in men with small, moderate, or large volume prostates.
- The body of evidence on Aquablation for the treatment of lower urinary tract symptoms due to BPH, consists
 of a single relatively small randomised controlled study (WATER trial) with limitations, several case series,
 conducted in different countries, and meta-analyses pooling their results. Except for WATER sub-study and
 WATER II studies, all the other single arm studies included men with any prostate volume (ranging from 20154 cc). All were sponsored by PROCEPT BioRobotics the manufacturer of the device used in Aquablation
 which can bias the research results.
- Though the published literature includes a RCT showing that aquablation is not inferior to TURP, and may be associated with better ejaculatory function and less adverse events in highly selected participants with LUTS/BPH and prostate volume 30-80ml, the study had its limitations and risk of bias, that lowers the certainly of evidence it provides.
- More independent randomized controlled trials are needed to confirm and /or provide more evidence on the comparative safety and efficacy of Aquablation therapy to other surgical or minimally invasive procedures currently used in practice for the treatment of LUTS attributed to BPH, in men with prostate volumes up to 80 cc and in men with larger prostate volumes.

<u>Articles:</u> The literature search for published studies comparing transurethral aquablation of the prostate versus TURP, robotic prostatectomy, or other MITs, identified one phase 3 multicenter, international clinical trial (WATER [Gilling et al, 2018, 2019, 2020 and 2022]) that compared Aquablation therapy vs. TURP for the treatment of LUTS/BPH in men with prostate volume 30-80 ml. Other published studies on Aquablation for BPH consisted of several small to relatively small prospective, multicenter, or single center studies without controls or comparison groups, as well as three systematic reviews with meta-analyses (Hwang, et al, 2019, Manfredi, et al, 2022, and Chen, et al, 2022), two network meta-analyses (Sajan, et al, 2022, and Tanneru, et al 2021), that indirectly compared the outcome of different minimally invasive treatments for BPH; and several qualitative systematic reviews.

The search did not identify any RCT that directly compared Aquablation to TURP in men with prostate volume larger than 80 ml, or any RCT that compared Aquablation versus simple prostatectomy, laser ablation of the prostate, laser enucleation of the prostate, REZUM, or any other minimally invasive therapy in men with prostate volume less or greater than 80 ml.

WATER trial was selected for critical appraisal. The single-arm studies and two meta-analyses (Chen, et al, 2022, and Manfredi et al, 2022) were also reviewed. The Cochrane review (Hwang, et al 2019) only included the WATER trial, and its assessment of the trial is a briefly summarized. The network meta-analyses with no direct comparison between aquablation and other interventions, were excluded from the current review of the technology. <u>See Evidence Table.</u>

The use of Transurethral Waterjet Ablation (Aquablation, Hydroblation) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate Artery Embolization (PAE) for BPH 04/14/2025: MTAC REVIEW

Evidence Conclusion:

- Low-quality evidence suggests that compared to TURP, PAE may be similarly effective in urologic symptoms, quality of life, erectile function, chronic prostatitis symptom index, and PSA in the long term. However, TURP may be more effective in improving maximum flow rate and post-void residual.
- There is uncertainty on whether PAE results in more or fewer major adverse events than TURP.
- Moderate-quality evidence suggests that PAE increases retreatment rates.
- Low-quality evidence indicates that PAE reduces ejaculatory disorders compared to TURP.

<u>Articles:</u> A PubMed search was conducted up to January 16, 2025. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Clinicaltrial.gov was also searched for new studies. One study (NCT02054013), whose status is completed, was identified. However, no results were available. <u>See Evidence Table.</u>

The use of Prostate artery embolization for benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

Aquablation therapy is a minimally invasive procedure that ablates overgrown prostatic tissue in order to restore patency to the urethral passageway. High-velocity saline is sprayed under robotic guidance in order to ablate only the targeted prostatic tissue while sparing all surrounding tissue.

Conclusion

A low-quality body of mainly single-arm studies suggests Aquablation may improve LUTS associated with BPH at short- to intermediate-term follow-up without impact on sexual function or serious safety issues. One comparative study suggests Aquablation may be comparable to TURP; however substantial uncertainty remains due to the paucity of comparative evidence and the limited long-term evidence regarding the durability and safety of Aquablation. Furthermore, clarity is lacking as to which patient populations are likely to benefit the most from Aquablation therapy.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Aquablation for Treatment of Benign Prostatic Hyperplasia. Dallas, TX: Hayes; March 30, 2021. Retrieved January 18, 2023, from https://evidence.hayesinc.com/report/htb.aquablation5017

Applicable Codes

Transurethral Waterjet Ablation -

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Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
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)
HCPC	Description
Codes	
C2596	Probe, image guided, robotic, waterjet ablation

Urolift - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT [®] Codes	Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
HCPC	Description
Codes	
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

Rezūm –

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

Prostate Artery Embolization (PAE) - Considered Not Medically Necessary:

CPT®	Description
Codes	
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
ICD-10	Description
Codes	
D29.1	Benign neoplasm of prostate
N35.010-	Urethral stricture
N35.016;	
N35.1-	
N35.919	
N40.0-N40.1	Enlarged prostate (EP)
N40.2-N40.3	Nodular prostate

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N42.30	Unspecified dysplasia of prostate
N42.31	Prostatic intraepithelial neoplasia
N42.32	Atypical small acinar proliferation of prostate
N42.39	Other dysplasia of prostate
C61	Malignant neoplasm of prostate

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/03/2019	12/03/2019 ^{MPC} , 05/05/2020 ^{MPC} , 05/04/2021 ^{MPC} , 05/03/2022 ^{MPC} , 05/02/2023 ^{MPC} , 06/04/2024 ^{MPC} , 06/03/2025 ^{MPC}	06/03/2025

Revision	Description
пізіогу	
12/03/2019	Merged all BPH criteria (Urolift, Rezūm, PAE) into one document
12/03/2019	MPC approved non-coverage policy for Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)
05/05/2020	Added diagnosis codes N35.010-N35.92, N40.0-N40.3 and C61 (PAE); Added CPT code 53854
	and removed 53899 (Rezum)
10/06/2020	MPC approved medical necessity criteria for Rezūm. Requires 60-day notice, effective date
	3/1/2021.
04/25/2022	Added statement to Medicare section – Medicare covers PAE if part of an IDE study.
02/07/2023	Added 0421T code with Medicare coverage LCD. Added Hayes report.
05/02/2023	Added MTAC review for Transurethral Waterjet Ablation. MPC endorsed MTAC's decision and
	continued a position of non-coverage.
5/23/2024	Updated Dx code list for PAE procedure
06/03/2025	MPC approved to MTAC's recommendation and to maintain policy of non-coverage.
	Added April 2025 MTAC review.