



Benign Prostatic Hyperplasia (BPH) Treatments

| | |
|---|--|
| LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid | State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington |
|---|--|

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Benign Prostatic Hyperplasia (BPH) is a noncancerous increase in size of the prostate gland. The enlarged prostate gland presses against the urethra. BPH can lead to symptoms like frequent urination, trouble starting to urinate, weak stream, inability to urinate, or loss of bladder control. BPH is treated with lifestyle changes, medication, and surgery (transurethral resection of the prostate (TURP). Alternative available treatment options include the prostatic urethral lift (PUL), the Rezum system, and AquaBeam® system.

The prostatic urethral lift (PUL) procedure is a treatment for benign prostatic hyperplasia (BPH) symptoms using implant(s) to separate enlarged prostate lobes to reduce pressure on the urethra.

Transurethral Water Vapor Therapy (e.g., Rezum System) delivers sterile water vapor (steam) directly into hyperplastic tissue. Heat is released as the vapor condenses, causing cell death and improving BPH symptoms

Waterjet tissue ablation (e.g., AquaBeam® System) is a medical device that is controlled with electromechanical precision and live ultrasound which delivers a high-velocity saline stream to ablate prostatic glandular tissue without the production of heat. High-velocity sterile saline is delivered to the prostate tissue. The ablated tissue from the procedure is removed and a laser light beam is used to cauterize the excised area.

Criteria

Commercial

Prior authorization is required

I. Prostatic Urethral Lift

PacificSource considers coverage of prostatic urethral lift (PUL), for the treatment of lower urinary tract symptoms (LUTS) due to BPH medically necessary when **ALL** of the following criteria is met:

- A. Age 45 years or older
- B. Prostate volume is not greater than 100 mL based on ultrasound imaging
- C. Median lobe of prostate is not obstructed
- D. Peak flow rate (Qmax) is less than or equal to 12 mL/second
- E. Intolerance to or failure of medication management (3 month or longer) for treatment of BPH symptoms (e.g., alpha blockers, PDE5 Inhibitor, finasteride, dutasteride)
- F. Lower urinary tract symptoms, to including **ANY** of the following:
 1. urinary frequency
 2. urgency
 3. nocturia
 4. weak stream
 5. straining
 6. intermittency

II. Transurethral Water Vapor Therapy

PacificSource considers coverage of a transurethral water vapor therapy procedure (e.g., Rezum system procedure), for lower urinary tract symptoms (LUTS) associated with Benign Prostatic Hyperplasia (BPH) medically necessary when **ALL** the following criteria have been met:

One treatment for LUTS/BPH is covered in patients with **BOTH** of the following:

- A. Age greater than or equal to 50
- B. Symptomatic despite maximal medical management including **ALL** of the following:
 1. International Prostate Symptom Score (IPSS) ≥ 13
 2. Maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume no greater than 125 mL)
 3. Intolerance to or failure of medication management (3 month or longer) for treatment of BPH symptoms (e.g., alpha blockers, PDE5 Inhibitor, finasteride, dutasteride)
 4. Prostate gland volume is estimated to be ≥ 30 to ≤ 100 mL (or grams in weight) by clinical or ultrasound assessment

III. Waterjet Tissue Ablation

PacificSource considers coverage of Waterjet Tissue Ablation (e.g., AquaBeam® System) medically necessary for treatment of lower urinary tract symptoms (LUTS) secondary to Benign Prostatic Hyperplasia (BPH) when **ALL** of the following criteria is met:

- A. Prostate gland volume is less than or equal to 150 mL based on ultrasound imaging
- B. International Prostate System Score (PPSS) \geq 13
- C. Intolerance to or failure of medication management (3 month or longer) for treatment of BPH symptoms (e.g., α 1-adrenergic antagonists, 5 α -reductase inhibitors, or combination medication therapy)

Medicaid

PacificSource Community Solutions (PCS) follows Oregon Administrative Rules (OARs) 410-141-3820, 410-141-3825, and 410-141-3830, and Guideline Note 145 of the OHP Prioritized List of Health Services for coverage of Benign Prostatic Hyperplasia (BPH) Treatments. PacificSource Community Solutions(PCS) follows Guideline Note 173 of the OHP Prioritized List of Health Services for codes 53855 and C97696 to have insufficient evidence of effectiveness.

PacificSource Community Solutions (PCS) follows EPSDT coverage requirements in OAR 410-151-0002 for members under the age of 21. Coverage of Benign Prostatic Hyperplasia (BPH) Treatments is determined through case-by-case reviews for EPSDT Medical Necessity and EPSDT Medical Appropriateness defined in OAR 410-151-0001. Guideline Note 145 and Guideline Note 173 may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review.

Medicare

PacificSource Medicare follows Local Coverage Determination (LCD) L38707 for coverage of Transurethral Waterjet Ablation of the Prostrate.

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

Experimental/Investigational/Unproven

PacificSource considers the use of temporary removable or biodegradable prostatic urethral stents to be experimental, investigational, and unproven

PacificSource considers Transurethral Balloon Dilation (TUDP) (e.g., Optilume BPH Catheter System) to be experimental, investigational, and unproven

PacificSource considers Prostate Arterial Embolization (PAE) (Transcatheter Embolization) for treatment of Benign Prostate Hyperplasia to be experimental, investigational, and unproven

PacificSource considers UroCuff test (Penile Cuff test) to be experimental, investigational, and unproven

PacificSource considers Waterjet Tissue Ablation to be experimental, investigational, and unproven for all other indications

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 0421T Transurethral waterjet ablation prostate control post-op bleeding including US guide/complete (vasect/meatotomy/cystourethro/urethral calibration/dilation & internal urethrot)
- 37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary
- 52441 Cystourethroscopy with transurethral resection or incision of ejaculatory ducts
- 52442 Each additional permanent adjustable transprostatic implant
- 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
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
- 53855 Insertion of a temporary prostatic urethral stent, including urethral measurement
- 53899 Unlisted procedure, urinary system
- 55899 Unlisted procedure, male genital system
- 75894 Transcatheter therapy, embolization, any method, radiological supervision, and interpretation
- C2596 Probe, image guided, robotic, waterjet ablation --
- C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
- C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
- C9769 Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS)

References

American Urological Association (AUA). (2023). Management of Benign Prostatic Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. Available at:

[https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline)

Bhojani, N., Nguyen, D. D., Kaufman, R. P., Jr, Elterman, D., & Zorn, K. C. (2019). Comparison of < 100 cc prostates and > 100 cc prostates undergoing aquablation for benign prostatic hyperplasia. *World journal of urology*, 37(7), 1361–1368. <https://doi.org/10.1007/s00345-018-2535-9>

Bhojani, N., Bidair, M., Zorn, K. C., Trainer, A., Arther, A., Kramolowsky, E., Doumanian, L., Elterman, D., Kaufman, R. P., Lingeman, J., Krambeck, A., Eure, G., Badlani, G., Plante, M., Uchio, E., Gin, G., Goldenberg, L., Paterson, R., So, A., Humphreys, M., ... Roehrborn, C. (2019). Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150 cc): 1-Year Results. *Urology*, 129, 1–7.

<https://doi.org/10.1016/j.urology.2019.04.029>

Das, A. K., Leong, J. Y., & Roehrborn, C. G. (2019). Office-based therapies for benign prostatic hyperplasia: a review and update. *The Canadian journal of urology*, 26(4 Suppl 1), 2–7. Accessed October 13, 2021, and February 21, 2022. <https://www.ncbi.nlm.nih.gov/pubmed/31481142>

Desai, M., Bidair, M., Bhojani, N., Trainer, A., Arther, A., Kramolowsky, E., Doumanian, L., Elterman, D., Kaufman, R. P., Jr, Lingeman, J., Krambeck, A., Eure, G., Badlani, G., Plante, M., Uchio, E., Gin, G., Goldenberg, L., Paterson, R., So, A., Humphreys, M. R., ... Zorn, K. C. (2020). Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 2-year results. *The Canadian journal of urology*, 27(2), 10147–10153.

ECRI Institute. ECRI Clinical Evidence Assessment -- AquaBeam Robotic System (Procept BioRobotics Corp.) for treating benign prostatic hyperplasia. Plymouth Meeting, PA: ECRI; July 2021.

Eure, G., Gange, S., Walter, P., Khan, A., Chabert, C., Mueller, T., Cozzi, P., Patel, M., Freedman, S., Chin, P., Ochs, S., Hirsh, A., Trotter, M., & Grier, D. (2019). Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study. *Journal of endourology*, 33(7), 576–584. <https://doi.org/10.1089/end.2019.0167>

Food and Drug Administration. (April 17, 2017). De Novo Classification Request for AQUABEAM System. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170024.pdf

Foster, H. E., Dahm, P., Kohler, T. S., Lerner, L. B., Parsons, J. K., Wilt, T. J., & McVary, K. T. (2019). Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Amendment 2019. *The Journal of urology*, 202(3), 592–598. <https://doi.org/10.1097/JU.0000000000000319>

Hayes Knowledge Center. (January 19, 2024). Annual Health Technology Assessment: Rezum (Boston Scientific Corp.) for Benign Prostatic Hyperplasia.

Hayes Knowledge Center. (July 13, 2023). Annual Health Technology Assessment: Prostatic Urethral Lift (UroLift System) for Treatment of Symptoms Associated with Benign Prostatic Hyperplasia.

Hayes Knowledge Center. (March 12, 2024). Annual Health Technology Assessment: Aquablation for Treatment of Benign Prostatic Hyperplasia.

Lim Ng, K., & Barber, N. (2019). Prostatic hydroablation (Aquablation): A new effective ultrasound guided robotic waterjet ablative surgery for treatment of benign prostatic hyperplasia. Hidroablación prostática (Aquablation): Una nueva cirugía ablativa por chorro de agua guiada por ecografía y robotizada, eficaz en el tratamiento de la hiperplasia benigna de próstata. *Archivos españoles de urología*, 72(8), 786–793. <https://pubmed.ncbi.nlm.nih.gov/31579037/>

McVary, K., Holland, B., and Beahrs, J. R. (2020) Water Vapor Thermal Therapy to Alleviate Catheter-Dependent Urinary Retention Secondary to Benign Prostatic Hyperplasia. *Prostate cancer and prostatic diseases*, 23(2), 303–308. https://pubmed.ncbi.nlm.nih.gov/31740738/?from_term=Rezuystem&from_filter=simsearch1.fha&from_filter=ds1.y_1&from_pos=3

McVary, K. T., (October 22, 2021). Surgical treatment of benign prostatic hyperplasia (BPH). UpToDate. https://www.uptodate.com/contents/surgical-treatment-of-benign-prostatic-hyperplasia-bph?topicRef=6889&source=see_link

National Institute for Health and Care Excellence (NICE). (June 24, 2020). Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. <https://www.nice.org.uk/guidance/mtg49>

Oregon Administrative Rules (OARs). Oregon Health Authority. Health Systems: Medical Assistance Programs – Chapter 410

<https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87>

Parsons, J. K., Dahm, P., Köhler, T. S., Lerner, L. B., & Wilt, T. J. (October 1, 2020). *Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Amendment 2020*. *The Journal of urology*, 204(4), 799–804.

<https://doi.org/10.1097/JU.0000000000001298>

Roehrborn, C. G., Rukstalis, D. B., Barkin, J., et.al. (2015). Three-year results of the prostatic urethral L.I.F.T. study. *The Canadian journal of urology*, 22(3), 7772–7782. http://www.canjurol.com/html/free-articles/V22I3_05_FREE_DrRoehrborn.pdf

The Health Evidence Review Commission (HERC) Prioritized List of Health Services

<https://www.oregon.gov/oha/HSD/OHP/Pages/Prioritized-List.aspx>

Westwood, J., Geraghty, R., Jones, P., Rai, B. P., & Somani, B. K. (2018). Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Therapeutic advances in urology*, 10(11), 327–333. <https://doi.org/10.1177/1756287218793084>

Appendix

Policy Number:

Effective: 12/31/2020

Next review: 12/1/2025

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s) LCD L38707, LCD L37808, OARs 410-141-3820,410-141-3825, 410-141-3830, 410-151-0000, 410-151-0001, 410-151-0002, 410-151-0003; Guideline Note 145 and 173 of the OHP Prioritized List of Health Services

Commercial Ops: 10/2024

Government Ops: 11/2024