Benign Prostatic Hyperplasia (BPH) Treatments

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

Enterprise Policy

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 determination 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) and the Rezum system.

The prostatic urethral lift (PUL) procedure is used to treat the symptoms of benign prostatic hyperplasia (BPH). The prostatic urethral lift procedure involves placement of 1 or more implants in the lateral lobes of the prostate using a transurethral delivery device. The implant (s) separate enlarged prostate lobes to reduce pressure on the urethra to allow for an easier urine flow.

The Rezum System procedure is a transurethral treatment for benign prostatic hyperplasia (BPH). This procedure is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostrate hyperplasia (BPH).The Rezum System utilizes convective radiofrequency water vapor energy to ablate the hyperplastic tissue of the prostate.

Criteria

Commercial

Prostatic Urethral Lift

Prior authorization is required.

PacificSource considers prostatic urethral lift (PUL), using an FDA approved device, for the treatment of lower urinary tract symptoms (LUTS) due to BPH to be **medically necessary** in individuals when **ALL** of the following criteria have been met:

a. Age 45 years or older
b. Prostate volume no greater than 100cc based on ultrasound imaging
c. No obstructive median lobe of the prostate identified on cystoscopy
d. Peak flow rate (Qmax) is **less than or equal to** 12mL/second
e. Intolerance, contraindication, or failure of medications (3 month trial) for treatment of BPH symptoms (e.g., alpha blockers, PDE5 Inhibitor, finasteride, dutasteride)
f. the following lower urinary tract symptoms:
    i. urinary frequency
    ii. urgency
    iii. nocturia
    iv. weak stream
    v. straining
    vi. intermittency

2. No contraindications including the following
    a. No active urinary tract infection, urinary incontinence, or gross hematuria

Not Medically Necessary

Prostatic urethral lift is considered not medically necessary when all of the criteria specified above are not met.

Rezum System - Transurethral Water Vapor Therapy

Prior authorization is required.

PacificSource considers the 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:

1. Indications Including **ALL** of the following;
    a. Age ≥50
    b. Symptomatic despite maximal medical management including **ALL** of the following:
        i. International Prostate Symptom Score (IPSS) ≥13
        ii. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume no greater than 125 cc)
        iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha adrenergic blockers, PDE5 Inhibitor, finasteride, dutasteride)
    c. Prostate gland volume is estimated to be ≥30 to ≤ 100 cc, by clinical or ultrasound assessment

3. No contraindications including **any** of the following

    a. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL
    b. Active urinary tract infection
    c. History of bacterial prostatitis in the past three months

d. Prior prostate surgery
e. Neurogenic bladder
f. Active urethral stricture (i.e., the source of the current LUTS)

Not Medically Necessary

The Rezum System is considered not medically necessary when all of the criteria specified above are not met.

Medicaid

PacificSource Community Solutions (PCS) follows Guideline Note 145 of the OHP Prioritized List of Health Services for coverage of Prostatic Urethral Lift.

PacificSource Community Solutions (PCS) follows Guideline Note 173 of the OHP Prioritized List of Health Services and considers treatment Insufficient Evidence of Effectiveness for Rezum System – Transurethral Water Vapor Therapy.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

PacificSource Medicare follows Local Coverage Determination L37808 for Water Vapor Therapy for LUTS/BPH.

Experimental/Investigational/Unproven

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

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

0582T Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance

52441 Cystourethroscopy with transurethral resection or incision of ejaculatory ducts

52442 each additional permanent adjustable transprostatic implant.

53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

53899 Unlisted procedure code, male genital system

C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants

C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

References

American Urological Association (AUA). Guideline: Management of Benign Prostatic Hyperplasia. 2010, reaffirmed 2014; Accessed June 20, 2018. March 19, 2020 http://www.auanet.org>

American Urological Association (AUA). Guideline. Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms (2018, amended 2019). Available at: https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline

Centers for Medicare and Medicaid Services. Water Vapor Thermal Therapy for LUTS/BPH. Local Coverage Determination (LCD) (L37808), 12/01/2019 https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37808&ver=17&Date=&DocID=L37808&bc=hAAAAAgAAAAA&

Das AK et al Office-based therapies for benign prostatic hyperplasia: a review and update. August:26 (Suppl 1):2-7 https://www.ncbi.nlm.nih.gov/pubmed/31481142

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. Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study. J Endourol 2019 Jul; 33(7): 576-584. PMID: 31115257.

Foster HE et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Amendment 2019. J Urol 2019; 202(3):592-598. https://pubmed.ncbi.nlm.nih.gov/31059668/

Hayes Technology Brief. Rezūm System (NxThera Inc.) for Benign Prostatic Hyperplasia. Winifred S. Hayes Inc. March 26, 2019, Annual review March 12, 2020

Hayes Health Technology Brief: UroLift System (NeoTract Inc.) for treatment of Benign Prostatic Hyperplasia. Winifred S. Hayes, Inc. November 9, 2018.

Hayes News- Government: FDA Clears Urolift System for Use in Expanded Patient Population. Winifred S. Hayes, Inc. February 21, 2018.

Jiwrajaka M et al. Drugs for benign prostatic hypertrophy. Australian Prescriber. 2018nOct:41(5): 50-153 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6202296/

McVary KT, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. J Sex Med. Jan 2014; 11(1):279-287. Accessed June 20, 2018, May 7, 2019, March 19, 2020 http://www.jsm.jsexmed.org/article/S1743-6095(15)30540-3/pdf.

McVary K et al. Water Vapor Thermal Therapy to Alleviate Catheter-Dependent Urinary Retention Secondary to Benign Prostatic Hyperplasia. 2020 Jun;(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

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

Nickel, JC et al. 2010 Update: Guidelines for the Management of Benign Prostatic Hyperplasia Can Urol Assoc J. 2010 Oct; 4(5): 310–316. Accessed June 20, 2018, May 7, 2019, March 19, 2020
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2950766/

O'Leary M P. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. Rev Urol. Winter 2005; 7(1):1-10. Accessed June 20, 2018, April 25, 2019, March 19, 2020 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1477553/

Prostatic Urethral Lift. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual, December 2015 Surgery 710.023 Accessed March 19, 2020
https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/prostatic_urethral_lift.pdf

Roehrborn CG, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. J Urol. Definitions Dec 2013; 190(6):2161-2167. Accessed June 20, 2018, April 25, 2019, March 19, 2020
https://www.ncbi.nlm.nih.gov/pubmed/23764081

Roehrborn CG, Rukstalis DB, Barkin J, et.al. Three year results of the prostatic urethral L.I.F.T. study. Can J Urol. Jun 2015; 22(3):7772-7782. Accessed June 20, 2018, May 7, 2019, March 19, 2020
http://www.canjurol.com/html/free-articles/V22I3_05_FREE_DrRoehrborn.pdf

Steele, GS et al. Combination of symptom score, flow rate and prostate volume for predicting bladder outflow obstruction in men with lower urinary tract symptoms. J Urol. 2000 Aug;164(2):344-8. Accessed June 20, 2018, May 7, 2019, March 19, 2020
https://www.ncbi.nlm.nih.gov/pubmed/10893581

Trumbeckas, D et al. Importance of prostate volume and urinary flow rate in prediction of bladder outlet obstruction in men with symptomatic benign prostatic hyperplasia. Cent European J Urol. 2011; 64(2): 75–79. Accessed June 20, 2018, May 7, 2019, March 19, 2020
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3921710/

UpToDate. Surgical treatment of benign prostatic hyperplasia (BPH). Wolters Kluwer, July 9, 2020
https://www.uptodate.com/contents/surgical-treatment-of-benign-prostatic-hyperplasia-bph?topicRef=6889&source=see_link

Westwood J et al. Rezum: a new transurethral water vapor therapy for benign prostatic hyperplasia Sage journals August 12, 2018.
https://journals.sagepub.com/doi/full/10.1177/1756287218793084

What Medicines Treat BPH. WebMD LLC 2020
https://www.webmd.com/men/prostate-enlargement-bph/enlarged-prostate-types-medication-that-work#2

Appendix

Policy Number: [Policy Number]

Effective: 12/31/2020 **Next review:** 3/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): [Applicable Regulations(s)]

Commercial Ops: 6/2021

Gov't Ops: 6/2021