

Subject: Water Vapor Thermal Therapy for LUTS/BPH (REZum® System)**Medical Policy #: 52.0****Original Effective Date: 11-17-2021****Status: Reviewed****Last Review Date: 12-13-2023**

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Water vapor thermal therapy:

The REZum® System water vapor thermal therapy received FDA 510(k) clearance in 2015 to treat lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH) in men ≥ 50 years old with a prostate volume 30-80cc. The use of REZum® System is to relieve lower urinary tract symptoms (LUTS) secondary to (BPH). This procedure involves the transurethral injection of steam into the prostate. Once injected, the steam condenses to water, imparting convective water vapor energy to ablate prostatic tissue causing cell death and damage. The technology uses radiofrequency (RF) to boil the water to create the steam that is injected but does not impart radiofrequency directly to the prostate tissue.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

Coverage Indications, Limitations, and/or Medical Necessity:

Water Vapor Thermal Therapy for LUTS/BPH for **Medicare, Medicaid and Commercial**.

For use of water vapor thermal therapy for the treatment of lower urinary tract symptoms attributable to benign prostatic hyperplasia (LUTS/BPH).

ONE treatment for LUTS/BPH treatment is covered **ONCE** in patients with **BOTH** the following:

1. Indications including **ALL** of the following:
 - a. Age ≥ 50
 - b. Symptomatic despite maximal medical management including **ALL** of the following:
 - International Prostate Symptom Score (IPSS) ≥ 13
 - Maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)
 - Failure, contraindication or intolerance to at least (3) months of conventional medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
 - c. Prostate volume of 30-80 cc,
 - d. Poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.), or at high risk of bleeding
2. No contraindications including **ALL** 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)

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT code	Code Description
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

ICD-10 Codes	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD

Medical Director: Ana Maria Rael MD

Date Approved: 12/13/2023

References

1. CMS, National Government Services, Inc., (Retired) LCD Water Vapor Thermal Therapy for LUTS/BPH (L37808) Revision 6, Original effective date: 12/01/2018, Revision effective date: 02/15/2024R7. [Cited 03-27-2024]
2. CMS, National Government Services, Inc., (Retired) Billing and Coding: Water Vapor Thermal Therapy for LUTS/BPH (A56590), Original Effective Date: 12/01/2019, RevisionEffective Date: 02/15/2024, R3. [Cited 03-27-2024]
3. Novitas Solutions, Inc., Billing and Coding: REZūm® Procedure, (A55352), Original date: 03/16/2017, RETIRED last updated: 03-23-20237. [Cited 10/04/2023]
4. Hayes, Rezūm System (NxThera Inc.) For Benign Prostatic Hyperplasia, Health Technology Assessment, Oct 18, 2021, Annual review Dec 09, 2022, [Cited 10/04/2023]
5. Aetna, Benign Prostatic Hyperplasia, #0079, Next Review: 01/11/2024. [Cited 10/04/2023]
6. Cigna, Benign Prostatic Hyperplasia (BPH) Treatments, Coverage # 0159, Next review date 10/15/2023. [Cited 10/04/2023]

Publication History

- 11-17-2021 Original effective date. Rezūm system is intended for the treatment of lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH). This was reviewed by Technical Assessment Committee on 10-19-2021 and a motioned to develop MPM for all product line was agreed upon. Reviewed by PHP Medical Policy Committee on 10-29-2021. The policy will follow (out of jurisdiction) criteria, LCD (L37808) and related article LCA (A56590) for all product line. Code (53854) will require PA. The only diagnosis that will be considered medically necessary is ICD-10 code (N40.1), for all product line. According to Novitas Billing and Coding: REZūm® Procedure, the applicable CPT is 53854 and not 53852.
- 11-16-2022 Annual review. Reviewed by PHP Medical Policy Committee on 10-21-2022. Continue to follow the LCD (L37808) and related article (LCA A56590) for Medicare, Medicaid and Commercial. The coverage determination guideline language has been removed from policy and reformatted to only include LCD/LCA weblinks. Novitas only provides billing recommendation per LCA A55352. Continue PA requirement for 53854 and continue the configuration set to only pay for ICD-10 (N40.1) for all product line.
- 12-13-2023 Annual review. Reviewed by PHP Medical Policy Committee on 10/04/2023. Continue to follow the LCD (L37808) and related article (LCA A56590) for ALOB. Continue PA requirement for 53854 and continue the configuration set during CY 2021 to only pay for ICD-10 (N40.1) for all product line.
- 03-29-2024 Update policy to provide criteria after the LCD L37808 was retired on or after February 15, 2024. The criteria will remain the same.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: [Click here for Medical Policies](#)

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.