

Patient Appeal Guidance

Employer-Sponsored Health Plan



You are currently enrolled in an employer-sponsored health plan that considers a Boston Scientific procedure to be investigational. Patients have the right to appeal disagreements about benefits through the health plan's internal appeals process as determined by federal law (the Employee Retirement Income Security Act, or ERISA) that took effect January 1, 2003. Self-funded insurance plan denials are **NOT** eligible for state external review, and disputes must go through an internal appeals process or through the patient's employer.1

What are the next steps to appeal?

- Reguest a copy of your employer Summary Plan Description (SPD). ERISA Law states that employers must supply a copy of the SPD within thirty days of your request.
- 2. Request an appeal with both the Plan Administrator (insurance company) AND your Employer.
- 3. Contact the Human Resources Manager of your company to request a meeting or a conference call to discuss your Boston Scientific procedure and ask your employer to authorize this treatment, based on medical necessity.

What information should I provide my employer to appeal my denial?

You may use the enclosed letter of medical necessity template, when speaking with your employer to help detail and summarize your health history. It is also recommended to work closely with your physician to help provide rationale on why the Boston Scientific procedure is considered medically necessary.

1. https://www.kff.org/wp-content/uploads/2005/07/7350consumerguidev4_080805.pdf

Physician payment rates are 2021 Medicare national averages. Source: Centers for Medicare and Medicaid Services. CMS Physician Fee Schedule – November 2020 release, CMS-1734-F file. https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1734-f.

The 2021 National Average Medicare physician payment rates have been calculated using the latest updated 2021 conversion factor of \$34.89. Rates subject to change.

Hospital outpatient payment rates are 2021 Medicare OPPS Addendum B national averages. Source: Centers for Medicare and Medicaid Services. CMS OPPS – November 2020 release, CMS-1736-FC file. https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-andnotices/cms-1736-fc.
ASC payment rates are 2021 Medicare ASC Addendum AP national averages. ASC rates are from the 2021 Ambulatory Surgial Center Covered Procedures List. Source: Centers for Medicare and Medicaid Services. CMS-ASC – November 2020 release, CMS-1736-FC file. https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1736-fc.

National average (wage index greater than one and hospital submitted quality data and is a meaningful HER user) M-PORG rates calculated using the national adjusted full update standardized labor, non-labor, and capital amounts (\$6,427.41). Source: September 2020 Federal Register, CMS-1735-FR. FY 2021 rates.

ICD-10 MS-DRG definitions from the CMS ICD-10-CM/PCS MS-DRG v37.0 Definitions Manual. Source: https://www.cms.gov/icd10m/version37-fullcode-cms/P0001.html. Please note: this coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any

Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Sequestration Disclaimer
Rates referenced in these guides do not reflect Sequestration, automatic reductions in federal spending that will result in a 2% across-the-board reduction to ALL Medicare rates as of January 1, 2021.

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SAMPLE APPEAL LETTER [PHYSICIAN LETTERHEAD]

REZUM

[Insert Date]
[Insert Health Insurer Name]
[Insert Physician Name]
[Insert Patient First and Last Name]
[Insert Patient ID Number]
[Insert Street Address]
[Insert City, State Zip]

SUBECT: APPEAL LETTER ON BEHALF OF [PATIENT FIRST AND LAST NAME]

Dear Medical Director,

I am writing on behalf of [patient name] who suffers from benign prostatic hyperplasia (BPH). We recently received a [Insert pre-authorization/pre-determination/or claim denial] for treatment of his BPH by performing transurethral radiofrequency thermotherapy ablation of the prostate (Rezūm = CPT 53854).

As [patient name]'s treating physician, I am asking you to reconsider your decision based upon my clinical evaluation, [Include additional information about why this is the preferred procedure].

The Rezūm System is now the only in-office BPH therapy with proven prostate volume reduction and long-term durability out to 5 years. Also note, the professional society, American Urological Association (AUA) recommends Rezūm therapy in their treatment guidelines.

FDA Status and Treatment Description

The Rezūm System received FDA 510k clearance (K150786) as a Class II device as of August 27, 2015. The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for \geq 50 years of age with a prostate volume 30 cm3 \leq 80 cm3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

It is my professional preference to use this procedure for treatment of my patient's enlarged prostate tissue. This office-based and outpatient therapy can be conducted under local anesthesia. As my patients treating physician, this procedure is the best option to treat this patient's BPH. His past treatment includes BPH drug medications with little to no symptom relief.

I urge you to approve my medical decision to utilize this procedure and provide the most optimal clinical outcome for my patient and your policyholder. I am happy to discuss this request at your convenience.

Sincerely,

[NAME AND ADDRESS]

Proof sources:

- 1. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-year outcomes of the multicenter randomized sham-controlled trial of Rezūm water vapor thermal therapy for treatment of moderate-to-severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol.* 2021 Apr 19. Online ahead of print.
- 2. Parsons JK, Dahm P, Köhler TS, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline Amendment 2020. *J Urol.* 2020 Oct;204(4):799-804.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.