

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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SpaceOAR™ Hydrogel [CPT 55874] Sample Private Payer Denial-Appeal Letter

This template is designed to assist providers in appealing a denial for the implantation of a hydrogel perirectal spacer. Although this information is designed to assist with securing coverage for the insertion of a perirectal hydrogel spacer only, providers may utilize it in securing coverage for the patient's entire episode of care when combined with prostate radiation therapy treatment. **Physician to** indicate variable patient-specific information, or revise in any other way. Please insert the information pertinent to your patient and his individual condition. Also, physicians are encouraged to include their professional opinions and experience with this procedure. This template is not intended to replace any professional judgment; it is merely intended to assist with organizing and structuring the appeal for coverage request and make the case for medical necessity. Finally, it is recommended that one use his own internal letterhead as deemed appropriate by one's internal policies.

Date: XXXXXX
Contact: XXXXXX

Insurance Company: XXXXXX

Address: XXXXXX
Fax: XXXXXX

Patient Name: XXXXXX
Date of Birth: XX-XX-XXXX
Date of Service: XX-XX-XXXX
Policy ID number: XXXXXX
Claim Number: XXXXXXX
Principal Diagnosis: XXXXXX
Secondary Diagnosis: XXXXXX
Procedure/Service Date: XXXXXX

RE: Request for Appeal of Insertion of a Perirectal Biodegradable Spacer Procedure with SpaceOAR Hydrogel (CPT 55874)

Dear Medical Director,

I am writing on behalf of my patient (patient name), requesting reconsideration of the above referenced denial of SpaceOAR Hydrogel, the Transperineal placement of the biodegradable material used to help reduce damage to the rectum during radiation treatment for prostate cancer. The original denial for non-coverage states that this procedure has been deemed (Enter denial reason here, i.e., unproven, experimental/investigational; therefore, not medically necessary).

I respectfully disagree with this denial reason and continue to appeal at all levels to garner coverage and changes to your current, overall non-coverage policy. As the patient's treating physician in his continuum of care during prostate cancer treatment, I recommended this procedure as medically necessary to help prevent the rectal toxicity effects of radiation therapy dosage and delivery, which can include bleeding and poor bowel function. Mr. (*Patient Name*) was diagnosed with prostate cancer (ICD-10 Code, C61) as Stage (*Enter T1 or T2*), Gleason Score (*Enter Score*), and PSA (*Enter PSA*)

Information). He underwent (*Enter the patient's RT plan including # of treatments, course of time, and dosage*) radiotherapy. I am writing today to draw to your attention the impact of rectal radiation toxicity and your non-coverage policy concerning the use of SpaceOAR Hydrogel (CPT 55874) for men who suffer from prostate cancer.

Please see below the two recently published research manuscripts outlining the benefits of SpaceOAR treatment – **JAMA Network** and **Gold Journal** [Urology] – the most comprehensive published meta-analysis and systematic literature reviews, respectively. Moreover, a published peer reviewed article in 2019 showed cost-effectiveness of SpaceOAR treatment.

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767246

https://pubmed.ncbi.nlm.nih.gov/34029607/https://pubmed.ncbi.nlm.nih.gov/30342180/

Mariados et al paper, 2015 (page 975, paragraph 2), states that the 10% rate of mild transient adverse events is "perineal discomfort and others." Please note the previous sentence states, "Regarding the primary safety endpoint, the rates of grade 1 or greater rectal or procedure AEs in the first 6 months were 34.2% and 31.5% in the spacer and control groups (P=.7), respectively." This indicates that these mild adverse events were comparable between SpaceOAR and controls.

https://www.redjournal.org/action/showPdf?pii=S0360-3016%2815%2900430-7

SpaceOAR Hydrogel procedure is fully supported as a treatment modality by the professional society, American Urological Association and American Society for Radiation Oncology. and typically billed using an American Medical Association (AMA) Category I CPT® code, 55874. CPT code 55874 became effective January 1, 2018 and is reimbursed by Medicare and several national payors including; Aetna, Anthem, Cigna, United Healthcare, and numerous BlueCross plans. Also note, 100,000+ SpaceOAR procedures have been performed to date worldwide.

For this reason and the strong evidence presented, I strongly request that you render a favorable decision to provide coverage for this patient.

Thank you for your consideration. I look forward to hearing from you soon.

Sincerely,

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