

SpaceOAR™ Hydrogel Sample Private Payer Denial-Appeal Letter

Instructions: 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. **Areas in red** indicate variable patient-specific information. 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.

SpaceOAR™ Hydrogel Procedure Reimbursement Support

**We offer assistance and resources to providers in their efforts to obtain benefit coverage and payment.
Contact a SpaceOAR Hydrogel Reimbursement Manager.**

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, 2020.

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(Physician letter head will need to be used)

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: **XXXXXXXX**

Principal Diagnosis: **XXXXXX**

Secondary Diagnosis: **XXXXXX**

Implant: The SpaceOAR™ Hydrogel System

Procedure/Service: Transperineal Insertion of a Perirectal Hydrogel Spacer

CPT code: 55874 - Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

RE: Request for Appeal of Insertion of a Perirectal Biodegradable Spacer Procedure with SpaceOAR Hydrogel

Dear Medical Reviewer:

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, poor bowel and urinary function, and a decrease in sexual 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. The SpaceOAR procedure allows advanced radiotherapy protocols, without compromising the surrounding organ. Please refer to my clinical notes, including the rationale supporting my clinical judgement to best maintain the patient's bowel, urinary and sexual quality of life (QOL).

The SpaceOAR Hydrogel System was FDA-cleared in April 2015 and is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer. By acting as a spacer, the hydrogel pushes the rectum over 1 cm away from the prostate so rectal side effects may be significantly reduced. With SpaceOAR Hydrogel in place, I am able to enhance radiation treatment while preserving healthy tissue to help ensure that rectal, urinary and sexual quality of life may be maintained. The SpaceOAR Hydrogel System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

The results of the clinical studies have demonstrated the procedure's safety and effectiveness within the study populations. In a prospective, randomized, multi-center, patient-blinded, clinical trial, the results show a 73% reduction in

the radiation delivered to the rectum and a 75% decrease of late rectal toxicity (Grade 1) with a 99% technical procedural success rate.* [Mariados N, et al Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. Int J Radiat Oncol Biol Phys; Vol. 92, No. 5, pp. 971e977, 2015.](#) Over 69 published articles, published in numerous journals, support the general consensus that a biodegradable perirectal implant creates a small, but necessary space (1.3cm post-implant space) between the organs to provide a substantial impact to the patient.

Due to the clinical effectiveness and benefits of the SpaceOAR procedure, many physicians in the Radiation Oncology and Urology communities have adopted this technology and increased their utilization. To date, over 35,000 cases have been performed worldwide with over 20,000 cases performed in the U.S. It is being performed in over 300 centers, including 18 of the 20 U.S. leading cancer institutions (source: US News and World Report).

The National Comprehensive Cancer Network (NCCN) incorporated use of the perirectal spacer in its guidelines for prostate cancer treatment. Several third-party Health Technology Assessments (HTA) have been completed and support coverage for the procedure, including the ECRI Institute and The National Institute for Health and Care Excellence (NICE), a UK organization.

The American Medical Association (AMA) issued a CPT Category I Code, 55874, effective January 2018, based upon the strong clinical evidence, widespread adoption and continuous utilization in this patient subset. The AMA's recognition of these important and fundamental factors of this procedure further supports that the SpaceOAR Hydrogel procedure fits its criteria in determining a standard of care and medical necessary.

To date, **all 7 Medicare Administrative Contractors** (CGS, [First Coast Service Options](#), [NGS](#), Noridian [JE](#) & [JF](#), [Novitas](#), [Palmetto GBA](#), and WPS) consider 55874 a reimbursable service, based upon medical necessity.

Additionally, eight of the top ten commercial insurance plans (*AIS'S Directory of Health Plans: 2017*) have a published positive medical policy for SpaceOAR Hydrogel CPT code 55874 or removed 55874 from a non-covered list, based upon medical necessity: [Aetna](#) (Policy No. 0926) considers transperineally periprostatic placement of biodegradable material (SpaceOAR) medically necessary for reducing rectal toxicity in men undergoing radiotherapy for prostate cancer, **United Healthcare** has issued favorable coverage policies for both the [Commercial \(Page 82. of the Omnibus Codes Policy #2019T0535ZZ Original Effective Date February 1, 2019\)](#) and [Medicare Advantage Plans \(Policy Guideline #MPG375.01 Original Effective Date November 14, 2018\)](#), [Cigna](#) (Policy# 0504) SpaceOAR Hydrogel is considered necessary for men undergoing external beam radiation therapy (EBRT) for prostate cancer, [Tricare](#) removed 55874 from the Government No Pay List (Original Effective Date April 2018) enabling patient access to its beneficiaries and [Humana](#) (Under the IMRT Policy #HCS-0322-019 Effective April 23, 2019) members may be eligible under the Plan for the placement of a transperineally biodegradable spacer (eg, SpaceOAR Hydrogel) for individuals receiving external beam radiation therapy (EBRT) for prostate cancer in the absence of contraindications listed in the Coverage Limitations section.

This procedure should be carefully reviewed as improving the patient's quality of life that would be highly affected by the damaging effects of radiation treatment to the rectum, but also an essential treatment for prostate cancer. For this reason and the strong evidence presented, I strongly request that you render a favorable decision to provide coverage for this patient.

Sincerely,

[Physician Name]
[Address]
[Phone]
[Email]