**Instructions:** This template is designed to assist providers with a statement of medical necessity for the implantation of a hydrogel perirectal spacer. Although this information is designed to assist with substantiating medical necessity 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 the structure of a 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® System Reimbursement Support**

**Augmenix offers assistance and resources to providers in their efforts to obtain benefit coverage and payment.**

**Contact a SpaceOAR Reimbursement Specialist at:**

**(781) 902-1657 or reimbursement@augmenix.com**

**Disclaimer:** This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Augmenix, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned a HCPCS code and payment rate does not imply coverage by the Centers for Medicare and Medicaid Services (CMS) Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Therefore, the information may not be current or comprehensive when you review. We strongly recommend you consult the payer organization for its reimbursement policies.

ML118

**Date: *XXXXXX***

**Contact: *XXXXXX***

**Insurance Company*: XXXXXX***

**Address: *XXXXXX***

**Fax: *XXXXXX***

**Patient: *XXXXXX***

**Date of Birth: XXXXXX**

**Subscriber: *XXXXXX***

**Policy ID number: *XXXXXX***

**Group Number: *XXXXXX***

**Date of Service: *XXXXXX***

**Claim Number: *XXXXXX***

**Procedure/Service:** **Insertion of a Perirectal Hydrogel Spacer**

**Implant: The SpaceOAR System**

**CPT code(s): 0438T - Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance**

**Dear Dr. *[Medical Director’s name]*:**

I am writing on behalf of my patient, ***(Name of patient)***, to request that ***(Name of health insurance company)***approve coverage and appropriate payment associated with **(radiotherapy type)** treatment for the treatment of ***(Patient’s condition – i.e., prostate cancer)****.* The patient will be treated with the SpaceOAR System prior to ***(radiotherapy type)****.* A reduction in rectal toxicity and tissue damage is expected to result in fewer complications, and improve my patient’s quality of life. This SpaceOAR System procedure has been proven safe and effective by the FDA, with no unanticipated or major adverse events cited during a robust clinical trial.

During a course of radiation therapy treatment, organs at risk (OAR) such as bowel and bladder are often damaged because of their proximity to the target volume being irradiated. For this reason, I have determined that ***(type)*** treatment planning, ***(radiotherapy type)*** treatment and use of the SpaceOAR System is the most medically appropriate and necessary method of care. The combination of these techniques allows an increase in the prescribed dose to the prostate gland while decreasing dose to the OAR.

SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer. In creating this space, it is the intent of the SpaceOAR System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR 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. Below, this letter outlines ***(Insert patients name)****’s* medical history, prognosis, treatment rationale, and anticipated treatment outcome for improved quality of life.

Summary of Patient Conditions, and medical history:

(Note: Exercise your medical judgment and discretion when providing a diagnosis, type of radiotherapy and characterization of the patient’s medical condition with anticipated treatment benefits and outcome).

Based on the above facts, I am confident you will agree that the SpaceOAR System is appropriate as indicated and medically necessary for this patient’s specific condition. If you have any further questions, please feel free to call me at ***(Physician's telephone number)***to discuss.

To aid in your review, I have enclosed the patients’ medical record and additional supporting information: (e.g., Consultation Report, Treatment Plan, Operative Report, Test Results, Summary of Relevant Clinical Literature, etc.)

***Medicare Patient supporting comment – please exclude the paragraph below (and this sentence) if this does not apply:***

***{****I attempted to comply with the Medicare Program Integrity Manual specific to section 13.5.1 – Reasonable and Necessary Provisions (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13). Where Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is: Safe and effective; not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient's medical need; and at least as beneficial as an existing and available medically appropriate alternative.****}***

Thank you in advance for your immediate attention to this request. I look forward to your timely reply.

***[Physician Name]***

***[Practice Name]***

***[Address]***

***[Phone]***

***[Email]***

***[Attachments if provided:]***