**Instructions:** This template is designed to assist providers in securing coverage 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 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.

ML119

**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***

**Principal Diagnosis: *XXXXXX***

**Secondary Diagnosis: *XXXXXX***

**Implant: The SpaceOAR System**

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

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

**RE: Request for coverage for insertion of a perirectal spacer procedure with the SpaceOAR System**

To Whom It May Concern:

I am contacting you on behalf of my patient ***(patient name),*** to establish medical necessity and gain pre-authorization (as advised through the benefit verification process) for the insertion of a perirectal hydrogel spacer before the scheduled prostate radiation therapy treatment regimen to treat the patients localized prostate cancer. The purpose of placing this perirectal spacer is to temporarily position the anterior rectal wall away from the prostate during the course of the patient’s radiotherapy, thus reducing the radiation dose delivered to the anterior rectum. Such patients are at risk for developing rectal toxicity due to radiotherapy especially those with risk factors such as: comorbidities, medication, age, heritage, smoking, and body habitus. ***These factors have been shown to increase the risk of rectal toxicity, in patients who are at risk of developing long term rectal side effects.***

***(Patient name)*** has been under my care for the past ***(# months or years).***  He was diagnosed with *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (this is the opportunity to discuss your patient’s specific diagnosis with the payer including staging, location, past treatments, etc. It is also imperative to include any other comorbidities that may impact their outcomes and quality of life (QOL) from their upcoming radiation treatment).*

I have discussed the placement of a perirectal hydrogel spacer with my patient and we have decided together that the best option for him at this time based on his specific health condition and to maximize his treatment outcomes is to insert a spacer prior to his radiation therapy.

Adenocarcinoma of the prostate is one of the most common cancers in the U.S. and the second leading cause of cancer death. ***(Insert Radiation Therapy Type)***therapy has been proven to be an effective treatment for this disease and is continually advancing. The success of radiation therapy in the treatment of localized prostate cancer is dependent on several factors including the radiation dose to the tumor and the avoidance of radiation to nearby healthy structures, in particular the rectum. While higher doses of radiation have been shown to improve biochemical disease-free survival, they are also associated with increased risk of rectal toxicity (radiation proctitis). While state of the art radiation therapy techniques have reduced the amount of radiation delivered to the gastrointestinal (GI) tract, rectal toxicity is still significant.

There are well-established clinical advantages and quality of life preservation that perirectal spacers provide. These benefits include a reduction in rectal pain throughout the course of radiotherapy, lower rates of long-term rectal toxicity, and fewer patients experiencing declines in bowel quality of life (QOL).

Creating a space between the prostate and the rectal wall is not a new procedure. Since 2007, physicians have injected a variety of materials with various techniques to create this space including blood patches, hyaluronic acid, and collagen injections. In addition, there have been over eight-thousand SpaceOAR system procedures performed worldwide, with over four-thousand performed within the United States.

It is important to note that the spacer material remains intact during the course of radiation therapy (approximately 3 months), after which it liquefies and is naturally absorbed and cleared in the patient’s urine within 6 months. The SpaceOAR System hydrogel is composed of water and polyethlyne glycol (PEG) a compound used widely in pharmaceuticals and cosmetics due to its high level of biocompatibility, lack of toxicity, and long term safety profile.

The SpaceOAR System procedure can safely be performed in a variety of clinical settings as noted in the attached Summary of Relevant Clinical Literature. I will be performing this procedure in the ***(setting of care).***

An overview of the procedure is as follows:

* Patient is positioned in the dorsal lithotomy position and the perineal skin is prepped with alcohol / povidone-iodine per the standard practice. Sterile drapes are then placed on the patient’s legs, genitals, ultrasound probe and the stepper.
* Patient is anesthetized ***(via what method).***
* Once the patient is anesthetized, implantation of the SpaceOAR System begins. A transrectal ultrasound probe (TRUS) is inserted into the rectum and the space between the prostate (mid gland) and rectum is measured.
* Under TRUS guidance, a saline syringe needle (15 cm 18G needle) is inserted through the perineal skin, rectourethralis muscle and past the prostate apex to the perirectal fat between Denonvilliers’ fascia at prostate mid-gland and the rectal wall.
* The needle position is confirmed in both sagittal and axial ultrasound fields, and saline is injected to dissect the space between the Denonvilliers’ fascia and anterior rectal wall (“hydrodissection”). Hydrodissection under ultrasound guidance confirms proper needle location and creates space for hydrogel injection.
* With the needle tip at mid gland, the axial field is viewed to confirm the needle is not in the rectal wall and is centered. Confirmation of proper placement in the perirectal fat is required.
* While maintaining the desired position, aspiration is performed to ensure that the needle is not in an intravascular space. The saline syringe is then removed and the SpaceOAR System syringe assembly is then attached to the same 18G needle.
* Under ultrasound guidance (sagittal plane), a smooth, continuous injection technique is used to dispense the hydrogel implant into the space between the prostate and rectum. The entire syringe contents (10 mL total) are injected without stopping, resulting in expansion of the peri-prostatic space with the liquid precursors that solidify within 10 seconds. Optimal visualization of the needle during hydrogel administration is maintained at all times.
* Following injection, the needle is removed, and the spent applicator and needle are discarded.
* An axial measurement of the space between the prostate (mid-gland) and rectum immediately post- injection is noted. The TRUS probe is removed from the patient, the stirrups are lowered, and patient is wheeled from the room for recovery.

It is important to note that the implantation of a perirectal spacer is a complete, standalone procedure. It is a separate and distinct procedure unrelated to any other preparatory radiation therapy procedure. The total anticipated time of this procedure is expected to be ***(XXX)*** minutes.

Overview of Clinical Results

The available clinical literature describes various methods clinicians have used to create a perirectal space with a biodegradable material to protect the rectum from complications associated with radiation therapy of the prostate. As a physician, I want to ensure that my patients are provided the best clinical outcomes with the fewest risk factors. Based on published clinical outcomes data from a rigorous pivotal trial, the SpaceOAR system provides me with this option for my patients.

Several studies have been published on clinical outcomes of perirectal spacer applications. The most robust of these studies was conducted to assess the SpaceOAR System safety and effectiveness. This study was a prospective, randomized, controlled, patient-blinded clinical study in 20 U.S. centers on 222 men with low and intermediate risk prostate cancer. In a landmark multi-institutional prospective randomized trial, prostate cancer patients being treated with Intensity Modulated Radiation Therapy (IMRT) with daily Image Guidance (IG) were randomized to either receive SpaceOAR or to be treated without SpaceOAR. The trial demonstrated that there was a 73% reduction in meaningful dose to the rectum in the SpaceOAR patients. On long-term follow-up, the perirectal hydrogel spacer patients had a 71% reduction in late rectal toxicity severity when compared to the control patients. The FDA cleared the use of the perirectal hydrogel spacer in patients being treated with radiation therapy for prostate cancer based on this data.

Most recently, 3-year results from the SpaceOAR System Prostate Cancer US Pivotal Clinical Trial were presented by Daniel Hamstra, MD, PhD, at the 2016 American Society for Radiation Oncology Annual Meeting in Boston, MA as a Late Breaking Abstract, an honor reserved for highly significant and timely findings in clinical oncology, radiobiology or medical physics. Entitled “Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial”, the study results demonstrated significantly lower rectal toxicity and higher patient bowel quality of life (QOL) scores when the SpaceOAR System was applied prior to radiotherapy as compared to the trial Control patients. The prospective, randomized, multi-center, patient-blinded clinical trial evaluated long-term rectal and urinary toxicity and impact on QOL between prostate radiotherapy patients treated either with SpaceOAR hydrogel or with no hydrogel (Controls).

Following radiotherapy through 3 years, no SpaceOAR patients (0%) experienced grade 2 or worse late rectal toxicity, compared to 5.7% in the Control patients (p=0.012). Additionally, from 6 months onward, bowel QOL consistently favored the spacer group (p=0.002), with the difference at 3 years (5.8 points; p<0.05) meeting the threshold for an MID (minimally important difference). At 3 years, more men in the control group than in the spacer group had experienced a MID decline in bowel QOL (41% vs 14%; p=0.002). The control group was also more likely to have experienced large declines (twice the MID) in bowel QOL (21% vs 5%; p=0.02). Unexpectedly, the SpaceOAR patients also showed benefits in urinary complications and QOL, relative to Controls. In the three years after radiotherapy, grade 1 urinary incontinence was experienced in 15% and 4% of the Control and SpaceOAR patients, respectively (p=0.046). Additionally, like bowel QOL at 3 years, more men in the control group than in the spacer group had experienced a MID decline in urinary QOL (30% vs 17%; p=0.04). The control group was also more likely to have experienced large declines (twice the MID) in urinary QOL (23% vs 8%; p=0.02). The data has since been published and can be found online (in press) in the red journal (International Journal of Radiation Oncology\*Biology\*Physics): <http://www.redjournal.org/article/S0360-3016(16)33598-2/pdf>

***NOTE: If fiducial markers are being inserted during the same episode of care it is important to discuss in this document because the payer may be confused about the reporting of the two procedures and think they are the same and not pay for each. The following may be advised:***

**{***I will also be placing fiducial markers in the prostate gland during the same episode of care. These two procedures are very distinct from one another. Although they may be performed at the same time, they are not integral to each other and have different levels of complexity and resource utilization. The anticipated codes/modifiers to be used are as follows: (insert codes, modifiers, and descriptions***}**

Presently, there is no specific HCPCS implant code that exists for physicians to report for the perirectal hydrogel spacer “SpaceOAR System”. The Centers for Medicare and Medicaid Services (CMS) National Level II HPCS Coding Program recognizes the SpaceOAR perirectal spacer system as an integral part of a procedure and payment for services that include SpaceOAR if it is used. Therefore, a HCPCS code is not required with CPT 0438T. We recommend to include the cost of the implant within 0438T for the placement of SpaceOAR System. The authorization request should include the following:

* 0438T Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance
* ***NOTE: If placing fiducials include those codes as well – please list all with descriptions individually***

The SpaceOAR System procedure has a zero-day global, similar to that the placement of prostate fiducial markers prior to radiation therapy. It requires no post procedure office visits or follow up care.

My charges for this procedure are the following:

**0438T $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**XXXXX $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**XXXXX $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I will be happy to provide a copy of the manufacturer’s invoice for the SpaceOAR System if requested.

I understand the challenges with adjudicating claims for new technologies, I am happy to discuss other options for reporting this procedure if you so desire. Please contact me and I can arrange a meeting with my staff to create a streamlined process for claims adjudication.

In summary, please accept this request to establish coverage based on medical necessity for the insertion of the SpaceOAR System for my patient. A reduction in rectal toxicity and tissue damage is expected to result in fewer complications, and improve my patients’ quality of life with cancer. This SpaceOAR System procedure has been proven safe and effective from the FDA, with no unanticipated or major adverse events cited during a robust clinical trial.

Additionally, to accommodate the value of services and direct costs associated, please establish an efficient mechanism for procedure evaluation to aid timely claims adjudication and payment. A proper resource for guidance and compliance would be greatly appreciated.

I welcome the opportunity to further discuss any of the information contained within this request via phone or meeting. Thank you in advance for your consideration. I look forward to your timely reply.

Sincerely,

***[Physician Name]***

***[Practice Name]***

***[Address]***

***[Phone]***

***[Email]***

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