# Sample Letter to Appeal Denial SpaceOAR® System

Instructions: This template is designed to assist providers in appealing a denial of the implantation of a hydrogel perirectal spacer. Although this information is designed to assist with appealing 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, 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

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ML121

Date: *XXXXXX*

Attention: Appeals Department Insurance Company*: XXXXXX* Address: *XXXXXX*

Fax: *XXXXXX*

Patient: *XXXXXX*

Date of Birth: 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

RE: Request for Coverage for insertion of the perirectal hydrogel spacer in the Prostate Cancer patient

Dear Medical Reviewer:

Please accept this letter as a request (on behalf of my patient) to appeal the decision made by *(name of health insurance company)* to deny payment for services rendered *(or services requested if appealing a preauthorization denial)* to *(patient name)* on *(date of service)*. The reason for the claim *(or preauthorization request)* denial *(enter claim #)* is *(enter remark code and description)*. We respectfully disagree with this denial decision as services rendered are in fact medically necessary.

*(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 QOL)*

On behalf of my patient suffering from prostate cancer and requiring radiotherapy, we would ask that *(Name of health insurance company)* approve the procedure of the rectal spacer gel placement, and for the rectal gel material themselves. We believe that this healthcare procedure

(and implant) is currently needed to treat an illness/disease (prostate cancer) and prevent injury (rectal toxicity and its long and short-term consequences and symptoms), and that this technology meets accepted standards of medicine. It is our belief that this technology improves health outcomes such as length of life, improved quality of life and functional ability.

Additionally, this procedure/implant has received final clearance (FDA April, 2015), it has demonstrated scientific evidence that permits conclusions concerning the effect of the technology on health outcomes, it improves the net health outcome (in this subset of patients), it is as beneficial as any established alternatives for this disease state and treatment and finally; it has attained improvement outside of investigational settings.

In April 2015, the FDA cleared the first system specifically intended for use as a perirectal hydrogel spacer. The purpose of placing a perirectal hydrogel 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 patients risk for developing long term rectal side effects. 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, improved activities of daily living and fewer patients experiencing declines in bowel quality of life (QOL).

Adenocarcinoma of the prostate is one of the most common cancers in the U.S. and the second leading cause of cancer death. Radiation 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.i,ii,iii,iv 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). Even though state of the art radiation therapy techniques have reduced the amount of radiation delivered to the gastrointestinal (GI) tract, rectal toxicity is still significant. Symptoms of radiation proctitis may begin as early as several months after therapy but, at times, not until several years later. These symptoms include diarrhea, rectal bleeding, and painful defecation. Side effects often require patients to wear pads or diapers, and significantly diminish patient quality of life. More serious symptoms include intestinal blockage and connections (fistulae) between the colon and other parts of the body, including the skin or urinary systems. These symptoms may require surgery and hospitalization. Moreover, the clinical adoption of dose escalation and hypo-fractionated treatment regimens being used with increasing frequency pose an even greater risk of GI toxicity. Additionally, the rectal spacer gel placement procedure can be safely performed in a variety of clinical settings as noted in the summary of relevant clinical literature provided.

The available clinical literature describes various methods which 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. Physicians with whom we have spoken want to ensure that their patients are provided the best clinical outcomes with the fewest risk factors. Based on published clinical outcomes data from a rigorous pivotal trial, the perirectal hydrogel spacer provides them with this option for their patients.

Several studies have been published on clinical outcomes of perirectal spacer applications. The most robust of these studies was conducted to assess the perirectal hydrogel spacer 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 the perirectal hydrogel spacer or to be treated without the perirectal hydrogel spacer. The trial demonstrated that there was a 73% reduction in meaningful dose to the rectum in the perirectal hydrogel spacer. 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.

There are over 45 peer reviewed publications in the current medical literature, which provide evidence for the safety and effectiveness of this procedure. Most recently, 3-year results from the Perirectal Hydrogel Spacer 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 perirectal hydrogel spacer was applied prior to radiotherapy as compared to the trial control patients. The prospective, randomized, multi-center, patient-blinded clinical trial evaluated rectal and urinary toxicity and impact on QOL between prostate radiotherapy patients treated either with the perirectal hydrogel spacer or with no hydrogel (controls). Previously published initial study results demonstrated spacer safety, and a significant 73% reduction in the volume of rectum receiving 70 Gray radiation in the perirectal hydrogel spacer treated subjects. 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](http://www.redjournal.org/article/S0360-3016%2816%2933598-2/pdf)-2/pdf

Long-Term Data

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).

Utilization Review

Per the Utilization Review Accreditation Commission (URAC); accreditation standards require that an accredited Independent Review Organization (IRO) clinical reviewer have an active clinical license, be board certified, and that the reviewer is a clinical peer of the attending provider; such so that the issue under review is within the reviewer’s scope of licensure. Standards also require that the reviewer have at least five years of clinical experience, the ability to evaluate alternative treatments to the one proposed, and finally, that the reviewer is to be free from conflict of interest. I am requesting, that the same or similar standard be applied in this case.

The Procedure: Pre-Service

Prior to the procedure, the patient typically receives antibiotics prophylactically, and immediately before the procedure receives an enema bowel prep. In the surgical suite, the 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. The patient is then anesthetized per physician and/or anesthesiologist discretion. Appropriate anesthesia for this procedure include bilateral pudendal nerve block, monitored anesthesia care (MAC) or general anesthesia. If MAC or general anesthesia is used an anesthesiologist will be present throughout the procedure. Once the patient is anesthetized, implantation of SpaceOAR begins.

The first component to be prepared is a saline filled sterile 10cc syringe, which is attached to an 18G 15cm needle and primed (Figure 2, left). This syringe/needle assembly will be used to access and hydro-dissect the peri-prostatic implant site. Next, the SpaceOAR hydrogel implant is prepared as described in the manufacturer’s instructions for use (enclosed). First, the SpaceOAR syringe assembly is prepared by injecting the SpaceOAR diluent into the powder vial, shaking until the powder is completely dissolved, setting aside to allow bubbles to dissipate, and then withdrawing 5 mL of this precursor solution back into the syringe. This syringe and the accelerator syringe are measured to contain the same amount of fluid and air before being assembled to the y-connector, syringe holder, and syringe plunger cap (Figure 2, right). This syringe assembly is for injecting the in-situ curing hydrogel, as described below.

Figure 2: Saline syringe and needle used for hydrodissection (left), with the SpaceOAR System syringe assembly (right).

Intra-Service

Equipment required for SpaceOAR hydrogel implantation includes a dorsal lithotomy table with stirrups, a side-fire transrectal ultrasound (TRUS) probe, ultrasound machine, and stepper/stabilizer to maintain proper TRUS probe positioning. Use of a TRUS probe stand-off balloon is recommended to improve visibility of the perirectal space. Prior to needle insertion, the physician (urologist or radiation oncologist) prepares the TRUS probe, balloon and stepper for TRUS imaging.

The TRUS probe is inserted into the rectum and the space between the prostate (mid gland) and rectum is measured. Under TRUS guidance, the 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. Fiducial markers may be implanted in the prostate gland during the same episode of care. These two procedures are very distinct. 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. An OR technician (nurse) and ultrasound technician are assisting the physician throughout the procedure.

Post-Service

In a recovery room, the patient is observed by a nurse post-procedure to ensure there is no onset of any complications.

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 complication’s 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.

In summary, please accept this request to establish medical necessity in this case, and approve payment for the insertion of a perirectal spacer for my patient. A reduction in rectal toxicity and tissue damage will result in fewer complications, and an improved quality of life living with his cancer.

*Please Indicate what you are enclosing for the appeals department to review.*

To aid in your review, I have enclosed the following medical records that indicate medical necessity: (e.g., *Instructions for Use, Consultation Report, Treatment Plan, Operative Report, Test Results, Summary of Relevant Clinical Literature, etc.)*

If you have any questions or require additional information, please feel free to call me at *(physician’s telephone number)*. Thank you in advance for your immediate attention to this request.

*[Physician Name] [Practice Name] [Address] [Phone]*

*[Email]*

*[Attachments if provided:]*

i Hanks GE, Hanlon AL, Schultheiss TE, et al. Dose escalation with 3D conformal treatment: Five year outcomes, treatment optimization, and future directions. Int J Radiat Oncol Biol Phys 1998;41: 501e510.

ii Jani AB, Su A, Correa D, et al. Comparison of late gastrointestinal and genitourinary toxicity of prostate cancer patients undergoing intensity-modulated versus conventional radiotherapy using localized fields. Prostate Cancer Prostatic Dis 2007;10:82e86.

iii Zelefsky MJ, Cowen D, Fuks Z, et al. Long term tolerance of high dose three-dimensional conformal radiotherapy in patients with localized prostate carcinoma. Cancer 1999;85:2460e2468.

iv Zelefsky MJ, Fuks Z, Happersett L, et al. Clinical experience with intensity modulated radiation therapy (IMRT) in prostate cancer. Radiother Oncol 2000;55:241e249.