Medical Coverage Policy | Hydrogel Spacer Use During Radiotherapy for Prostate Cancer

EFFECTIVE DATE: 05|01|2019
POLICY LAST UPDATED: 02|06|2020

OVERVIEW
For low or intermediate risk prostate cancer, radiation therapy is an option. Because the rectum lies in close proximity to the prostate, the risk of rectal toxicity is high. One approach is to push the rectum away from the prostate, increasing the space between the two and reducing the radiation dose to the rectum. A variety of biomaterials, including polyethylene glycol hydrogels (eg, SpaceOAR System) have been evaluated as perirectal spacers

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Polyethylene-glycol (PEG) hydrogel is covered in patients with clinically localized prostate cancer

Commercial Products
Hydrogel spacer use during radiotherapy for prostate cancer or for any other indication is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery or not medically necessary benefits/coverage.

BACKGROUND
DIAGNOSIS
Prostate cancer is a complex, heterogeneous disease, ranging from microscopic tumors unlikely to be life-threatening to aggressive tumors that can metastasize, leading to morbidity or death. It is the second most common cancer in men, with over one in ten men diagnosed with prostate cancer over their lifetime. Cancer is typically suspected due to increased levels of prostate-specific antigen upon screening. A digital rectal exam may detect nodules, induration, or asymmetry, and followed by an ultrasound-guided biopsy with evaluation of the number and grade of positive biopsy cores.

Clinical staging is based on the digital rectal exam and biopsy results. T1 lesions are not palpable while T2 lesions are palpable but appear to be confined to the prostate. T3 lesions extend through the prostatic capsule, and T4 lesions are fixed to or invade adjacent structures. The most widely used grading scheme for a prostate biopsy is the Gleason system. It is an architectural grading system ranging from 1 (well differentiated) to 5 (poorly differentiated); the score is the sum of the primary and secondary patterns. A Gleason score of 6 or less is low-grade prostate cancer that usually grows slowly; 7 is an intermediate grade; 8 to 10 is high-grade cancer that grows more quickly. A revised prostate cancer grading system has been

adopted by the National Cancer Institute and the World Health Organization. A cross-walk of these grading systems is shown below.

Grade Group	Gleason Score (Primary and Secondary Pattern)	Cells
1	6 or less	Well differentiated (low grade)
2	7 (3 + 4)	Moderately differentiated (moderate grade)
3	7 (4 + 3)	Poorly differentiated (high grade)
4	8	Undifferentiated (high grade)
5	9-10	Undifferentiated (high grade)

TREATMENT

Early localized disease can usually be treated with surgery and radiotherapy, although active surveillance may be adopted in men whose cancer is unlikely to cause major health problems during their lifespan or for whom the treatment might be dangerous. In patients with inoperable or metastatic disease, treatment consists of hormonal therapy and possibly chemotherapy. Treatment decisions are based on the anatomic extent of the lesion, the histologic grade from biopsy, and serum prostate-specific antigen level. Other factors in treatment decisions are expected outcomes, potential complications, along with medical condition, age, comorbidities, and personal preferences. For patients with clinically localized low-risk cancer (no palpable tumor and prostate-specific antigen of ten or less), active surveillance is an option. Definitive therapy with radical prostatectomy or radiation therapy (RT) with external beam and/or brachytherapy is also an option for low or intermediate risk disease. Dose escalation of RT improves cancer outcomes but also increases the risk of urinary or bowel toxicity. Image-guided RT and intensity-modulated RT may be used to limit margins and reduce toxicity but because the rectum lies in close proximity to the prostate, the risk of rectal toxicity remains high. Hypofractionation, dose escalation, and salvage RT protocols can be particularly prone to rectal toxicity.

PERIRECTAL SPACERS

One approach to the problem of rectal toxicity is to push the rectum away from the prostate, increasing the space between the two organs and reducing the radiation dose to the anterior rectal wall. A variety of biomaterials, including collagen, polyethylene glycol (PEG) hydrogels, and absorbable balloons have been evaluated as a means to reduce rectal radiation exposure. The SpaceOAR System is the first PEG hydrogel that was cleared by the U.S Food and Drug Administration specifically for use during RT of the prostate. The chemical composition of the SpaceOAR is similar to a PEG-based hydrogel that is Food and Drug Administration approved as a dural sealant. Hydrodissection is achieved with saline between the retroprostatic (Denonvilliers) fascia and the anterior rectal wall using a transperineal approach. Once the needle placement is confirmed, two solutions in a two-channel syringe are injected into the perirectal space. The hydrogel then polymerizes to form a soft mass. The hydrogel maintains the space for approximately 3 months, the duration of radiotherapy, and is completely absorbed by 12 months. The PEG hydrogel may be injected at the same time as the placement of fiducial markers in the prostate.

In October 2014, SpaceOAR® (Augmenix, a subsidiary of Boston Scientific) was cleared by the Food and Drug Administration through the De Novo process (DEN140030). "SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR System to reduce the radiation dose delivered to the anterior rectum."

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal randomized controlled trial with a three year follow-up.

The relevant outcomes include symptoms, quality of life, and treatment-related morbidity. The pivotal randomized controlled trial indicates the hydrogel spacer can reduce the radiation dose to the rectum with a statistically significant decrease in Grade 1 or greater late toxicity and a number needed to treat of 14.3. There were few events of greater than Grade 1 toxicity in either group. Patient-reported declines in rectal and urinary quality of life at three years were statistically lower in the spacer group and met the threshold for a clinically significant difference, although it is not clear if patients were blinded to treatment at the longer-term follow-up. The numbers needed to treat for late improvement in rectal and urinary quality of life were 6.3 to 6.7, respectively. Limitations to the study include the lack of blinding and the exclusion of patients who might be at greater risk of rectal toxicity. Additional study is needed to corroborate the findings of the pivotal randomized controlled trial, to identify the factors that increase the risk of rectal toxicity and determine who is likely to benefit from the use of a spacer. The evidence is insufficient to determine the effects of the technology on health outcomes.

BlueCHiP for Medicare
Summery of Evidence
Some of the literature endorses that the injection of the PEG spacer is usually safe and without untoward events once the physician becomes familiar with the procedure. Other references not cited here have described materials used to increase the distance between the prostate and rectum during radiation therapy for prostate cancer. Hyaluronic acid, human collagen, interstitial balloons, as well as synthetic polyethylene glycols have been used.

Reducing rectal radiation exposure during prostate cancer radiotherapy is desirable. The PEG spacer can be considered selectively when state-of-the-art localization techniques do not suffice to either improve oncologic cure rates or reduce side effects.

CODING
The following CPT code is covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:
55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

RELATED POLICIES
Not applicable

PUBLISHED
Provider Update, April 2020
Provider Update, May 2019

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