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

EFFECTIVE DATE: 05|01|2019
POLICY LAST UPDATED: 07|20|2022

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 2 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
Medicare Advantage Products
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 over1 in 10 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, which is then followed by an ultrasound-guided biopsy with an 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 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.

Hydrogel Perirectal Spacer

Early localized prostate cancer 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, other medical conditions, age, and comorbidities, and personal preferences. For patients with clinically localized low-risk cancer (no palpable tumor and prostate-specific antigen of 10 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 rectal 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 that reduces the number of treatments, dose-escalation, and salvage RT protocols can be particularly prone to rectal toxicity.
One approach to the problem of rectal toxicity is to push the rectum away from the prostate, increasing the space between the 2organs 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 (FDA) specifically for use during RT of the prostate.

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal RCT with a 3-year follow-up, observational studies, and systematic reviews of these studies. Relevant outcomes include symptoms, quality of life, and treatment-related morbidity. The

combined evidence indicates that the hydrogel spacer can reduce the radiation dose to the rectum with a statistically significant decrease in Grade 1 or greater late toxicity and an NNT of 14.3. There were few events of greater than Grade 1 toxicity in either group, and the NNT for a reduction in clinically significant Grade 2 toxicity has been reported as 68. Patient-reported declines in rectal and urinary quality of life at 3 years were statistically lower in the spacer group and met the threshold for a clinically significant difference, although patients were not blinded to treatment at the longer-term follow-up. The NNT for late improvement in rectal and urinary quality of life was 6.3 to6.7, respectively. Limitations to the study include the lack of blinding and the exclusion of patients who might be at greater risk of rectal toxicity. Evidence from observational studies is inconclusive but generally shows a decrease in radiation dose to the rectum with the insertion of a hydrogel spacer. However, the potential benefits of the hydrogel spacer must be balanced against the risks of an additional procedure. Additional study is needed to corroborate the findings of the pivotal RCT, to identify the factors that increase the risk of rectal toxicity, and to determine who is likely to benefit from the use of a spacer. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Medicare Advantage Products
Summary 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 Medicare Advantage Products 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, September 2022
Provider Update, March 2021
Provider Update, April 2020
Provider Update, May 2019

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