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

EFFECTIVE DATE: 01|01|2025
POLICY LAST REVIEWED: 09|18|2024

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

Medicare Advantage Plans and Commercial Products
Not applicable

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products
Not applicable

POLICY STATEMENT

Medicare Advantage Plans
Polyethylene-glycol (PEG) hydrogel is covered in patients with clinically localized prostate cancer.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by CMS.

Commercial Products
Effective 1/1/2025, Hydrogel Spacer Use During Radiotherapy for Prostate Cancer is covered for Commercial Products.

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.

The Gleason score is calculated by adding together the two grades of cancer cells that make up the largest areas of the biopsied tissue sample. The Gleason score usually ranges from 6 to 10. The lower the Gleason score, the more the cancer cells look like normal cells and are likely to grow and spread slowly.

In intermediate-risk prostate cancer the tumor is confined to the prostate with a prostate-specific antigen (PSA) between 10 and 20, and Gleason score of 7.

Low-risk prostate cancer may be defined by a Gleason score of 6 or less, PSA less than 10 mg/ml, and a tumor that is either non-palpable or only palpable in less than half of one lobe of the prostate.

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.

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

Medicare Advantage Plans and Commercial Products
The following CPT code is covered for Medicare Advantage Plans and Commercial Products:

55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2024
Provider Update, July 2023
Provider Update, September 2022
Provider Update, March 2021
Provider Update, April 2020

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