FEP 7.01.164 Hydrogel Spacer use During Radiotherapy for Prostate Cancer

Effective Date: July 1, 2019
Related Policies: None

Hydrogel Spacer use During Radiotherapy for Prostate Cancer

Description
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 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.

OBJECTIVE
The objective of this evidence review is to determine whether the use of a perirectal hydrogel spacer in patients with prostate cancer who are undergoing external beam radiation therapy improves the net health outcome.

POLICY STATEMENT
Hydrogel spacer use during radiotherapy for prostate cancer is considered investigational.
Use of a hydrogel spacer for any other indication is investigational.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS
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.”

**Rationale**

**Summary of Evidence**

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal RCT with a three year follow-up. The relevant outcomes include symptoms, QOL, and treatment-related morbidity. The pivotal RCT 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 an NNT of 14.3. There were few events of greater than Grade 1 toxicity in either group. Patient-reported declines in rectal and urinary QOL 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 NNTs for late improvement in rectal and urinary QOL 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 RCT, 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.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**National Comprehensive Cancer Network**

The National Comprehensive Cancer Network (V2:2018) provides the following recommendation in principles of radiation therapy, “Perirectal spacer materials may be employed when the previously mentioned techniques [highly conformal RT, photon or proton beam, brachytherapy boost] are insufficient to improve oncologic cure rates and/or reduce side effects due to anatomic geometry or other patient-related factors, such as medication usage and/or comorbid conditions. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation.”

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2017) published guidance on the biodegradable spacer. The National Institute for Health and Care Excellence concluded that “current evidence on the safety and efficacy of insertion of a biodegradable spacer to reduce rectal toxicity during radiotherapy for prostate cancer is adequate to support the use of this procedure.”

**American Society of Clinical Oncology, the American Urological Association, and the American Society for Radiation Oncology**

The American Society of Clinical Oncology, the American Urological Association, and the American Society for Radiation Oncology (2018) published a joint guideline on hypofractionated radiation therapy for localized prostate cancer. The guideline recommends that men be counseled about the small increased risk of acute gastrointestinal toxicity with hypofractionation. “Moderately fractionated EBRT has a similar risk of acute and late genitourinary and late GI toxicity compared with conventionally fractionated EBRT. However, physicians should discuss the limited follow-up beyond 5 years for most existing RCTs.
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[ranged controlled trials] evaluating moderate hypofractionation.” This was a strong recommendation based on high-quality evidence and 100% consensus.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


POLICY HISTORY

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