



Louisiana

Hydrogel Spacer use During Radiotherapy for Prostate Cancer

Policy # 00662

Original Effective Date: 07/01/2019

Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers hydrogel spacer use during radiotherapy for prostate cancer to be **not medically necessary**.**

Based on review of available data, the Company considers use of a hydrogel spacer for any other indication to be **not medically necessary**.**

Background/Overview

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 1 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, 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 are shown in Table 1.

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Table 1. Prostate Cancer Grading Systems

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)

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In October 2014, SpaceOAR^{®‡} (Augmenix, a subsidiary of Boston Scientific) was cleared by the FDA 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."

DuraSeal^{®‡} Exact (Integra) was approved by the FDA through the premarket approval process as a spine and cranial sealant (dura mater) and has been used off-label as a perirectal spacer.

Rationale/Source

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.

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

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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, or the number needed to treat 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 number 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. Evidence from observational studies is inconclusive, and 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 the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (V4:2019) 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."

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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 [randomized 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT01999660 ^a	Prospective National Post-marketing Surveillance for the Investigation of the Efficacy and Safety of SpaceOAR ^{TM‡} to Maintain Space Between the Rectum and Prostate During Radiation Therapy	250	Jan 2019 (status unknown last update posted Feb 2015)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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04/04/2019 Medical Policy Committee review

04/24/2019 Medical Policy Implementation Committee approval. New policy.

04/02/2020 Medical Policy Committee review

04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/01/2021 Medical Policy Committee review

04/14/2021 Medical Policy Implementation Committee approval. Coverage changed from investigational to not medically necessary.

Next Scheduled Review Date: 04/2022

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	55874
HCPCS	No codes
ICD-10 Diagnosis	C61

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical

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judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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