Hydrogel Spacer use During Radiotherapy for Prostate Cancer

Policy # 00662
Original Effective Date: 07/01/2019
Current Effective Date: 02/13/2023

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.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of an implanted hydrogel spacer between the prostate and rectum when primary definitive radiation therapy will be used to treat low risk or intermediate risk prostate cancer (See Policy Guidelines) using EITHER of the following techniques to be **eligible for coverage:****

Patient Selection Criteria
Coverage eligibility will be considered when either of the following criteria when met:

- Hypofractionated radiotherapy (28 fractions or fewer); or
- Stereotactic Body Radiation Therapy

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of an implanted hydrogel spacer for all other indications to be **not medically necessary.****

Policy Guidelines

Disease Definitions:

Low risk of recurrence (**ALL** must be present to qualify as low risk)

- Stage T1-T2a

- Gleason score of 6
- Prostate-specific antigen (PSA) below 10 ng/mL

Intermediate risk of recurrence (**ANY** one characteristic)

- Stage T2b to T2c
- Gleason score of 7
- PSA 10-20 ng/mL

High risk of recurrence (**ANY** one characteristic)

- Stage T3a
- Gleason score 8-10
- PSA greater than 20 ng/mL

Localized disease (**BOTH** must apply)

- T stage of T1-3a (tumor has spread through the capsule on one or both sides but has not invaded theseminal vesicles or other structures)
- N0 (no lymph node involvement)

Locally advanced disease (**EITHER** must apply)

- Any T status with N1 disease (either no spread to lymph nodes or there has been spread to the regional lymph nodes)
- T3b and above, no distant metastatic disease beyond local lymph nodes

Distant metastatic disease

- Beyond the local lymph nodes

Background/Overview

Radiation Oncology Considerations

Because the anterior wall of the rectum abuts the posterior prostate, radiotherapy for prostate cancer exposes that portion of the rectum to the full dose of radiation delivered to the prostate, which poses the risk of rectal bleeding for months to years after treatment. Modern radiation planning techniques,

such as intensity modulatedradiation therapy (IMRT), allow significantly higher doses of radiation to be safely delivered to the prostate while maintaining an acceptable risk of late rectal complications by limiting the portion of the rectum treated to full dose. In recent years, attempts to reduce rectal toxicity have focused on increasing the physical distance between the prostate and rectum by injection of a biodegradable hydrogel to push the rectum away from the high dose region to allow additional dose sparing.

The use of an implanted hydrogel spacer between the prostate and rectum has been studied as a way to minimize rectal symptoms during and after definitive radiotherapy for adenocarcinoma of the prostate. A pilot study authored by Song et al. documented the ability to increase the space between the prostate and rectum to an average of 7.5 mm. The additional space resulted in significant reductions in rectal dose across the range of 10 Gy to 75 Gy. No clinical outcomes were reported. Favorable early gastrointestinal(GI) and genitourinary (GU) toxicity profiles were reported in a phase II study by Uhl, but there was no control group for comparison.

External Beam Radiation Therapy
The only randomized controlled trial (RCT) of hydrogel spacer placement was reported by Mariados. It randomlyassigned patients 2:1 for either spacer placement or placebo. Study participants had stage T1 or T2 stage prostate cancer without extracapsular extension. A total of 149 patients had the spacer placed prior to radiotherapy and were compared to 73 patients treated without spacer injection. Both groups were treated with image-guided IMRT to a dose of 79.2 Gy in 44 fractions.

The initial report was published in 2015 and showed no significant reduction in rectal adverse events in the first 6 months (34.2% with spacer vs 31.5% without, P=.7). Significant reduction in late (3-15 month) rectal toxicity was associated with spacer placement, with 2% (3 patients) and 7% (5 patients) experiencing grade 1 or greater GI symptoms in the hydrogel and control arms (P=.044), respectively. Urinary toxicity was not significantly different between the groups.

Hamstra et al. subsequently reported 36-month results of a subset of the original trial participants. They reporteda0% grade 2 or higher rectal toxicity with spacer use versus a 5.7% rate without the spacer (P=.012). They alsonoted a significant reduction in grade 1 urinary incontinence favoring spacer placement (15% vs 4%, P=.046). A subsequent analysis reported an improvement in sexual function with the spacer, but this did not meet statistical significance.

There is a strong secular trend toward the use of shorter courses of external beam radiation therapy to treat low-risk and intermediate-risk prostate cancer. Multiple randomized controlled trials (RCT) of shorter course radiation, also called hypofractionated radiation, have shown equivalent cure rates to conventionally fractionated radiation but with a higher incidence acute rectal toxicity. Given the higher GI toxicity of this regimen, the use of a hydrogel spacer would be most advantageous in this cohort of patients and has become standard of care in this setting.

Stereotactic Body Radiation Therapy
Stereotactic body radiation therapy (SBRT), also termed ultrahypofractionated radiation therapy is an alternative radiation modality to treat low-risk and intermediate risk prostate cancer. Treatment is given in 5 or fewer daily sessions or fractions. Fried et al. reported on the use of a perirectal hydrogel spacer in association with SBRT. The retrospective report demonstrated significant improvement in rectal and penile bulb dosimetry with the use of the spacer in 66 patients compared to 28 patients who had not undergone spacer placement.

A much larger study by Zelefsky and colleagues examined outcomes in 551 patients with low-risk and intermediate-risk prostate cancer treated with SBRT. The treatment consisted of 37.5-40 Gy in 5 fractions directed to the prostate and seminal vesicles. About half of the patients (269/551) received a rectal spacer asthis became a standard part of the group's treatment protocol in November 2016. The use of a spacer was associated with a significant reduction in any late GI toxicity (1% with spacer vs 6% without, P=.010). Spacer placement also significantly reduced late GU toxicity (15% for spacer vs 32% without, P<.001).

Brachytherapy
The use of a hydrogel spacer in the setting of low dose rate (LDR) brachytherapy has been reported by Khan et al. Forty patients who underwent perirectal hydrogel injection were compared to 40 patients who had not undergone spacer placement. Some of the patients also received external beam radiation. There was a reduction in rectal toxicity at 1 month, but no difference in toxicity at either one or 2-year follow-up. This finding was similar to a previous report by Taggar et al. comparing toxicity in 74 patients with spacer placement prior toPd-103 LDR brachytherapy to a similar cohort without spacers. Similarly, a report by Lin et al. examining non-randomized outcomes of hydrogel spacer use prior to LDR brachytherapy showed reduced rates of grade 1 toxicity but no significant difference in grade 2 or 3 toxicities. Despite improvements in rectal dosimetry, there was no

significant improvement in acute rectal toxicity. Further studies are needed to define the role of hydrogelspacer placement, if any, in the setting of brachytherapy.

Systematic Reviews
A systematic review of the use of a hydrogel spacer to reduce toxicity during and after radiotherapy for prostate cancer was recently published by Armstrong et al. This review is more extensive than previous reviews by Milleret al. and the Canadian Agency for Drugs and Technologies in Health (CADTH). In addition to the RCT described above, they reviewed 18 additional spacer studies looking at several radiotherapy techniques. Sevenof the 18 studies evaluated hydrogel use with conventionally fractionated IMRT. Two studies examined outcomes when used with SBRT, and one looked at spacer use with proton therapy. Most of the other studies included patients treated with combinations of external beam radiation and brachytherapy.

A recent Cochrane review of interventions to reduce acute and late adverse GI effects of pelvic radiotherapy concluded that "low-certainty evidence on balloon and hydrogel spacers suggests that these interventions for prostate cancer RT may make little or no difference to GI outcomes."

Toxicity and Risk
A recent commentary published in Lancet Oncology urged caution in the widespread use of the hydrogel spacer given the small expected benefit and the rising number of reported adverse events associated with the procedure. Despite excellent safety in the small trial, there are a growing number of reports of significant adverse events in real-world use. By examining the FDA Manufacturer and User Facility Device (MAUDE) database, the authors identified 85 reported events. The majority of these could be converted into graded toxicities using Common Terminology Criteria for Adverse Events. Approximately 70% of the events were graded 3, 4, or 5, with about 24% falling into the grade 4 category, including colostomy, anaphylactic events, rectal wall injection, and pulmonary embolism. There was one death. They concluded that critical reflection and careful consideration of the need, toxicity, and benefits of perirectal hydrogel spacer placement should precede any recommendation for its use.

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guideline for prostate cancer (v4.2022) provides the following recommendation in principles of radiation therapy (PROS-F), "Overall, the panel believes that biocompatible and biodegradable perirectal spacer materials may be implanted

between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions."

National Institute for Health and Care Excellence
In 2017, the National Institute for Health and Care Excellence (NICE) published guidance on the biodegradable spacer. The NICE 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
In 2018, the American Society of Clinical Oncology, the American Urological Association, and the American Society for Radiation Oncology 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.

American College of Radiology
American College of Radiology appropriateness criteria, last reviewed in 2016, for dose-volume constraints for the rectum with external beam radiotherapy are described in Table 1.

Table 1. Dose Constraints for the Rectum With External Beam Radiotherapy

EBRT Dose-Volume	Dose	<15%	<25%	<35%	<50%
Conventional Fractionation	1.8 Gy X 44 fractions (79.2 Gy total)	V75	V70	V65	V60
Hypofractionation	2.5 Gy X 25 fractions (70 Gy total)	V74	V69	V64	V59

EBRT: External beam radiotherapy; Gy: gray.
V100 = volume of structure (X%) receiving 100% of the dose

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
Ongoing			
NCT04905069	Effectiveness of the SpaceOAR Vue System in Subjects With Prostate Cancer Being Treated With Stereotactic Body Radiotherapy	500	July 2028

Unpublished			
NCT01999660[a]	Prospective National Post-marketing Surveillance for the Investigation of the Efficacy and Safety of SpaceOAR™‡ to Maintain Space Between the Rectum and Prostate During Radiation Therapy	119	Aug 2019 (terminated - PI retired)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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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.
11/10/2021	Medical Policy Implementation Committee approval. Coverage changed from Not Medically necessary to eligible with criteria.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. No change to coverage.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 01/2024

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

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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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