LOUISIANA BLUE

Hydrogel Spacer use During Radiotherapy for Prostate Cancer

Policy # 00662
Original Effective Date: 07/01/2019
Current Effective Date: 04/04/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 prostate cancer using any form of external beam radiation therapy (only Photon-based 3D conformal, IMRT, SBRT) to be **eligible for coverage:****

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.****

Based on review of available data, the Company considers the use of hydrogel spacer for prostate brachytherapy or proton beam therapy (PBT) to be **not medically necessary.****

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.

There are currently two types of hydrogel spacer. SpaceOar, is a water based hydrogel spacer and Barrigel is a Hyaluronic acid rectal spacer. Both remain in place for approximately 3 months before being absorbed by the body.

External Beam Radiation Therapy
The first 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 reported a 0% 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 ultra hypofractionated 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. A recent observational study by Nakai et al found no benefit in urinary, sexual, or hormonal domain scores for hydrogel spacer with LDR brachytherapy alone, but improved bowel QOL for patients who are undergoing LDR brachytherapy with IMRT.

Systematic Reviews
A systematic review of the use of a hydrogel spacer to reduce toxicity during and after radiotherapy for prostate cancer was 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. Seven of 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.

An updated systematic review on biodegradable hydrogel spacer done by Wong et al. included 3 RCTs, 3 prospective cohorts, and 11 retrospective cohorts. Over 3200 patients were included with 1471 patients who received per-rectal spacer and 1729 who did not use of spacer was associated with lower likelihood of late and early grade 2 or above rectal toxicity. No difference was seen in grade 3 or above GI (acute or late) events. There was also no statistical difference in bowel-related QOL. Perirectal spacer was not associated with negative impact to urinary or sexual QOL either.

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 U.S. Food and Drug Administration (FDA) through the De Novo process (DEN140030). Barrigel Injectable Gel (Palette Life Sciences) was approved by the FDA via the premarket approval process in March 2022 (K220641; FDA product code: OVB), followed by BioProtect Balloon Implant System (BioProtect, Ltd) in 2023 (K222972; FDA product code: OVB).The intended and approved use of SpaceOAR System, Barrigel, and BioProtect Balloon Implant is 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 these hydrogel spacers 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. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to 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.

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

American Society for Radiation Oncology and American Urological Association
A 2022 guideline from the American Society for Radiation Oncology and the American Urological Association on clinically localized prostate cancer states that, "clinicians should utilize available target localization, normal tissue avoidance, simulation, advanced treatment planning/delivery, and image-guided procedures to optimize the therapeutic ratio of external beam radiation therapy delivered for prostate cancer." Rectal spacers are included in the list of strategies for optimizing the therapeutic ratio in simulation procedures. The guideline authors highlight rectal spacers as the only optimization strategy that has been studied in randomized trials, but not as combination therapy with hypofractionated or ultra hypofractionated therapy.

National Comprehensive Cancer Network
The National Comprehensive Cancer Network guideline for prostate cancer (v2.2025) 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 for the purpose of toxicity reduction."

National Institute for Health and Care Excellence
In 2023, NICE updated their guidance on the biodegradable spacer. The NICE recommendations state that: "Evidence on the safety and efficacy of biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

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			
NCT06451614[a]	SpaceIT Hydrogel System for Perirectal Spacing in Subjects With Low to Intermediate Risk Prostate Cancer Undergoing External Beam Radiotherapy (EBRT)	230	Mar 2028
NCT06594887	Use of Rectal Spacers for Proton Beam Radiation Therapy for Localized Prostate Cancer: Prospective Clinical Study	50	Dec 2025
NCT06599476	Use of Rectal Spacers in Prostate Cancer Patients Undergoing Radiation Therapy: a Prospective Clinical Study	150	Dec 2025
NCT04905069[a]	Effectiveness of the SpaceOAR Vue System in Subjects With Prostate Cancer Being Treated With Stereotactic Body Radiotherapy	500	Apr 2030
NCT05597852	Feasibility of Integrating Rectal Hydrogel Spacer for Salvage Treatment Using Stereotactic Ablative Body Radiotherapy for Locally Recurrent Prostate Cancer	10	Nov 2027
NCT05650021	Radiopaque Hydrogel Rectal Spacer for Prostate Cancer Radiation Image Guidance	30	Sep 2025
NCT05354440[a]	Long-Term Prospective Post Marketing Clinical Follow Up for Evaluation of the BioProtect Balloon Implant System	80	Jan 2026
Unpublished			
NCT05354427[a]	Evaluation of Commercially Available Implantable Spacers, in Prostate Cancer Patients Undergoing Radiotherapy	175	Jan 2022

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

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Policy History

Original Effective Date: 07/01/2019
Current Effective Date: 04/04/2026

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.

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01/04/2024	Medical Policy Committee review
01/10/2024	Medical Policy Implementation Committee approval. No change to coverage.
01/02/2025	Medical Policy Committee review
01/08/2025	Medical Policy Implementation Committee approval. Removed "low risk or intermediate risk" prostate cancer using "EITHER of the following techniques". And added "any form of external beam radiation therapy (3D conformal, IMRT, SBRT)" to be eligible for coverage. Also removed patient selection citeria and the policy guidelines sections from policy.
01/05/2026	Medical Policy Committee review
01/07/2026	Medical Policy Implementation Committee approval. Added "only Photon-based" to the eligible for coverage statement. Added "Based on review of available data, the Company considers the use of hydrogel spacer for prostate brachytherapy or proton beam therapy (PBT) to be not medically necessary."

Next Scheduled Review Date: 01/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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	All related diagnoses

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

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan.