

MEDICAL POLICY

POLICY TITLE	HYDROGEL SPACER USE DURING RADIOTHERAPY FOR PROSTATE CANCER
POLICY NUMBER	MP 4.054

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	10/1/2026

POLICY

Hydrogel Rectal Spacer use during radiotherapy for prostate cancer is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Use of hydrogel spacer for any other indication is **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:

MP 1.147 Prostatic Urethral Lift

MP 1.164 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

MP 4.043 Focal Treatments for Prostate Cancer

MP 4.053 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

MP 5.053 Magnetic Resonance–Guided Focused Ultrasound

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

DESCRIPTION/BACKGROUND

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 approximately 1 in 8 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.

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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 crosswalk of these grading systems are shown in Table 1.

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)

Regulatory Status

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

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal randomized controlled trial (RCT) with a 3-year follow-up for the SpaceOAR system, a pivotal RCT with up to 6-month follow-up for the Barrigel, 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 the radiation dose to the rectum with a statistically significant decrease in Grade 1 or greater late toxicity and a number needed to treat (NNT) of 14.3. There

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were few events of greater than Grade 1 toxicity in either group across all trials, and the NNT for a reduction in clinically significant Grade 2 toxicity has been reported as 68 for SpaceOAR. Patient-reported declines in rectal and urinary quality of life at 3 years in the SpaceOAR studies 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 NNT for late improvement in rectal and urinary quality of life was 6.3 to 6.7, respectively, for SpaceOAR analysis. Limitations to all RCTs 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 but generally shows a decrease in radiation dose to the rectum with the insertion of a hydrogel spacer. However, the potential benefits of the hydrogel spacer must be balanced against the risks of an additional procedure. Additional studies are needed to corroborate the findings of the pivotal RCTs, 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 that the technology results in an improvement in the net health outcome.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational for Hydrogel Therapy

Procedure Codes							
55874	C1889						

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POLICY HISTORY

MP 4.054	04/01/2026 Major Review; creation of new policy. Statements and procedure code moved from MP 4.043

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