



MASSACHUSETTS

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## Medical Policy

# Hydrogel Spacer use During Radiotherapy for Prostate Cancer

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### Policy Number: 743

BCBSA Reference Number: 7.01.164

NCD/LCD: Local Coverage Determination (LCD): Prostate Rectal Spacers (L37485)

### Related Policies

Intensity-Modulated Radiotherapy of the Prostate, #[090](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Hydrogel spacer use during radiotherapy for prostate cancer is considered [INVESTIGATIONAL](#).

Use of a hydrogel spacer for any other indication is [INVESTIGATIONAL](#).

#### Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Prostate Rectal Spacers (L37485)

**Note:** To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

## Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
<b>Commercial Managed Care (HMO and POS)</b>	This is <b>not</b> a covered service.
<b>Commercial PPO and Indemnity</b>	This is <b>not</b> a covered service.
<b>Medicare HMO Blue<sup>SM</sup></b>	Prior authorization is <b>not required</b> .
<b>Medicare PPO Blue<sup>SM</sup></b>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The following CPT code is considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity**:

### CPT Codes

CPT codes:	Code Description
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

### Description

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.<sup>1</sup> 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.<sup>2</sup> A cross-walk 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)
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## Summary

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 the radiation dose to the rectum with a statistically significant decrease in Grade 1 or greater late toxicity and number needed to treat of 14.3. There were few events of greater than Grade 1 toxicity in either group, and 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.

## Policy History

Date	Action
2/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2019	New medical policy describing ongoing investigational indications for Commercial members. Effective 6/1/2019.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Classification of prostatic carcinomas. Cancer chemotherapy reports. Mar 1966;50(3):125-8. PMID 5948714
2. SEER Database. 2018; <https://seer.cancer.gov/seerinqury/index.php?page=view&id=20170036&type=q>. Accessed October 26, 2019.
3. Forero DF, Almeida N, Dendukuri N. Hydrogel Spacer to reduce rectal toxicity in prostate cancer radiotherapy: a health technology assessment. Report No. 82. April 16, 2018. <https://muhc.ca/sites/default/files/micro/m-TAU/SpaceOAR.pdf>. Accessed December 6, 2019.
4. Minimally important difference for the Expanded Prostate Cancer Index Composite Short Form. Urology. Jan 2015;85(1):101-5. PMID 25530370

5. Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.* Aug 1 2015;92(5):971-977. PMID 26054865
6. Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys.* Apr 1 2017;97(5):976-985. PMID 28209443
7. Hydrogel spacer distribution within the perirectal space in patients undergoing radiotherapy for prostate cancer: Impact of spacer symmetry on rectal dose reduction and the clinical consequences of hydrogel infiltration into the rectal wall. *Pract Radiat Oncol.* May - Jun 2017;7(3):195-202. PMID 28089528
8. Whalley D, Hruby G, Alfieri F, et al. SpaceOAR Hydrogel in Dose-escalated Prostate Cancer Radiotherapy: Rectal Dosimetry and Late Toxicity. *Clin Oncol (R Coll Radiol).* 2016 Oct;28(10):e148-54. PMID 27298241
9. Te Velde BL, Westhuyzen J, Awad N, et al. Can a peri-rectal hydrogel spaceOAR programme for prostate cancer intensity-modulated radiotherapy be successfully implemented in a regional setting? *J Med Imaging Radiat Oncol.* 2017 Aug;61(4):528-533. PMID 28151584
10. Pinkawa M, Piroth MD, Holy R, et al. Quality of life after intensity-modulated radiotherapy for prostate cancer with a hydrogel spacer. Matched-pair analysis. *Strahlenther Onkol.* 2012 Oct;188(10):917-25. PMID 22933033
11. Pinkawa M, Berneking V, Konig L, et al. Hydrogel injection reduces rectal toxicity after radiotherapy for localized prostate cancer. *Strahlenther Onkol.* 2017 Jan;193(1):22-28. PMID 27632342
12. Pinkawa M, Berneking V, Schlenter M, Krenkel B, Eble MJ. Quality of Life After Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: 5-Year Results. *International journal of radiation oncology, biology, physics.* 2017;99(2):374-377.
13. Te Velde BL, Westhuyzen J, Awad N, et al. Late toxicities of prostate cancer radiotherapy with and without hydrogel SpaceAOR insertion. *J Med Imaging Radiat Oncol.* 2019 Dec;63(6):836-841. PMID 31520465
14. Chao M, Ow D, Ho H, et al. Improving rectal dosimetry for patients with intermediate and high-risk prostate cancer undergoing combined high-dose-rate brachytherapy and external beam radiotherapy with hydrogel spacer. *J Contemp Brachytherapy.* 2019 Feb;11(1):8-13. PMID 30911304
15. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer V4.2019  
[https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed December 6, 2019.
16. National Institute for Health and Care Excellence. Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. IPG590 2017  
[/https://www.nice.org.uk/guidance/ipg590](https://www.nice.org.uk/guidance/ipg590). Last Accessed December 6, 2019.
17. Hypofractionated Radiation Therapy for Localized Prostate Cancer: An ASTRO, ASCO, and AUA Evidence-Based Guideline. *J Urol.* Oct 9 2018. pii: S0022-5347(18):43963-8. PMID 30316897