



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/03/24  
LAST REVIEW DATE: 09/03/24  
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LAST CRITERIA REVISION DATE: 09/03/24  
ARCHIVE DATE:

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## HYDROGEL SPACER USE DURING RADIOTHERAPY FOR PROSTATE CANCER

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

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 two and reducing the radiation dose to the rectum. A variety of biomaterials, including polyethylene glycol hydrogels (e.g., SpaceOAR™ System), hyaluronic acid hydrogels (Barrigel Injectable Gel), or absorbable balloon implants (BioProtect Balloon Implant™ System), have been evaluated as perirectal spacers.

In October 2014, SpaceOAR™ was cleared by the U.S. Food and Drug Administration (FDA) through the De Novo process (DEN140030). Barrigel Injectable Gel was approved by the FDA via the premarket approval process in March 2022, followed by BioProtect Balloon Implant™ System in 2023. 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 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.

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### Criteria:

- Hydrogel spacer use during radiotherapy for prostate cancer is considered **experimental or investigational** based upon:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.
  
- Use of a hydrogel spacer for any other indication is considered **experimental or investigational** based upon:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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## HYDROGEL SPACER USE DURING RADIOTHERAPY FOR PROSTATE CANCER

### Resources:

Literature reviewed 09/03/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 09/03/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. American Cancer Society. Key Statistics for Prostate Cancer. Updated January 19, 2024. Accessed May 22, 2024. <https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html>
2. American College of Radiology. ACR appropriateness criteria for external beam radiation therapy treatment planning for clinically localized prostate cancer. 2016. Accessed May 22, 2024. <https://acsearch.acr.org/docs/69396/Narrative/>
3. Babar M, Katz A, Ciatto M. Dosimetric and clinical outcomes of SpaceOAR in men undergoing external beam radiation therapy for localized prostate cancer: A systematic review. *J Med Imaging Radiat Oncol*. Jun 2021;65(3):384-397. doi:10.1111/1754-9485.13179
4. Butler WM, Kurko BS, Scholl WJ, Merrick GS. Effect of the timing of hydrogel spacer placement on prostate and rectal dosimetry of low-dose-rate brachytherapy implants. *J Contemp Brachytherapy*. Apr 2021;13(2):145-151. doi:10.5114/jcb.2021.105281
5. 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*. Feb 2019;11(1):8-13. doi:10.5114/jcb.2019.82836
6. Fischer-Valuck BW, Chundury A, Gay H, Bosch W, Michalski J. 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. doi:10.1016/j.prro.2016.10.004
7. Forero DF, Almeida N, Dendukuri N. Hydrogel Spacer to reduce rectal toxicity in prostate cancer radiotherapy: a health technology assessment. Report number: 82. Updated April 16, 2018. Accessed May 22, 2024. <https://muhc.ca/sites/default/files/micro/m-TAU/SpaceOAR.pdf>
8. Gleason DF. Classification of prostatic carcinomas. *Cancer Chemother Rep*. Mar 1966;50(3):125-8.
9. Hamstra DA, Mariados N, Sylvester J, et al. 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. doi:10.1016/j.ijrobp.2016.12.024

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10. Kahn J, Dahman B, McLaughlin C, et al. Rectal spacing, prostate coverage, and periprocedural outcomes after hydrogel spacer injection during low-dose-rate brachytherapy implantation. *Brachytherapy*. Mar-Apr 2020;19(2):228-233. doi:10.1016/j.brachy.2019.11.002
11. Mariados N, Sylvester J, Shah D, et al. 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. doi:10.1016/j.ijrobp.2015.04.030
12. Mariados NF, Orio PF, 3rd, Schiffman Z, et al. Hyaluronic Acid Spacer for Hypofractionated Prostate Radiation Therapy: A Randomized Clinical Trial. *JAMA Oncol*. Apr 1 2023;9(4):511-518. doi:10.1001/jamaoncol.2022.7592
13. McDonald AM, Baker CB, Popple RA, et al. Different rectal toxicity tolerance with and without simultaneous conventionally-fractionated pelvic lymph node treatment in patients receiving hypofractionated prostate radiotherapy. *Radiation oncology (London, England)*. Jun 3 2014;9:129. doi:10.1186/1748-717x-9-129
14. Miller LE, Efstathiou JA, Bhattacharyya SK, Payne HA, Woodward E, Pinkawa M. Association of the Placement of a Perirectal Hydrogel Spacer With the Clinical Outcomes of Men Receiving Radiotherapy for Prostate Cancer: A Systematic Review and Meta-analysis. *JAMA Netw Open*. Jun 1 2020;3(6):e208221. doi:10.1001/jamanetworkopen.2020.8221
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16. National Institute for Health and Care Excellence. Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. IPG752. 2023. Accessed May 22, 2024. <https://www.nice.org.uk/guidance/ipg752>
17. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer v4.2024. Accessed May 22, 2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf)
18. Nehlsen AD, Sindhu KK, Moshier E, Sfakianos JP, Stock RG. The impact of a rectal hydrogel spacer on dosimetric and toxicity outcomes among patients undergoing combination therapy with external beam radiotherapy and low-dose-rate brachytherapy. *Brachytherapy*. Mar-Apr 2021;20(2):296-301. doi:10.1016/j.brachy.2020.09.018
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22. SEER Database. Accessed May 22, 2024. <https://seer.cancer.gov/seerinqury/index.php?page=view&id=20170036&type=q>
23. Seymour ZA, Hamstra DA, Daignault-Newton S, et al. Long-term follow-up after radiotherapy for prostate cancer with and without rectal hydrogel spacer: a pooled prospective evaluation of bowel-associated quality of life. *BJU Int*. Sep 2020;126(3):367-372. doi:10.1111/bju.15097
24. Skolarus TA, Dunn RL, Sanda MG, et al. Minimally important difference for the Expanded Prostate Cancer Index Composite Short Form. *Urology*. Jan 2015;85(1):101-5. doi:10.1016/j.urology.2014.08.044
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### Coding:

CPT: 55874

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<b><u>History:</u></b>	<b><u>Date:</u></b>	<b><u>Activity:</u></b>
Medical Policy Panel	09/03/24	Approved guideline
Medical Director (Dr. Raja, Dr. Sutanto)	08/01/24	Review with revisions

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### **Policy Revisions:**



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

