



MEDICAL COVERAGE GUIDELINES  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/29/15  
LAST REVIEW DATE: 09/18/18  
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## HYDROGEL SPACER FOR USE IN RADIOTHERAPY TREATMENT OF 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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

Hydrogel is a liquid that is injected through the perineum under transrectal ultrasound. The spacer is placed using a small needle, which delivers the liquid hydrogel that solidifies, and creates a physical barrier between the prostate and the rectum thus shielding the anterior rectum from radiation directed at the prostate gland. The solidified hydrogel stays in place around 3 months, after which it is reabsorbed into the body.

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## HYDROGEL SPACER FOR USE IN RADIOTHERAPY TREATMENT OF PROSTATE CANCER (cont.)

### Criteria:

- Hydrogel spacer for use in the radiotherapy treatment of prostate cancer is considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These devices include, *but are not limited to*:

- SpaceOAR®

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### Resources:

**Literature reviewed 09/12/17. We do not include marketing materials, poster boards and non-published literature in our review.**

1. 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.
2. 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 01 2017;97(5):976-985.
3. Hedrick SG, Fagundes M, Case S, et al. Validation of rectal sparing throughout the course of proton therapy treatment in prostate cancer patients treated with SpaceOAR(R). *J Appl Clin Med Phys*. Jan 2017;18(1):82-89.
4. Hedrick SG, Fagundes M, Robison B, et al. A comparison between hydrogel spacer and endorectal balloon: An analysis of intrafraction prostate motion during proton therapy. *J Appl Clin Med Phys*. Mar 2017;18(2):106-112.
5. Hutchinson RC, Sundaram V, Folkert M, Lotan Y. Decision analysis model evaluating the cost of a temporary hydrogel rectal spacer before prostate radiation therapy to reduce the incidence of rectal complications. *Urologic oncology*. Jul 2016;34(7):291.e219-226.

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## **HYDROGEL SPACER FOR USE IN RADIOTHERAPY TREATMENT OF PROSTATE CANCER (cont.)**

### **Resources:** (cont.)

6. Juneja P, Kneebone A, Booth JT, et al. Prostate motion during radiotherapy of prostate cancer patients with and without application of a hydrogel spacer: a comparative study. *Radiation oncology (London, England)*. 2015;10:215.
7. 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.
8. Muller AC, Mischinger J, Klotz T, et al. Interdisciplinary consensus statement on indication and application of a hydrogel spacer for prostate radiotherapy based on experience in more than 250 patients. *Radiol Oncol*. Sep 01 2016;50(3):329-336.
9. Pinkawa M, Berneking V, Konig L, Frank D, Bretgeld M, Eble MJ. Hydrogel injection reduces rectal toxicity after radiotherapy for localized prostate cancer. *Strahlenther Onkol*. Jan 2017;193(1):22-28.
10. Pinkawa M, Schubert C, Escobar-Corral N, Holy R, Eble MJ. Application of a hydrogel spacer for postoperative salvage radiotherapy of prostate cancer. *Strahlenther Onkol*. Apr 2015;191(4):375-379.
11. RajECKi M, Thurber A, Catalfamo F, Duff M, Shah D. SU-E-T-284: Dose Plan Optimization When Using Hydrogel Prostate-Rectum Spacer: A Single Institution Experience. *Med Phys*. Jun 2015;42(6):3398.
12. Te Velde BL, Westhuyzen J, Awad N, Wood M, Shakespeare TP. 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*. Aug 2017;61(4):528-533.
13. UpToDate.com. External beam radiation therapy for localized prostate cancer. 04/10/2017.
14. Whalley D, Hrubby G, Alfieri F, Kneebone A, Eade T. SpaceOAR Hydrogel in Dose-escalated Prostate Cancer Radiotherapy: Rectal Dosimetry and Late Toxicity. *Clinical oncology (Royal College of Radiologists (Great Britain))*. Jun 10 2016.
15. Whalley D, Hrubby G, Alfieri F, Kneebone A, Eade T. SpaceOAR Hydrogel in Dose-escalated Prostate Cancer Radiotherapy: Rectal Dosimetry and Late Toxicity. *Clinical oncology (Royal College of Radiologists (Great Britain))*. Oct 2016;28(10):e148-154.
16. Wilton L, Richardson M, Keats S, et al. Rectal protection in prostate stereotactic radiotherapy: a retrospective exploratory analysis of two rectal displacement devices. *J Med Radiat Sci*. Aug 08 2017.



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## HYDROGEL SPACER FOR USE IN RADIOTHERAPY TREATMENT OF PROSTATE CANCER (cont.)

### 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 nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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.

