HYDROGEL SPACER FOR USE IN RADIOThERAPY TREATMENT OF PROSTATE CANCER

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.
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®

Resources:

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


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

**Resources:** (cont.)


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. 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: Dii kwe’ę atah nillinígíi Blue Cross Blue Shield of Arizona haada yít’éego bina’idílikdígo éí doodago Háida bíjá aniyeedígíí t’áadoo le’é yina’idílikdígo beehaz’aanii hóló díí t’áa hazaad’ehí háká a’doo wolgo bee ház’a doo baq’ă nthł’óó nílinígóó. Ata’hánlé’ígíí kójí‘ bích’į’ hódlíilhíi 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.
HYDROGEL SPACER FOR USE IN RADIOTHERAPY TREATMENT OF PROSTATE CANCER (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulanan, ay may mga katawan ng tumong sa Blue Cross Blue Shield of Arizona, may karapatang na magbagsik ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makaupot ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 안녕히 계세요 또는 휴게 되는 어떤 사람이 Blue Cross Blue Shield of Arizona의 관련된 질문이 있다면, 귀하의 요청을 받지 못하는 이유로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 되는 경우, 877-475-4799로 문의하십시오.

French: Si vous, ou quelqu’un qui vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi: آگاه شوید، که شما یا یک کمک میکنید، سوال در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: ئەگەر شوێن، یەکە لە کەمکیکەکە دەکەی، سەواکە دەورە دەستە بچێتییەکەیە، بەتە بە خۆیەکەیە، 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovorali sa prevodioceom, nazovite 877-475-4799.

Thai: หากคุณหรือผู้ที่คุณช่วยเหลือคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เก็บค่าใช้จ่าย ที่หมายเลขโทรศัพท์ 877-475-4799.