BRACHYTHERAPY FOR TREATMENT OF BREAST 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:**

Radiation therapy is frequently used as a treatment for breast cancer. Conventional radiation therapy is delivered to the whole breast over the course of 5-8 weeks. Brachytherapy is an alternative form of radiation which places the radioactive material directly into the cancer or immediately around it.
BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Description: (cont.)

Accelerated Partial Breast Irradiation (APBI):
APBI, also referred to as high dose rate (HDR) breast brachytherapy, is a technique in which the portion of the breast at the highest risk receives a shortened course of high dose radiation therapy. APBI is typically delivered in 10 treatments over 5 days, with treatments separated by at least 6 hours. Several approaches can be used to deliver APBI:

- Interstitial brachytherapy: placement of multiple hollow needles and catheters to guide placement of the radioactive material.
- Balloon brachytherapy (e.g., MammoSite®): balloon is inserted into the tumor bed and inflated with radioactive material. Some brachytherapy systems combine aspects of interstitial and balloon brachytherapy.
- External-beam APBI is delivered in the same way as conventional or accelerated whole-breast radiotherapy but to a smaller area. All 3 external-beam regimens can use 3-dimensional, conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT).
- Intraoperative APBI is performed during breast-conserving surgery, when a single dose of radiation is delivered to the exposed tumor bed.

Brachytherapy Boost with Whole-Breast Irradiation:
Brachytherapy can also be used as an alternative to external-beam radiation therapy to deliver boost radiation therapy combined with whole-breast external-beam radiation therapy. Local boost brachytherapy may use temporarily implanted needles, wires or seeds after an individual has recovered from surgery and completed whole-breast radiation therapy.

Electronic Brachytherapy:
Electronic brachytherapy can be used to deliver APBI treatment procedures.

The Axxent® Electronic Brachytherapy System® uses a miniature x-ray tube rather than radioactive material to deliver intracavitary or interstitial radiation to the surgical margins after a lumpectomy. It can be used with balloon and interstitial brachytherapy and with intraoperative brachytherapy. The Intrabeam® System is another electronic brachytherapy device that is used for intraoperative or intracavity radiotherapy. The Intrabeam Spherical Applicators are indicated for use with the Intrabeam System to deliver a prescribed dose of radiation to the treatment margin or tumor bed. Electronic brachytherapy has been investigated in the treatment of breast cancer.

Noninvasive Brachytherapy:
Noninvasive brachytherapy can be used to deliver brachytherapy boost with whole breast irradiation therapy or APBI treatment procedures.

The AccuBoost System is an image-guided radiation therapy (IGRT) technique that targets the radiation dose to the intended site. Real-time mammographic images pinpoint the tissue that needs to be irradiated. The AccuBoost System is able to position the applicator that delivers the therapeutic dose to irradiate the part of the breast that has been designated to receive the additional dose.
BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Criteria:

- APBI as the sole form of radiotherapy for stage I or stage II breast cancer after surgical excision is considered **medically necessary** with documentation of **ALL** of the following:
  1. Invasive carcinoma, ductal carcinoma in situ, infiltrating ductal, lobular, medullary, mucinous (colloidal) or tubular carcinoma
  2. Tumor size no greater than 3 cm
  3. No more than 3 positive axillary nodes with no extracapsular extension (bursting)
  4. Negative microscopic surgical margins with no tumor cells on ink
  5. No evidence of tumor in other quadrants of the treated breast
  6. No evidence of sarcoma

- Interstitial or balloon brachytherapy for stage I or II breast cancer is considered **medically necessary** when used as local boost irradiation for an individual undergoing initial treatment that is also being treated with breast-conserving surgery and whole breast external beam radiotherapy.

- Electronic brachytherapy for the treatment of breast 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 settings.
BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Criteria: (cont.)

- Noninvasive brachytherapy using Accuboost for individuals undergoing initial treatment for stage I or II breast cancer when used as local boost irradiation in individuals who are also treated with breast-conserving surgery and whole-breast external-beam radiotherapy 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 settings.

- Breast brachytherapy for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon insufficient evidence to support improvement of the net health outcome.

Resources:

Literature reviewed 02/28/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 10/29/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Resources: (cont.)


BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Resources: (cont.)


20. UpToDate LJP, MD. . Adjuvant radiation therapy for women with newly diagnosed, non-metastatic breast cancer. UpToDate. 02/02/17, 01/16/15, 11/18/14 2014.

21. UpToDate TM, MD, PhD. Radiation therapy techniques in cancer treatment. UpToDate,. 01/14/16, 01/16/15, 05/22/14 2014.


BRACHYTHERAPY FOR TREATMENT OF BREAST 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: Díí kwe’é atah níilínígíí Blue Cross Blue Shield of Arizona haada yit’éego bina’ídiłkidgo éí doodago Háída bíjá anilyeeéígií t’aadoo le’e yina’ídiłkidgo beeñah’ánii hólo díí t’áá hazaad’ehií háká a’doowolgo bee ház’a doo bąq’ ilíígóó. Atá’ halne’ígíí kojí bích’í hodílííh níí 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。洽询一位翻译员，再拨电话 在此插入数字 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تسامحه أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية بلغتك من دون اية تكلفة، للتحدث مع مترجم الصل ب 877-475-4799.
BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makahusga ng tulong at impormasyon sa iyong wiha ng walang gastos. Upang makuasa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu’un que 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: 

فرانسه‌ای: برای پاسخ به پرسش‌های شما در مورد Blue Cross Blue Shield of Arizona، شما حق برای دریافت اطلاعات، به همراه با حمایت نیازمند، رایگان دارید. سوالات مربوط به سرمایه‌گذاری کنید که این ممکن است.

Assyrian:

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

Thai: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลภาษาของคุณโดยไม่เสียค่าใช้จ่าย โปรดโทรมาที่ 877-475-4799.