BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER

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.

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. Intrabeam® Photon Radiosurgery Device is another electronic brachytherapy device that is used for intraoperative radiotherapy. 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.

- 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.
BRACHYTHERAPY FOR TREATMENT OF BREAST CANCER (cont.)

Criteria: (cont.)

➢ 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:

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.)


FDA 510K Summary for MammoSite Multi Lumen (ML) Radiation Therapy System (RTS):

- FDA-approved indication: To provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

FDA 510K Summary for Axxent Electronic Brachytherapy System:

- FDA-approved indication: To provide brachytherapy when the physician chooses to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer.

FDA 510K Summary for Intrabeam System:

- FDA-approved indication: For radiation therapy treatments. 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 during intracavity or intraoperative radiotherapy treatments.