

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	BRACHYTHERAPY AFTER BREAST-CONSERVING SURGERY, AS BOOST WITH WHOLE BREAST IRRADIATION OR ALONE AS ACCELERATED PARTIAL BREAST IRRADIATION
Policy Number	6.01.30
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

- I. Based upon our criteria and review of the peer-reviewed literature, accelerated partial breast irradiation (APBI) using either interstitial or balloon brachytherapy of the breast (e.g. the MammoSite™ Radiation Therapy System) has been medically proven to be effective, and is therefore a **medically appropriate** treatment option when all of the following conditions are met:
 - A. in BRCA 1 or 2 mutation negative women aged 45 years or older; and
 - B. with Stage T1, N0, ER-positive or negative invasive ductal breast cancer with negative or close margin or ductal carcinoma in situ (DCIS); and
 - C. tumor size is less than or equal to 3 cm (including pure DCIS); and
 - D. lymphovascular space invasion (LSVI) is not present.
- II. Based upon our criteria and review of the peer-reviewed literature, accelerated partial breast irradiation using either interstitial or balloon brachytherapy of the breast (e.g. the MammoSite™ Radiation Therapy System) as a boost treatment in women who are treated with breast-conserving surgery and whole-breast external beam radiation therapy is considered **not medically necessary**.
- III. Based upon our criteria and review of peer-reviewed literature, intra-operative breast radiotherapy, is considered **medically appropriate** in women aged 50 years or older who meet criteria for accelerated partial breast irradiation (APBI) (please refer to Policy Statement I).
- IV. Based upon our criteria and review of peer-reviewed literature, electronic brachytherapy is considered investigational. Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services

POLICY GUIDELINES

- I. This policy addresses the use of either interstitial or balloon brachytherapy as alternatives to external beam radiation therapy in three settings:
 - A. Alone, for accelerated partial breast radiation therapy after breast-conserving surgery; or
 - B. In the intra-operative setting; or
 - C. To replace external beam for boost radiation therapy, combined with whole-breast external-beam radiation therapy and breast-conserving surgery.
- II. Methods other than brachytherapy are also used for partial breast irradiation (PBI), including several types of external beam therapy. They are not addressed in this policy.

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III. A cavity evaluation device may be placed at the time of surgery as a place holder to simplify insertion of the MammoSite™ balloon catheter at a later date, when final pathology and staging is known and a decision regarding the role of brachytherapy in the patient's treatment plan is established.

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Survival after breast-conservation therapy (BCT) is equivalent to survival after mastectomy for patients diagnosed with tumors categorized as stage I or II. BCT is a multi-modality treatment that consists of breast-conserving surgery to excise the tumor with adequate margins, followed by whole-breast external-beam radiation therapy (WB-EBRT) administered as 5 daily fractions per week over 5 to 6 weeks. For those at higher risk of recurrence, local "boost" irradiation narrowly directed to the tumor bed often is added to whole breast irradiation, to provide a higher dose of radiation at the site where recurrence most frequently occurs. For some patients BCT also includes axillary lymph node dissection or irradiation of the axilla.

Brachytherapy for breast cancer uses radiate sources placed inside the breast. When used after breast-conserving surgery, brachytherapy is one of several methods of accelerated partial breast irradiation (APBI). APBI differs from WB-EBRT in two ways. First, APBI radiation targets only a segment surrounding the tumor rather than the entire breast. Second, since the duration of APBI treatment is 4 to 5 days rather than 5 to 6 weeks, radiation is delivered in fewer fractions at larger doses per fraction.

Interstitial breast brachytherapy. Various interstitial brachytherapy techniques have been investigated. They differ in the timing of implantation relative to other components of breast-conserving therapy, the radiation dose rate, the loading technique, the number and volumetric distribution of radioactive sources, and the radioisotopes used. Older forms of local boost irradiation brachytherapy implanted the needles, wires, or seeds for brachytherapy after recovery from surgical tumor excision and WB-EBRT. More recently the hollow needles and catheters that guide placement of the radioactive material are perioperatively implanted. This can be done during the initial lumpectomy if the decision to use brachytherapy has already been made, or at the time of re-excision if pathologic evaluation of margins shows that additional surgery is necessary. Intraoperative implantation avoids the need for a separate surgical procedure with anesthesia for brachytherapy. Both low-dose rate and high-dose rate techniques have been used. In the low-dose rate technique, radioactive seeds are temporarily implanted in hospitalized patients, which deliver radiation continuously over four days and are then removed. In the high-dose rate technique, a computer-controlled device loads highly radioactive isotope sources into catheters that have been placed into the tumor bed. The patient is exposed to the radiation therapy for a brief period (15 minutes) and the radioactive sources are withdrawn. It is typically administered to outpatients as 8 fractions given twice daily over 4 days. Most brachytherapy for stage I or II breast cancer uses high dose-rate iridium-192 in the form of wires or needles. Sometimes seeds containing iodine-125 are used in place of iridium-192.

Intracavity breast brachytherapy. Intracavitary brachytherapy is a method for delivering very localized radiation to small tumors, which have not spread, or to deliver an additional dose of radiation to a small volume at high risk for recurrence. It is achieved by placing a small radiation source directly into a naturally occurring body cavity or in a cavity left by a tumor. The brachytherapy can be delivered using the ClearPath HDR Breast Brachytherapy System (NAS Medical, Chatsworth, CA), Contura Multi-Lumen Balloon (SenoRx, Inc., Irvine, CA), Strut-Adjusted Volume Implant (SAVI) (Cianna Medical, Inc., Aliso Viejo, CA). The MammoSite™ radiation therapy system is the most commonly used device and is discussed below.

The MammoSite™ radiation therapy system is a brachytherapy device developed to provide a simpler technique for performing breast brachytherapy than interstitial catheter brachytherapy. It reduces the complex procedure and treatment

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planning of interstitial catheter brachytherapy and does not have the steep learning curve needed for the interstitial technique. It was designed for the purpose of delivering radiation therapy to the lumpectomy bed with breast conserving surgery. MammoSite™ consists of a hollow catheter to which an inflatable balloon is attached. It is implanted into the lumpectomy cavity during or shortly after breast-conserving surgery. The balloon is inflated with sterile solution of contrast media in saline, and its position is confirmed radiographically using computed tomography. A high-dose rate source of iridium-192 is then centrally positioned within the applicator by a remote afterloader. This system is used to deliver 34 Gy in 10 fractions over 5 days. Balloon brachytherapy uses a single radioactive source that delivers radiation to a spherical or elliptical target volume. No radiation remains inside the breast between treatments. The MammoSite™ balloon catheter is usually removed on the last day of treatment. The manufacturer states it may be used to deliver local boost or accelerated partial-breast radiation therapy.

The Axxent™ Electronic Radiotherapy device is a balloon brachytherapy system that uses a disposable, microminiature radiation source to deliver radiation rather than radioisotopes. It is designed to deliver doses of x-ray radiation directly to the excised tumor bed to deliver intracavitary or interstitial radiation to surgical margins following lumpectomy for breast cancer. It is comprised of three components: the controller (a mobile platform responsible for overall operation of the device), a balloon applicator and an x-ray source. A breast surgeon implants a balloon applicator into the lumpectomy cavity, and the balloon is inflated with sterile saline. Radiation is delivered by a disposable micro-miniature x-ray source located at the end of a flexible cable and is comparable in dosage strength to iridium 192. Use of the Axxent™ device does not utilize a radioactive isotope or require a high dose-rate (HDR) afterloader. Therefore, it does not require the heavily-shielded treatment rooms necessary for the delivery of isotope-based HDR brachytherapy. Treatments are given in 10 fractions, twice a day for five days

RATIONALE

Implanting the guides used to insert radioisotopes for brachytherapy is a surgical procedure and therefore not subject to government regulation. Iodine-125 seeds were marketed prior to enactment of the 1976 Medical Device Amendments. Therefore, they were cleared for marketing on a “grandfathered” basis. Subsequent radioactive isotope implants, including iridium-192, were approved by the FDA via 510(k) as substantially equivalent to the radioactive iodine seeds.

The U.S. Food and Drug Administration (FDA) cleared the MammoSite™ Radiation Therapy System (Cytac Surgical Products, formerly Proxima Therapeutics) for marketing via 510(k) in May 2002 as substantially equivalent to other commercially available brachytherapy applicators used with sealed radiation sources. The FDA Office of Device Evaluation judged it reasonably likely that the device will be used in ways outside those specified in the proposed labeling, and that such use could cause harm. Therefore, the FDA required inclusion of the following statement in the Warnings section of the device’s labeling: “The safety and effectiveness of the MammoSite™ RTS as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.” In August 2004 the FDA approved a new version of the MammoSite™ RTS, which offers a thinner catheter shaft and a smaller balloon profile to further minimize intrusion into the lumpectomy cavity during brachytherapy. Additional brachytherapy devices have received FDA 510(k) marketing clearance, such as the SenoRad Multi-lumen Balloon Source Applicator for Brachytherapy (May 2007) and the Contura Multi-Lumen Balloon Source Applicator for Brachytherapy (April 2008), both manufactured by SenoRx, Inc.

In December 2005, the FDA cleared the Axxent Electronic Radiotherapy device (Xoft, Inc.) via 510(k) as substantially equivalent to the MammoSite™ and other brachytherapy systems. As with MammoSite™, the FDA required a warning in a black box stating, “The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.”

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MammoSite™ balloon brachytherapy. Initial published results of the MammoSite™ Patient Registry addressed results of 1,403 women with early stage breast cancer regarding cosmetic results and early toxicity. Cosmetic results at 12 months were comparable to those reported with whole-breast radiation therapy. 95% of patients (1,030 of 1,084 patients) who had a cosmetic assessment had good/excellent result at the last follow-up visit. Early toxicity rates (infections, radiation recall) appeared to be acceptable. 8.1% (92 of 1,140 patients) developed an infection in the treated breast. A radiation recall reaction was reported in 3.4% (15 of 442 patients) who had this information recorded. At the time of publication, one local recurrence (.1%) was reported, which was a new primary cancer. Of 158 ductal carcinoma in situ (DCIS) patients, 2-24 months follow-up of 104 patients showed 94% had an excellent or good cosmetic result and 5% had fair or poor results (Jeruss, 2006). Lowest toxicity was obtained in patients with the greatest device-to-skin distance. Long-term follow-up data regarding patient satisfaction, cosmesis and efficacy are needed. These results are preliminary since the planned follow-up period of the registry is seven years. Data continue to accrue from uncontrolled studies on the use of Mammosite® balloon brachytherapy. The longest follow-up found was 5 years in a study of 36 patients, with no local recurrences reported. Based on development of recurrences beyond five years, longer follow-up is needed, as well as controlled trials. Studies using the Contura multi-lumen balloon show similar results as MammoSite™. Studies are sparse regarding other devices.

Interstitial, multi-catheter brachytherapy. Several single-institution, non-randomized studies using the multicatheter technique have shown low local recurrence rates that are comparable to standard external beam radiation therapy. Data on newer techniques are not yet as mature but show comparable results at shorter follow-up.

Electronic brachytherapy (EBT). No published clinical studies are available that address the clinical impact of use of the Axxent Electronic Brachytherapy System. Current studies are small and early outcome data was similar to early outcome for iridium-based brachytherapy. The ASTRO emerging technology committee report on electronic brachytherapy states the advantages of electronic brachytherapy over existing technologies are as yet unproven in terms of efficacy or patient outcomes. The impact of clinical use of EBT could be far-reaching and, if used properly, has potential to benefit patients. EBT is currently an unregulated treatment delivery modality for cancer therapy, with minimal clinical data available from small single institution studies, none with any significant follow-up. The effects of EBT on tumor and normal tissues are not yet well understood, given the paucity of clinical studies. Although the clinical data on this technology is limited, it appears very likely that it will result in results equivalent to those using HDR brachytherapy for APBI.

National Comprehensive Cancer Network (NCCN) (v1.2018) Breast Cancer guidelines. Preliminary studies of APBI suggest rates of local control in selected patients with early stage breast cancer may be comparable to those treated with standard whole breast RT. Follow-up is limited and studies are on-going. Women with early stage breast cancer are encouraged to participate in clinical trials. If not trial eligible, per the consensus statement from the American Society for Radiation Oncology (ASTRO), patients who may be suitable APBI are women 50 years or older with invasive ductal carcinoma measuring less than or equal to 2 cm (T1 disease) with negative margin width of greater than or equal to 2 mm no lymph node involvement, ER positive and BRCA negative; or low/intermediate nuclear grade, screening detected DCIS measuring size less than or equal to 2.5 cm with negative margin widths of greater than or equal to 3 mm.

The American Society of Breast Surgeons (revised 2018 June), Consensus Statement of Accelerated Partial Breast Irradiation:

1. Outside of multi-institutional studies and institutional protocols, patients should be carefully selected for APBI and properly informed of the benefits and risks of this type of radiation treatment. The American Society of Breast Surgeons recommends the following selection criteria when considering patients for treatment with APBI, as a sole form of radiation therapy, in lieu of whole breast irradiation:
 - a. Age greater than 45 years old,
 - b. Invasive ductal carcinoma or ductal carcinoma in situ,
 - c. Total tumor size (invasive and DCIS) less than or equal to 3 cm in size,

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- d. No tumor on ink for invasive tumors and invasive tumors with associated DCIS; greater than 2mm for DCIS
 - e. Sentinel lymph node negative.
 - f. Multifocal disease is allowed as long as the combined area of tumor is less than or equal to 3cm;
 - g. Tumor may be estrogen receptor positive or estrogen receptor negative;
 - h. Lymphovascular invasion is allowed as long as it is focal
 - i. Patients should not be treated with APBI if they have a BRCA genetic mutation or other genetic mutation that confers an increased risk of breast cancer;
 - j. There is no evidence to support use of APBI in male patients;
 - k. Patients with a history of ipsilateral breast cancer treated with radiation should only be treated with APBI as part of specific clinical trial;
 - l. No contraindication to APBI in patients with history of contralateral breast cancer.
2. Patient selection and counseling should be performed in a multidisciplinary fashion with collaboration between the treating surgeon and the treating radiation oncologist.
 3. It is preferred that all patients treated are part of a clinical trial or registry.
 4. All patients should be monitored regularly to identify adverse events as well as local recurrences.
 5. The published dataset for APBI supports the recommendations summarized above. Continuous, long-term, outcomes-based monitoring of APBI is desirable. The American Society of Breast Surgeons maintains an ongoing Mammosite® Registry (registration completed in 2004) collecting data on 1440 patients treated via the Mammosite® balloon catheter technique. As is the case with all cancer treatments, participation in multi-institutional clinical studies, including NSABP/RTOG B39, or in single-site protocols, or in the context of data-gathering registries, is desirable, if available.
 6. These recommendations are intended as a guide to treat patients but individual treatment decisions could allow treatment outside of the parameters listed above with appropriate discussion with the patient.

The American Society of Radiation Oncology (ASTRO) (2009), *Consensus Statement of Accelerated Partial Breast Irradiation* was updated in 2016. The task force proposed three patients groups; 1) a “suitable” group for whom APBI outside a clinical trial is acceptable, 2) a “cautionary” group for whom caution and concern should be applied when considering APBI outside of a clinical trial, and 3) an “unsuitable” group, for whom APBI outside of a clinical trial is not generally considered warranted. Patients who choose treatment with APBI should be informed that whole breast irradiation is an established treatment with a much longer track record that has documented long-term effectiveness and safety. The suitable group selection criteria includes women 50 years or older, stage T1 breast cancer, negative margins by at least 2 mm, and in DCIS which has been screen-detected, is low to intermediate nuclear grade, size less than or equal to 2.5 cm, and resected with margins negative at greater than or equal to 3 mm. Electron beam IORT should be restricted to women with invasive cancer considered “suitable” for PBI while low-energy x-ray IORT for PBI should be used within the context of a prospective registry or clinical trial. Patients should be counseled that the risk of ipsilateral breast tumor recurrence was higher with IORT

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
19294	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (list separately in addition to code for primary procedure) <i>(effective 1/1/2018)</i>

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Code	Description
19296	Placement of radiotherapy afterloading balloon catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19297	Placement of radiotherapy afterloading balloon catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (list separately in addition to code for primary procedure)
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
0394T (E/I)	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
0395T (E/I)	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed

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HCPCS Codes

Code	Description
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie
C1717	Brachytherapy source, non-stranded, high dose rate iridium-192, per source
C2634	Brachytherapy source, high activity, iodine 125, greater than 1.01 mCi (NIST), per source
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure

ICD10 Codes

Code	Description
C50.011- C50.922	Malignant neoplasm of the breast (code range)
C79.81	Secondary malignant neoplasm of breast
D05.00-D05.92	Carcinoma in situ of the breast (code range)
Z85.3	Personal history of malignant neoplasm of breast

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*Key Article

KEY WORDS

Accelerated partial breast irradiation; APBI, Axxent, Electronic brachytherapy, Interstitial brachytherapy, MammoSite

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Brachytherapy.

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