



Louisiana

Breast Brachytherapy

Policy # 00201

Original Effective Date: 12/01/2006

Current Effective Date: 12/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Intraoperative Radiation Therapy (IORT)

Based on review of available data, the Company may consider breast brachytherapy for breast cancer using intraoperative radiation therapy (IORT) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for breast brachytherapy for breast cancer using intraoperative radiation therapy (IORT) may be considered when **ALL** of the following criteria are met:

- Age 50 or greater; **AND**
- Tumor less than or equal to 3 cm with grossly uninvolved surgical margins; **AND**
- Lymph nodes are grossly negative and negative on intraoperative frozen section if performed; **AND**
- Distance between the edge of the applicator and the skin will be at least 6 mm.

Note: Intraoperative radiation therapy (IORT) is given as a single fraction. More than one fraction is not medically necessary.

Note: If intraoperative radiotherapy was used at the time of surgery but the final pathologic evaluation reveals indications for whole breast irradiation (WBI), the intraoperative radiation therapy (IORT) will be considered the boost portion of the treatment.

Accelerated Partial Breast Irradiation (APBI)

Based on review of available data, the Company may consider breast brachytherapy for breast cancer using accelerated partial breast irradiation (APBI) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for breast brachytherapy for breast cancer using accelerated partial breast irradiation (APBI) may be considered when **ALL** of the following criteria are met:

- Age 45 or greater for invasive disease or greater than 50 for ductal carcinoma in situ (DCIS); **AND**
- Tumor less than or equal to 3 cm with pathologically negative surgical margins; **AND**
- Lymph nodes are negative or show only immunohistochemical involvement, N0 or N0(i+); **AND**
- Distance between the edge of the applicator and the skin is at least 6 mm.

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Note: Accelerated partial breast irradiation (APBI) is delivered with up to 10 fractions delivered twice daily. More than 10 fractions are not medically necessary.

When Services Are Considered Not Medically Necessary

The use of breast brachytherapy for breast cancer when patient selection criteria are not met is considered to be **not medically necessary**.**

The use of breast brachytherapy boost after whole breast radiation therapy is considered to be **not medically necessary**.**

Background/Overview

Accelerated Partial Breast Irradiation

Although the randomized clinical trials supporting radiotherapy have relied on WBI, the majority of the benefit came from reducing recurrence in and immediately adjacent to the lumpectomy site. This observation has prompted investigation of whether local radiation, delivered only to the tumor bed and immediately adjacent tissue, could achieve similar results in selected patients. APBI describes the treatment of the tumor bed alone with an accelerated treatment delivery schedule. Treatment can be given with brachytherapy delivered via implanted single or multilumen catheters, with external beam radiotherapy or with intraoperative radiotherapy given at the time of surgery.

A large cohort of patients who received APBI using the MammoSite^{®‡} applicator have been studied and the 5-year actuarial rate of ipsilateral breast tumor recurrence was 3.8%. More than 90% of patient in this study reported good to excellent cosmesis. Long term high quality data for APBI is currently lacking. The NSABP B-39/RTOG 0413 trial is a prospective, phase 3 trial which randomized patients to WBI versus APBI. The study allowed the APBI to be delivered via brachytherapy or with 3D conformal techniques. Although the results of the study have not been published, a preliminary report of toxicity in the 3D conformal arm was reported in abstract form at the 2011 American Society of Clinical Oncology (ASCO) meeting. Of the 1,386 patients treated with 3D conformal APBI, there were less than 12% with grade 2 toxicity and less than 3% with grade 3 toxicity. In a conflicting report, Canadian investigators comparing WBI with 3D conformal APBI have recently published a report of adverse cosmetic outcomes seen in the RAPID trial. They found that 29% of 3D conformal APBI patients had adverse cosmetic outcomes versus 17% for WBI patients. Until further data are available regarding efficacy and safety are available, the use of 3D conformal or intensity-modulated radiation therapy (IMRT) techniques to deliver APBI are considered not medically necessary.

IORT is a form of APBI in which the entire partial breast treatment is delivered at the time of lumpectomy. Several systems have been approved to deliver treatment with either electrons or 50 kV x-rays. Two large randomized trials of this approach have been published. The ELIOT trial compared electron-based IORT to WBI in women 48 years or older and tumors less than 2.5 cm. For all patients, the ipsilateral breast tumor recurrence rate was 4.4% for the IORT patients vs. 0.4% for the WBI patients ($p < 0.0001$). A subsequent subset analysis looking only patients who qualify as "suitable" for APBI using the American Society for Therapeutic Radiation and Oncology (ASTRO) criteria revealed more favorable recurrence rates of 1.5%

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with electron IORT. Results of the TARGIT-A trial were recently updated and with a shorter median follow-up of 29 months they reported a local recurrence rate of 3.3% for IORT vs. 1.3% for WBI. When only the patients treated at the time of lumpectomy are considered, the local recurrence rates were 2.1% for IORT vs. 1.1% for WBI. In these patients, if high-risk features such as positive margins, extensive intraductal component, lobular histology, high grade histology, lymphovascular invasion or positive nodes were present on the final pathology, WBI was often added to the treatment. Survival was similar in both arms.

It is recommended that individuals considering APBI as an alternative to WBI be counseled that WBI is the more well-established treatment with documented long-term effectiveness and safety and that treatment with APBI may be associated with an increased risk of local recurrence and need for mastectomy. Society recommendations regarding patient suitability have been published, but are not all in agreement.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2002, the MammoSite Radiation Therapy System (Proxima Therapeutics; Alpharetta, GA), the first device specifically designed for breast brachytherapy, was cleared for marketing by the U.S. FDA through the 510(k) process. Its intended use is “to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.”

Since 2002, several other devices for breast brachytherapy have been cleared for marketing by FDA through the 510(k) process. FDA determined that several devices (eg, Axxent[®] Electronic Brachytherapy System [Xoft; San Jose, CA][‡], Strut-Adjusted Volume Implant [SAVI[™]][‡] Applicator Kit [Biolument (now Cianna Medical); Aliso Viejo, CA], Contura^{®‡} Multi-Lumen Balloon Source Applicator for Brachytherapy [SenoRx; Aliso Viejo, CA], ClearPath^{™‡} Adjustable Multi-Catheter Source Applicator [North American Scientific; Chatsworth, CA], Intrabeam^{®‡} System [Carl Zeiss Surgical; Oberkochen, Germany]) were substantially equivalent to predicate devices. Each includes an FDA-required warning that the safety and effectiveness of the device “as a replacement for whole-breast irradiation in the treatment of breast cancer has not been established.”

Although the Intrabeam System (discussed in the Intraoperative Brachytherapy subsection) is subject to FDA regulation, it does not fall under the regulatory purview of the U.S. Nuclear Regulatory Commission. In some states, participation of radiation oncologists in delivering radiation is not required.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield

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Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Society Recommendations for APBI

The National Comprehensive Cancer Network^{®†} (NCCN, 2017)

Guideline indicates that preliminary studies have shown that APBI may result in similar rates of local control in early breast cancer compared to WBI. They also note that cosmesis may be inferior and follow-up is limited. NCCN recommends treatment with APBI to be provided in a prospective clinical trial when possible. If APBI is provided off trial, then brachytherapy is recommended for those with a low risk of recurrence. They cite the ASTRO criteria for suitable candidates for APBI.

ASTRO

An update to the Evidence-Based Consensus statement was published in 2017. There were several changes in the criteria for who are "Suitable" candidates for APBI. The age for the suitable group was lowered to 50 or older. The criteria were also broadened to include DCIS. The criteria are summarized below:

- Age ≥ 50 y;
- Surgical margins ≥ 2 mm for invasive ductal cancer and ≥ 3 mm for DCIS;
- Size < 2 cm for invasive ductal cancer and < 2.5 cm for DCIS;
- DCIS must be low to intermediate grade and non-palpable;
- No lymphovascular invasion;
- ER positive;
- No invasive lobular cancer.

American College of Breast Surgeons

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 WBI:

- Age 45 years old or older for invasive cancer and age 50 years or older for DCIS;
- Invasive carcinoma or DCIS;
- Total tumor size (invasive and DCIS) less than or equal to 3 cm in size;
- Negative microscopic surgical margins of excision;
- Sentinel lymph node negative.

References

1. AIM Specialty Health, AIM Guidelines for Image Guidance in Radiation Oncology, "Breast Cancer", November 1, 2017. Last Reviewed June 13, 2017.
2. Blue Cross and Blue Shield Association, Medical Policy Reference Manual. "Accelerated Breast Irradiation and Brachytherapy Boost After Breast-Conserving Surgery for Early-Stage Breast Cancer" 8.01.13, 1:2017.

Policy History

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08/02/2006 Medical Director review

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08/09/2006	Medical Policy Committee approval
07/18/2007	Medical Policy Committee approval. Brachytherapy in patients with stage I or II disease as the sole form of radiotherapy after surgical excision is now considered to eligible for coverage with criteria. Rationale replaced.
05/07/2008	Medical Director review
05/21/2008	Medical Policy Committee approval. No change to coverage eligibility.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2015	Coding Update
05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/01/2016	Coding update
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Investigational statement on accelerated partial breast irradiation using an electronic radiotherapy device removed and investigational statement added on Accuboot. Rationale, background, FDA section and references updated.
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage changed to follow AIM Guidelines.
11/15/2017	Coding update
Next Scheduled Review Date:	09/2018

Coding

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Code Type	Code
CPT	0395T, 19296, 19297, 19298, 77295, 77316, 77317, 77318, 77402, 77407, 77412, 77424, 77425, 77469, 77770, 77771, 77772
HCPCS	G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, Q3001
ICD-10 Diagnosis	C50.011-C50.029 C50.111-C50.129 C50.211-C50.229 C50.311-C50.329 C50.411-C50.429 C50.511-C50.529 C50.611-C50.629 C50.811-C50.829 C50.911-C50.929 C79.81

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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