



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Breast Brachytherapy

Policy # 00201

Original Effective Date: 12/01/2006

Current Effective Date: 05/21/2014

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.

Based on review of available data, the Company may consider brachytherapy for the initial treatment of stage I or stage II breast cancer as local boost irradiation when used in conjunction with breast-conserving surgery and whole breast external beam radiotherapy to be **eligible for coverage**.

Based on review of available data, the Company may consider brachytherapy for the treatment of stage I or stage II breast cancer as the sole form of radiotherapy after surgical excision of the tumor to be **eligible for coverage** if the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for the use of breast brachytherapy for the treatment of stage I or stage II breast cancer as the sole form of radiotherapy after surgical excision of the tumor is considered to be eligible for coverage when all of the following criteria are met:

- Age 45 years old or greater; and
- Invasive carcinoma or ductal carcinoma in situ (DCIS) and
- Total tumor size (invasive and DCIS) less than or equal to 3 cm in size; and
- Negative microscopic surgical margins of excision; and
- Axillary lymph nodes/sentinel lymph node negative.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers interstitial or balloon brachytherapy for treatment of stage I or II breast cancer to be **investigational*** when patient selection criteria are not met.

Based on review of available data, the Company considers interstitial or balloon brachytherapy to be **investigational*** for local boost irradiation when combined with whole breast radiotherapy but without surgical excision.

Based on review of available data, the Company considers accelerated partial breast irradiation using an electronic radiotherapy device to be **investigational.***



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Background/Overview

Breast conservation therapy (BCT) is a multi-modality alternative to mastectomy to treat early (stage I or II) breast cancer. In current practice, most conventional BCT includes breast-conserving surgical excision of the tumor (lumpectomy, segmentectomy or quadrantectomy) and whole-breast radiotherapy (WBRT), delivered 5 days/week over 5–7 weeks using external beam radiation (EBR). For those at higher risk of recurrence (based on age younger than 50 years, tumor size greater than 2-3 cm, nodal involvement, inadequate tumor-free margins, etc.), "boost" radiotherapy narrowly directed to the tumor bed is included in WBRT. In randomized trials, WBRT reduced local (i.e., in-breast) recurrence, and meta-analysis showed it also improved survival compared with breast-conserving surgery alone. Other trials and meta-analysis showed that efficacy of BCT with WBRT is equivalent to mastectomy. The radiation is hypothesized to eliminate residual cancer near the surgical site and treat any undetected multicentric disease. Radiation alone (i.e., without resection) is not recommended in current guidelines to manage early breast cancer.

Breast brachytherapy uses radiation sources placed inside the breast. Interstitial brachytherapy uses multiple sources spaced in two or more planes through the breast, with computerized treatment planning to optimize dose homogeneity in the target. The number, spacing, and radiation strength of sources vary with the breast volume to be treated. Balloon brachytherapy uses a single source placed in an inflatable catheter inside the surgical cavity. It treats the cavity plus a surrounding margin of 1–2 cm, with radiation dose declining as a function of distance from the source.

Differences between interstitial and balloon brachytherapy in geometry and target dose homogeneity are of less concern for boost therapy, since the target volume is limited to the tumor bed close to the radiation source. External beam radiation separate from the boost adequately treats breast tissue outside the tumor bed.

However, when brachytherapy is used alone without EBR to the remaining breast, i.e., for partial breast irradiation (PBI), target volume extends beyond the tumor bed, and these differences may have greater impact on outcomes. For PBI, it is thus uncertain whether outcomes of interstitial brachytherapy could be used to reliably predict outcomes of balloon brachytherapy.

Methods other than brachytherapy are also used for PBI, such as several types of external beam therapy. They are not discussed in this policy.

This policy separately addresses use of interstitial or balloon brachytherapy as alternatives to EBR therapy in two settings:

1. To replace external beam for boost radiation therapy, combined with whole-breast EBR therapy and breast-conserving surgery.
2. Alone, for accelerated partial breast radiation therapy after breast-conserving surgery.

This second, more recent application of brachytherapy methods is based partly on the observation that most ipsilateral breast recurrences after breast-conserving surgery and radiation therapy occur near the tumor bed, with only a minority of recurrences located elsewhere in the breast. In addition, in trials of breast-conserving surgery with versus without radiation therapy, most recurrences also occurred near the



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tumor bed, suggesting that undetected multicentric disease may not be common. Together these findings suggested that tumor bed irradiation may provide the major benefit from whole-breast EBR therapy. Also, the extended treatment course for WBRT may be difficult for some patients, for example, those living in remote locations, or the elderly or disabled.

Both methods of brachytherapy usually are delivered over a week. This shortened, more convenient treatment course, which has been termed accelerated partial-breast irradiation (APBI), may increase the proportion of patients choosing breast-conserving surgery. On the other hand, APBI may sacrifice some or all of the radiobiological advantage associated with fractionated doses and the slower repair of sublethal radiation damage in tumor versus normal cells.

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. Most of the older studies of local boost brachytherapy temporarily implanted needles, wires or seeds after patients recovered from surgery and completed WBRT. Since the 1990s, investigators have perioperatively implanted hollow needles or catheters that guide placement of the radioactive material. This can be done during the initial lumpectomy if brachytherapy has been selected already or at re-excision if the lumpectomy specimen has positive surgical margins. Intraoperative implantation avoids the need for a separate surgical procedure with anesthesia for brachytherapy.

Both low- and high-dose rate interstitial techniques are used, with high-dose rate techniques increasing in popularity. In the low-dose rate technique, radioactive seeds are temporarily implanted in hospitalized patients. They deliver radiation continuously over four days and then are 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—e.g., 15 minutes—and then the radioactive sources are withdrawn. High-dose rate brachytherapy is typically administered to outpatients as 8 fractions given twice daily over 4 days.

A balloon catheter system (the Mammosite™ RTS device; Cytoc Corp; Alpharetta, GA)[‡] is also available for brachytherapy. The device is implanted in the lumpectomy cavity during or shortly after breast-conserving surgery. The balloon is inflated with sterile solution of contrast media in saline solution, 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. Thus, balloon brachytherapy uses a single radioactive source that delivers radiation to a spherical or elliptical target volume. Like interstitial brachytherapy, it can be used to deliver local boost or accelerated partial-breast radiation therapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The various radiotherapy modalities presented in this report have been approved or cleared for marketing by the U.S. FDA (for more details, see Appendix in TEC 2010). All brachytherapy devices have been approved through the 510(k) process and are either balloon brachytherapy or hybrid balloon-interstitial



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brachytherapy devices. The FDA has required a black box warning on each stating that “The safety and effectiveness of the ... [brachytherapy device] as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.”

Centers for Medicare & Medicaid Services (CMS)
There is no national coverage determination.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual. “Accelerated Breast Irradiation after Breast-Conserving Surgery for Early Stage Breast Cancer and Breast Brachytherapy as Boost with Whole-Breast Irradiation” 8.01.13, 12:2013.
2. Blue Cross and Blue Shield Association. Brachytherapy for Accelerate Partial Breast Irradiation after Breast-Conserving Surgery for Early Stage Breast Cancer. TEC Assessment, December 2002, 17(18).
3. American College of Radiology. ACR Practice Guideline for Breast Conservation Therapy in the Management of Invasive Breast Carcinoma. 1/1/2002.
4. American College of Radiology. ACR Practice Guideline for the Performance of Low-Dose Rate Brachytherapy. 10/01/2000.
5. American College of Radiology. ACR Practice Guideline for the Performance of High-Dose-Rate Brachytherapy. 10/01/2005.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0182T, 19296, 19297, 19298, 20555, 77261, 77262, 77263, 77280, 77285, 77290, 77295, 77326, 77327, 77328, 77370, 77431, 77750, 77761, 77762, 77763, 77776, 77777, 77778, 77785, 77786, 77787, 77789, 77790, 77799
HCPCS	C1717, C9726, Q3001
ICD-9 Diagnosis	174.0 thru 174.9, 175.0 thru 175.9, 198.81
ICD-9 Procedure	85.0, 92.27

Policy History

Original Effective Date: 12/01/2006
Current Effective Date: 05/21/2014

08/02/2006 Medical Director review
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.

Next Scheduled Review Date: 05/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

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**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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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.