

Corporate Medical Policy

Brachytherapy Treatment of Breast Cancer

File Name: brachytherapy_treatment_of_breast_cancer
Origination: 7/1996
Last CAP Review: 5/2010
Next CAP Review: 5/2011
Last Review: 5/2010

Description of Procedure or Service

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 2 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 external beam radiation therapy in two settings:

1. To replace external beam for boost radiation therapy, combined with whole-breast external-beam radiation 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

Brachytherapy Treatment of Breast Cancer

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 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 external beam radiation 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 whole-breast radiation therapy. 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 4 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; Cytac 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.

In December 2005, the U.S. Food and Drug Administration (FDA) cleared the Axxent Electronic Radiotherapy device (Xoft, Inc., Fremont, CA) via 510(k) as substantially equivalent to the Mammosite and other brachytherapy systems. The Axxent device is a balloon brachytherapy system that uses a disposable, microminiature radiation source to deliver the radiation rather than radioisotopes. Additional brachytherapy devices have received FDA 510(k) marketing clearance, e.g., the SenoRad multi-lumen balloon source applicator for brachytherapy (SenoRx, Inc., Aliso Viejo, CA, May 18 2007).

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Brachytherapy Treatment of Breast Cancer when it is determined to be medically necessary because the medical criteria and guidelines shown below are

Brachytherapy Treatment of Breast Cancer

met.

Some members may be eligible for specific coverage of accelerated partial breast radiotherapy through their benefit plan. Please see Accelerated Partial Breast Radiotherapy. (Breast Brachytherapy)

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Brachytherapy Treatment of Breast Cancer is covered

When the following criteria are met:

- Brachytherapy is used for patients undergoing initial treatment for stage I or II breast cancer when used as local boost irradiation in patients who are also treated with breast-conserving surgery **and** whole breast external beam radiotherapy.

When Brachytherapy Treatment of Breast Cancer is not covered

1. When the above medical criteria are not met
2. Brachytherapy is considered investigational when used in patients with Stage I or II diseases as the **sole** form of radiotherapy after surgical excision.
3. Brachytherapy is considered investigational for local boost irradiation when combined with whole breast radiotherapy **but without** surgical excision.
4. Accelerated partial breast irradiation using an electronic radiotherapy device is considered investigational.

Policy Guidelines

Refer to the individual certificate for prior plan review/precertification requirements.

In review of the MammoSite® website in April 2009 the following statement was included in their information "About MammoSite®" that states; "The safety and effectiveness of the MammoSite® as a replacement for whole breast irradiation in the treatment of breast cancer has not been established."

The FDA 510k clearance for the MammoSite® device issued May 2002 and Axxent issued in 2005 requires of the manufacturer of the devices: "in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear 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."

"The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole

Brachytherapy Treatment of Breast Cancer

breast irradiation in the treatment of breast cancer has not been established."

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0182T, 19296, 19297, 19298, 77326, 77776, 77777, 77778, 77785, 77786, 77787.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

TEC Assessment - 5/96

National Association issued policy 7/96

Medical Policy Advisory Group Review 3/99

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel 11/2001

BCBSA Medical Policy Reference Manual, 8.01.13; 5/15/2002

BCBSA Medical Policy Reference Manual, 8.01.13; 12/16/02

Specialty Matched Consultant Advisory Panel - 10/2003

The American Society of Breast Surgeons. (2003, April). Consensus statement for accelerated partial breast irradiation. Retrieved 8/4/2004 from <http://www.breastsurgeons.org/officialstmts/officialstmt3.shtml>.

ECRI Target Report # 829. (2003, November). Intracavitary balloon brachytherapy for early-stage breast cancer. Retrieved on 1/24/04 from http://65.213.73.177/summary/detail.aspx?doc_id=4921.

NCCN Practice Guidelines in Oncology. (2004, April). Breast cancer. Retrieved 10/7/04 from http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf.

ICSI. (2004, September). Breast cancer treatment health care guideline. Retrieved 10/7/04 from <http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=54>.

Proxima Therapeutics, Inc. (2004). About mammosite. Retrieved 10/8/04 from http://www.proxima.org/mammo_abomamrts.asp.

Brachytherapy Treatment of Breast Cancer

Medical Policy Advisory Group - 12/2/2004

"Phase III Randomized Study of Adjuvant Whole Breast Versus Partial Breast Irradiation in Women with Ductal Carcinoma In Situ or Stage I or II Breast Cancer" (Protocol IDs NSABP-B-39, NCT00103181, RTOG-0413, SWOG-NSABP-B-39). Retrieved 9/20/05 from <http://cancernet.nci.nih.gov/search/View-ClinicalTrials.aspx?cdrid=409590&version=HealthProfessional&protocolsearchid=1840297>.

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 11/9/04

Specialty Matched Consultant Advisory Panel - 9/2005

The American Society of Breast Surgeons. (2005, December). Consensus statement for accelerated partial breast irradiation. Retrieved 1/29/07 from <http://www.breastsurgeons.org/apbi.shtml>.

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 10/10/06

National Comprehensive Cancer Network. Breast Cancer. Clinical practice guidelines in oncology, V.1.2007. Retrieved 1/29/07 from http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf

CYTYC Corporation. (2007). MammoSite targeted radiation therapy. About MammoSite RTS. Retrieved 3/27/07 from <http://www.mammosite.com/mammosite-about.htm>

Xoft Incorporated. (2007). Axxent electronic brachytherapy system. Breast cancer and brachytherapy. Retrieved 6/18/07 from <http://www.xoftmicrotube.com/axxentproductoverview.html>.

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 4/17/2007

BCBSA Technology Evaluation Center. (2007). Accelerated partial breast irradiation as sole radiotherapy after breast-conserving surgery for early stage breast cancer. Retrieved 6/1/2007 from <http://www.bcbsa.com/betterknowledge/tec/press/accelerated-partial-breast.html>.

Specialty Matched Consultant Advisory Panel - 8/2007

CYTYC Corporation. (2009). MammoSite targeted radiation therapy. About MammoSite RTS. Retrieved 4/24/09 from <http://www.mammosite.com/physicians/radiation-therapy/about-mammosite.cfm>

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 4/17/2007

Specialty Matched Consultant Advisory Panel - 8/2009

BCBSA Medical Policy Reference Manual [Electronic version] 8.01.13, 5/2008

Specialty Matched Consultant Advisory Panel 5/2010

Policy Implementation/Update Information

- 7/96 Original policy issued.
- 11/96 Reaffirm: National policy issued 7/96. No changes.
- 3/99 Reviewed by MPAG. Reaffirmed.
- 6/99 Reformatted, Description of Procedure or Service revised, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 10/00 System coding changes.
- 11/01 Coding format change.
- 11/01 Specialty Matched Consultant Advisory Panel - Revised section under when it is covered. Format changes.
- 8/02 Reaffirmed. Source added to Scientific Reference Sources section.

Brachytherapy Treatment of Breast Cancer

11/03 Specialty Matched Consultant Advisory Panel review. No change in criteria. Updated Billing/Coding and Benefit Application sections. Scientific sources added.

11/25/04 No change in criteria for coverage. Added rationale to Policy Guidelines section. Added CPT code 77326 and 77781 to Billing/Coding section. References added. Notice given 11/25/2004. Effective date 2/3/2005.

2/3/05 Policy reviewed at the Medical Policy Advisory Group meeting 12/2/2004. No changes to criteria. Corrected wording from incision to excision under the second bullet in the When Brachytherapy Treatment of Breast Cancer is not covered section. Added new 2005 CPT codes 19296, 19297, and 19298 to Billing/Coding section.

10/8/05 Specialty Matched Advisory Panel review 9/19/2005. Updated "Description of Procedure or Services" section. Added the statement; "BCBSNC will cover partial breast radiotherapy when performed in a National Cancer Institute-approved Phase III Clinical Trial (for members who have clinical trial benefits). An example of such a trial is "Phase III Randomized Study of Adjuvant Whole Breast Versus Partial Breast Irradiation in Women with Ductal Carcinoma In Situ or Stage I or II Breast Cancer" (Protocol IDs NSABP-B-39, NCT00103181, RTOG-0413, SWOG-NSABP-B-39). Information regarding this trial can be found at <http://cancernet.nci.nih.gov>. ***Please note that prior approval for phase III clinical trials is required for BCBSNC members." to the "Policy" section. Added "Partial breast radiotherapy when performed in a National Cancer Institute-approved Phase III Clinical Trial for members who have clinical trial benefits." under the "When covered" section. Rationale updated in the "Policy Guidelines" section. Key words added. "3-D conformal external beam radiation" and "lumpectomy" added to "Medical Term Definitions". References added.

4/1/07 Added statement in "Policy" section, "Some patients may be eligible for specific coverage of accelerated partial breast radiotherapy through their benefit plan. Please see Accelerated Partial Breast Radiotherapy (Breast Brachytherapy), policy number ADM9100." Removed the following from the "Policy" section; "BCBSNC will cover partial breast radiotherapy when performed in a National Cancer Institute-approved Phase III Clinical Trial (for members who have clinical trial benefits). An example of such a trial is "Phase III Randomized Study of Adjuvant Whole Breast Versus Partial Breast Irradiation in Women with Ductal Carcinoma In Situ or Stage I or II Breast Cancer" (Protocol IDs NSABP-B-39, NCT00103181, RTOG-0413, SWOG-NSABP-B-39). Information regarding this trial can be found at <http://cancernet.nci.nih.gov>." Removed coverage indication under the "When Covered" section indicating "Partial breast radiotherapy when performed in a National Cancer Institute-approved Phase III Clinical Trial for members who have clinical trial benefits." Updated "Policy Guideline" section and added statement, "Refer to the individual certificate for prior approval/precertification requirements." References added.

7/16/07 Added new CPT code 0182T to "Billing/Coding" section.

9/24/07 Specialty Matched Consultant Advisory Panel review 8/23/2007. No changes to policy statement. "Policy Guidelines" updated to add information regarding the "Axxent" device. References added.

1/5/09 Added new CPT codes 77785, 77786, and 77787 to the "Billing/Coding" section. Removed deleted CPT codes 77781 and 77782. (btw)

10/12/09 Specialty Matched Consultant Advisory Panel review 8/28/09. "Description" section revised. Added an additional indication under the "When Not Covered" section to state; "Accelerated partial breast irradiation using an electronic radiotherapy device is considered investigational." Updated the rationale in the "Policy Guidelines" section. Removed "3-D conformal external beam radiation" from the "Definitions" section. References added. Notice given 10/12/09. Policy effective 1/19/2010. (btw)

6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/10. Removed Medical Policy number. No policy statement changes. References updated. (lr)

Brachytherapy Treatment of Breast Cancer

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.