



Corporate Medical Policy

Brachytherapy Treatment of Breast Cancer

File Name: brachytherapy_treatment_of_breast_cancer
Policy Number: RAD5020
Origination: 7/1996
Last Review: 8/2007
Next Review: 8/2009

Description of Procedure or Service

Breast conservation therapy (BCT) involves various treatment modes that offer an alternative to [mastectomy](#) for treatment of stage I or II breast cancer. Brachytherapy is a term given to a treatment that involves placing radioactive material directly in the tissue near the tumor. This allows a higher radiation dose than possible with external beam radiation therapy. It also provides a better chance for local control. When brachytherapy is included in breast conservation therapy, it has largely been used as a source of local boost irradiation. This means it has been used in conjunction with breast-conserving surgery and whole breast external-beam radiation therapy.

There are two types of partial radiation brachytherapy currently being studied in clinical trials. The study is to compare whole breast radiation to partial breast radiation as sole form of radiotherapy for the treatment of stage I and II breast cancer after [lumpectomy](#). Multicatheter brachytherapy uses 15 -20 hollow tubes that are placed at the [lumpectomy](#) site. Radioactive pellets are inserted into the tubes and left in place for several minutes and then the pellets are removed. The tubes are left in place for 1-2 weeks of treatment. Balloon catheter brachytherapy (MammoSite®) uses only one tube with a balloon on the end. The balloon is inserted into the [lumpectomy](#) site and left in place. A radioactive substance is placed into the balloon delivering radiation to the walls of the [lumpectomy](#) cavity twice a day for 5 days of treatment.

The National Cancer Institute is sponsoring a prospective randomized clinical trial which began in 2005 to compare the safety and efficacy of partial breast irradiation to that of the standard whole breast irradiation. The study will include three types of partial radiation; multi-catheter brachytherapy, balloon catheter brachytherapy such as MammoSite®, and [3-D conformal external beam radiation](#).

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 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), policy number ADM9100.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

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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

- ◆ When the above medical criteria are not met
- ◆ Brachytherapy is considered investigational when used in patients with Stage I or II diseases as the **sole** form of radiotherapy after surgical excision.
- ◆ Brachytherapy is considered investigational for local boost irradiation when combined with whole breast radiotherapy **but without** surgical excision.

Policy Guidelines

Refer to the individual certificate for prior approval/precertification requirements.

In a 2007 literature search and review of independent technology evaluation services there were no published reports from controlled studies comparing long-term rates of in-breast recurrence after whole-breast versus accelerated partial-breast radiotherapy. In review of the MammoSite® website in January 2007 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."

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.

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Policy Key Words

Key Words: Brachytherapy, Breast, BCT, Radiotherapy, Cancer, MammoSite, partial breast irradiation, accelerated partial breast irradiation, lumpectomy, mastectomy, 3-D conformal external beam radiation, Axxent, RAD5020

Medical Term Definitions

Lumpectomy

is the excision of a breast tumor (lump or mass) including a limited amount of surrounding tissue.

Mastectomy

a surgical removal of all or a part of the breast, generally performed for breast cancer or breast disease.

3-D conformal external beam radiation

is external radiation to the breast targeted only to the tumor site and a small amount of tissue around the area instead of irradiating the whole breast.

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.

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

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->

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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

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CYTEC 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

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.
- 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 per-

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formed 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.

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.