

Corporate Medical Policy

Breast Brachytherapy for Accelerated Partial Breast Radiotherapy

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Description of Procedure or Service

Radiation therapy is the standard of care for patients with breast cancer undergoing breast-conserving surgery (BCS), as it reduces recurrences and lengthens survival. Nonetheless, not all patients undergo radiation therapy following breast-conserving surgery; the duration and logistics of treatment may be barriers for some women as the conventional whole breast radiation therapy regimen consists of about 25 treatments of 2 Gray (Gy) delivered over 5-6 weeks. Accelerated radiotherapy approaches have been proposed to make the regimen less burdensome for patients with early stage breast cancer at low risk of recurrence:

- Accelerated (also called hypofractionated) whole-breast irradiation (AWBI) reduces the number of fractions and the duration of treatment to about 3 weeks. This approach has been commonly used in Canada and Europe.
- Accelerated partial-breast irradiation (APBI) irradiates a limited part of the breast in and close to the tumor cavity. By reducing the area irradiated, fewer treatments are needed and the total treatment takes about 1 week. Several approaches can be used to deliver APBI, including interstitial brachytherapy, intracavitary (Balloon) brachytherapy, external beam radiotherapy,

The critical question is whether these three approaches are equivalent in outcomes and adverse events to the conventional radiation therapy regimen.

Background

Breast Conservation Therapy

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 multimodality treatment that initially consisted of breast conservation surgery (BCS) to excise the tumor with adequate margins, followed by whole-breast external-beam radiation therapy administered as 5 daily fractions per week over 5 to 6 weeks. Local boost irradiation 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, sentinel lymph node biopsy, or irradiation of the axilla. A number of randomized, controlled trials (RCTs) have demonstrated that the addition of radiotherapy after BCS reduces recurrences and mortality. In an individual-level meta-analysis, the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) reported that radiotherapy halved the annual recurrence rate after 10 years for women with node-negative disease (n=7,287) from 31.0% for those not receiving radiotherapy to 15.6% for those receiving it. It also reduced the 15 year risk of breast cancer death from 20.5% to 17.2% (p=0.005). For women with node-positive disease (n=1,050) radiotherapy reduced the 1 year recurrence risk from 26.0% to 5.1%. Radiotherapy also reduced the 15 year risk of breast cancer death from 51.3 to 42.8% (p=0.01). Consequently, radiation therapy is generally recommended following BCS.

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Controversy continues on the length of follow-up needed to determine whether APBI is equivalent to whole breast irradiation. However, the issue may be resolved by statistical issues rather than biological ones. Because recurrences are relatively rare among low-risk early breast cancer patients, it may take considerable time for there to be enough recurrences to achieve sufficient power to compare rates for each radiotherapy approaches. Additionally, radiation-induced adverse cardiovascular effects and radiation-induced non breast cancers tend to occur 10 or more years after treatment. For example, in the large NSABP-39/RTOG 0413 trial comparing whole breast irradiation versus APBI, enrollment has reached the revised target of 4,214. The length of the trial (presumably barring early termination) is determined by the occurrence of a pre-specified number (175) of in-breast recurrences. The researchers expect that reaching that number of recurrences will take about 10 years.

Most patients diagnosed with stage I or II breast cancer now are offered a choice of BCT or modified radical mastectomy, but BCT is selected less often than expected. Studies have shown that those living furthest from treatment facilities are least likely to select BCT instead of mastectomy and most likely to forgo radiation therapy after breast-conserving surgery. A study using data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registries from 1992 to 2002 examined how many women with early stage (I or II) breast cancer received radiotherapy within 4 months following breast-conserving surgery. After adjusting for age, they found that in 2002, 30.8% of Caucasian women and 44.7% of African-American women had not received radiotherapy. Furthermore, these rates had increased from 24.7% for Caucasians and 34.0% for African Americans in 1992.

Given that duration and logistics appear to be barriers to completion of treatment, there has been interest in developing shorter radiotherapy regimens. Two approaches have been explored.

The first method is to provide the same dose to the whole breast in a shorter time by increasing the dose provided per treatment (hypofractionation). This approach was initially avoided out of concern that increasing doses might induce more severe adverse events from radiation exposure, thus, tipping the balance between benefits and harms. More recent research, some of which is highlighted below, has allayed most of these concerns. Accelerated whole breast irradiation (AWBI) has been used especially in Canada and Europe.

The second approach to reducing radiotherapy treatment time is accelerated partial breast irradiation (APBI). It differs from conventional whole-breast irradiation in several ways. First, the radiation only targets the segment of the breast surrounding the area where the tumor was removed, rather than the entire breast. This approach was based in part on the finding that recurrences are more likely to occur close to the tumor site rather than elsewhere in the breast. Second, the duration of treatment is 4 to 5 days (or 1 day with intraoperative radiotherapy) rather than 5 to 6 weeks, because the radiation is delivered in fewer fractions at larger doses per fraction to the tumor bed. Third, the radiation dose is intrinsically less uniform within the target volume when APBI uses brachytherapy (i.e., the implantation of radioactive material directly in the breast tissue).

*****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 Breast Brachytherapy for Accelerated Partial Breast Radiotherapy when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

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

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design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Breast Brachytherapy for Accelerated Partial Breast Radiotherapy is covered

- 1) Breast Brachytherapy for Accelerated Partial Breast Radiotherapy is considered medically necessary when the American Society of Breast Surgeons (ASBS) or the American Brachytherapy Society (ABS) criteria are met.

The American Society of Breast Surgeons (ASBS) criteria are as follows:

- a) The patient is 45 years old or older for invasive cancer and age 50 years or older for DCIS, **AND**
- b) The patient has invasive ductal carcinoma or ductal carcinoma in situ (DCIS), **AND**
- c) The total tumor size (invasive and DCIS) is less than or equal to 3 cm in size, **AND**
- d) There are negative microscopic surgical margins of excision, **AND**
- e) The axillary lymph nodes/sentinel lymph nodes are negative (Not applicable with a diagnosis of DCIS);

OR

The American Brachytherapy Society (ABS) criteria are as follows:

- a) Age \geq 50, **AND**
- b) Size \leq 3 cm, **AND**
- c) All invasive subtypes and DCIS, **AND**
- d) Estrogen Receptor Positive or Negative, **AND**
- e) Surgical margins negative, **AND**
- f) Lymphovascular space invasion absent, **AND**
- g) Nodal status negative.

- 2) Breast Brachytherapy with interstitial or balloon brachytherapy may be considered medically necessary for patients undergoing initial treatment for stage I or II breast cancer when used as a local boost irradiation in patients who are also treated with breast conserving surgery and whole breast external beam radiotherapy.

When Breast Brachytherapy for Accelerated Partial Breast Radiotherapy is not covered

- 1) Breast Brachytherapy for Accelerated Partial Breast Radiotherapy is considered not medically necessary when criteria from when the American Society of Breast Surgeons (ASBS) or the American Brachytherapy Society (ABS) are not met.
- 2) Breast Brachytherapy with interstitial or balloon brachytherapy is considered not medically necessary when the criteria above under “When Breast Brachytherapy for Accelerated Partial Breast Radiotherapy is covered” are not met.
- 3) Non-invasive brachytherapy using Accuboot is considered investigational for patients who have undergone an initial treatment for stage I or II breast cancer when used as a local boost irradiation in patients who are also treated with BCS and whole breast external beam radiotherapy.

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- 4) Accelerated partial breast irradiation, using an electronic radiotherapy device, is considered investigational.

Policy Guidelines

Refer to the member's benefit booklet for prior plan review/precertification requirements.

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.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0395T, 19294, 19296, 19297, 19298, 77316, 77770, 77771, 77772, 77778

Diagnoses that are subject to medical necessity review: C50.0 - C50.929, C79.81, D05.10, D05.11, D05.12

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

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

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

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BCBSA Technology Evaluation Center. (2007). Accelerated partial breast irradiation as soleradiotherapy 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>.

Senior Medical Director review - 8/2007

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 5/8/2008

Specialty Matched Consultant Advisory Panel - 8/2009

Food and Drug Administration (FDA) Website:
www.accessdata.fda.gov/cdrh_docs/pdf9/K092405.pdf

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The American Society of Breast Surgeons. (2005 December). Consensus statement for accelerated partial

breast irradiation. Retrieved 8/2/11 from http://breastsurgeons.org/statements/PDF_Statements/APBI_statement_revised_100708.pdf

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BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 4/14/11 Specialty Matched Consultant Advisory Panel 8/2011

The American Society of Breast Surgeons. (2005 December). Consensus statement for accelerated partial breast irradiation. Retrieved 7/18/12 from http://breastsurgeons.org/statements/PDF_Statements/APBI_statement_revised_100708.pdf

CYTYC Corporation. (2012). MammoSite targeted radiation therapy. About MammoSite RTS. Retrieved 7/18/12 from <http://www.mammosite.com/physicians/radiation-therapy/about-mammosite.cfm>

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Specialty Matched Consultant Advisory Panel 8/2012

CYTYC Corporation. (2012). MammoSite targeted radiation therapy. About MammoSite RTS.

Retrieved 5/30/13 from <http://www.mammosite.com/physicians/radiation-therapy/about-mammosite.cfm>

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BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 4/11/13

Specialty Matched Consultant Advisory Panel 5/2013

The American Society of Breast Surgeons. Consensus statement for accelerated partial breast irradiation. Retrieved 3/18/14 from https://www.breastsurgeons.org/new_layout/about/statements/PDF_Statements/APBI.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 12/12/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 2/13/14

Specialty Matched Consultant Advisory Panel 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 12/11/14

Specialty Matched Consultant Advisory Panel 5/2015

Specialty Matched Consultant Advisory Panel 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 1/12/17

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American Brachytherapy Society (ABS). <https://www.americanbrachytherapy.org/>
Accessed 1/19/18.

Senior Medical Director review 1/2018

Specialty Matched Consultant Advisory Panel 5/2018

Medical Director review 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.13, 7/12/18

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

Policy Implementation/Update Information

For Policy Titled: Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

- 4/1/07 New policy implemented. See policy entitled, Brachytherapy Treatment for Breast Cancer, for those plans that do not offer specific coverage for accelerated partial breast radiotherapy.
- 7/16/07 Added new CPT code 0182T to "Billing/Coding" section.
- 9/24/07 Senior Medical Director review 8/23/2007. Added statement, e. "(Not applicable with a diagnosis of DCIS)" and "***Please note that node sampling is not routinely done with a diagnosis of DCIS and would not be required to meet the criteria." to the "When Covered" section. "Policy Guidelines" updated to add information regarding the "Axxent" device. References added.
- 1/5/09 Removed deleted CPT codes 77781 and 77782 from the "Coding/Billing" section. Added new CPT codes "77785, 77786, and 77787". (btw)
- 10/12/09 Specialty Matched Consultant Advisory Panel review 8/28/2009. Added statement to "Description" section indicating; "***Note: The Medical Policy on accelerated partial breast radiotherapy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician." No changes to policy statement. Updated rationale in the "Policy Guidelines" section and removed reference to "Axxent" as it does not apply to this policy. Reference added.
- 6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/10. Removed CPT 0182T from "Billing Code Section" The code is not specific to the Accelerated Partial Breast Radiotherapy policy, it is investigational and is noted in the Breast Brachytherapy policy. No changes to policy statement. (lpr)
- 9/13/11 Description section extensively revised. Under "When Not Covered" added Accelerated partial breast irradiation using an electronic radiotherapy device is considered investigational. Specialty Matched Consultant Advisory Panel review 8/31/2011. (lpr)

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- 9/4/12 Specialty Matched Consultant Advisory Panel review 8/15/2012. No change to policy statement. (lpr)
- 7/1/13 Updated the Description section. Specialty Matched Consultant Advisory Panel review 5/15/2013. Reference added. No change to policy statement. (lpr)
- 4/15/14 Updated the Description section and Regulatory status. Under “When Covered” section added to statement a.: The patient is 45 years old or **older** for invasive cancer and **age 50 years or older for DCIS.** References updated. Medical director review 3/2014. Policy noticed on 4/15/14 for effective date 7/1/14. (lpr)
- 7/29/14 Specialty matched consultant advisory panel review meeting 6/24/14. No change to policy statement. (lpr)
- 12/30/14 Added CPT code 77316 and deleted CPT code 77326 in Billing/Coding section for effective date 1/1/2015. (lpr)
- 2/10/15 Updated Description section. No change to policy statement. Reference added. (lpr)
- 7/1/15 Specialty Matched Advisory Panel review 5/27/2015. No change to policy statement. (lpr)
- 12/30/15 Added the following CPT codes: 77770, 77771, 77772 and deleted the following CPT codes: 77776, 77777, 77785, 77786, 77787 in Billing/Coding section for effective date 1/1/2016. (lpr)
- 2/29/16 Added the following ICD-10 diagnoses codes to the Billing/Coding section: Diagnoses that are subject to medical necessity review: C50.0 - C50.929, C79.81, D05.0 – D05.92, D48.60 - D48.62, D49.3 (Effective 3/11/2016). No change to policy statement. (lpr)
- 7/1/16 Specialty Matched Advisory Panel review 5/25/2016. No change to policy statement. (lpr)

ForPolicy Titled: Breast Brachytherapy for Accelerated Partial Breast Radiotherapy

- 2/9/18 Extensive revisions of the entire policy. “Brachytherapy Treatment of Breast Cancer” policy archived and content that is pertinent combined with this Accelerated Partial Breast Radiotherapy policy. Title changed from Accelerated Partial Breast Radiotherapy to Breast Brachytherapy for Accelerated Partial Breast Radiotherapy. Updated Description section and removed benefit statement from top of page 1 as well as in Policy section. Added American Brachytherapy Society (ABS) criteria to “When Covered” section. Added the following ICD-10 codes to the “Billing/Coding section: D05.10, D05.11, D05.12; deleted the following ICD-10 codes: D05.0-D05.92, D48.60-D48.62, D49.3. Reference added. Senior Medical Director review 1/2018. (lpr)
- 6/8/18 Specialty Matched Consultant Advisory Panel review 5/2018. No changes to policy statements. Medical Director review 5/2018. (mco)
- 6/11/19 Specialty Matched Consultant Advisory Panel review 5/15/19. No change to policy intent. Reference added. Medical Director review 5/2019. (lpr)

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.

