Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

**File Name:** accelerated_partial_breast_radiotherapy_(breast_brachytherapy)

**Origination:** 4/2007

**Last CAP Review:** 5/2017

**Next CAP Review:** 5/2018

**Last Review:** 5/2018

This policy applies only to members whose benefit plans provide specific coverage for accelerated partial breast radiotherapy (APBR)

**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. The conventional radiation therapy regimen consists of about 25 treatments of 2 Gray (Gy) delivered over 5 to 6 weeks. Nonetheless, not all patients undergo radiation therapy following breast-conserving surgery; the duration and logistics of treatment may be barriers for some women. 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, balloon brachytherapy, external beam radiotherapy, or intraoperative radiotherapy (which occurs on only 1 day).

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-bread 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)
Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

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.

A potential exception is for older women at low risk of recurrence. For example, the National Comprehensive Cancer Network (NCCN) guidelines state that women aged 70 or older may omit radiotherapy if they have estrogen receptor positive, T1 tumors, clinically negative lymph nodes, and plans to take adjuvant endocrine therapy.

Controversy continues on the length of follow-up needed to determine whether APBI is equivalent to whole breast irradiation (for more information, see the most recent update to the TEC Assessment on Accelerated Radiotherapy after Breast-Conserving Surgery for Early Stage Breast Cancer); some 10-year data are already available on accelerated 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).

Brachytherapy Boost with Whole Breast Irradiation
Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

Brachytherapy can also be used as an alternative to external beam radiation therapy to deliver boost radiation therapy combined with whole-breast external-beam radiation therapy. Most of the studies of local boost brachytherapy use temporarily implanted needles, wires, or seeds after patients recovered from surgery and completed whole-breast radiation therapy.

Regulatory Status
The various radiotherapy modalities presented in this report have been approved or cleared for marketing by the U.S. Food and Drug Administration (FDA) (for more details, see Appendix in TEC 2013). All brachytherapy devices have been approved for marketing through the 510(k) process and are balloon brachytherapy hybrid balloon-interstitial brachytherapy devices. One device can provide either intraoperative or intracavity treatments. 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.” The breast brachytherapy applicator used for noninvasive brachytherapy (a precursor of Accuboost ®) was approved for marketing through the 510(k) process in June 2006. It does not have the black box warning.

Related policies:
Brachytherapy Treatment of Breast Cancer

***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

Some BCBSNC benefit plans provide coverage for Accelerated Partial Breast Radiotherapy (Breast Brachytherapy) as an alternative to standard whole breast radiation therapy when the American Society of Breast Surgeons (ASBS) criteria are met. This policy applies only to those benefit plans. All others must refer to the following policy as necessary: Brachytherapy Treatment of Breast Cancer.

BCBSNC provides coverage for Accelerated Partial Breast Radiotherapy (APBR) treatment when used as a local boost in addition to whole breast radiation therapy (WBRT).

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 Accelerated Partial Breast Radiotherapy (Breast Brachytherapy) is covered

Accelerated Partial Breast Radiotherapy is covered when the benefit plan allows coverage, and when the American Society of Breast Surgeons (ASBS) 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
Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

e) The axillary lymph nodes/sentinel lymph nodes are negative (Not applicable with a diagnosis of DCIS).

***Please note that node sampling is not routinely done with a diagnosis of DCIS and would not be required to meet the criteria.

When Accelerated Partial Breast Radiotherapy (Breast Brachytherapy) is not covered

When the above criteria are not met or when the benefit plan does not provide coverage.

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.

In review of the MammoSite® website, 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 requires the manufacturer of the device: "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 website at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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

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)

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


BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 10/10/06
Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)


Senior Medical Director review - 8/2007


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


TEC Assessment 7/2010.


Specialty Matched Consultant Advisory Panel 8/2012

Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)


Specialty Matched Consultant Advisory Panel 5/2017

Policy Implementation/Update Information

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.
Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

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. (Ir)


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)

6/30/17 Specialty Matched Advisory Panel review 5/31/17. No change to policy statement. Reference added. (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.