

Corporate Medical Policy

Accelerated Partial Breast Radiotherapy (Breast Brachytherapy)

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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, 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.

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 consists of 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 5-year risk of local recurrence of 7.3% among breast-conserving-surgery patients allocated to radiotherapy versus 25.9% among those not (2p<0.00001; n=51,958 woman-years). (1) Whole-breast irradiation reduced the 15-year breast cancer mortality risk from 35.9% to 30.5% (breast cancer death rate ratio: 0.83; standard error [SE]=0.05; 95% confidence interval [CI]: 0.75, 0.91; 2p=0.0002; n=7,311 women); there was a similar reduction in mortality from all causes (5.3%, SE=1.8, 2p=0.005).

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Radiotherapy provided benefits for both node-negative and node-positive women. 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. (2)

Eight to 10 years of follow-up is needed to assess the outcomes from different treatments for early stage breast cancer. The EBCTCG individual-level meta-analysis provides data on the pattern of recurrences among BCS patients with and without radiotherapy for more than 10 years. In web figure 6a (Available online at: <http://www.ctsu.ox.ac.uk/~ebctcg/local2000/annex.pdf>), data on the percentage of patients per year with isolated local recurrence is 2.7% and 9.0% for those with and without whole-breast irradiation, respectively, in year 0; 1.5% and 4.8% in years 1–2; 1.1% and 3.7% in years 3–4; 0.8% and 1.9% in years 5–9; and 0.2% for both groups in years 10 and higher (trend $\chi^2_1=4.3$, $2p=0.04$). While the recurrence rate falls over time, it persists for more than 10 years. In another study, local recurrence was highest between years 3 to 5 of follow-up, and 67% of events took place in the first 5 years. However, that means 33% of events took place after 5 years. (3) For additional information on the length of follow-up needed, see the two TEC Assessments on APBI. (4,5)

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. (6-8) 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. (9) 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 to target the tumor more effectively 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 some of these concerns. AWBI has been used especially in Canada and Europe.

The second approach to reducing radiotherapy treatment time is 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

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 2010 [4]). All brachytherapy devices have been approved through the 510(k) process and are either

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balloon brachytherapy or hybrid balloon-interstitial 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.”

*****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

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

- a. The patient is 45 years old or greater, **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).

*****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 in April 2009, the following statement was included in their

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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 web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 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

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>.

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Senior Medical Director review - 8/2007

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Specialty Matched Consultant Advisory Panel - 8/2009

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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

TEC Assessment 7/2010.

BCBSA Medical Policy Reference Manual [Electronic version]. 8.01.13, 4/14/11

Specialty Matched Consultant Advisory Panel 8/2011

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.
- 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. (lr)
- 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)

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.