Medical Policy

Accelerated Breast Irradiation after Breast-Conserving Surgery for Early Stage Breast Cancer and Breast Brachytherapy as Boost with Whole-Breast Irradiation

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- Policy: Medicare
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Policy Number: 326
BCBSA Reference Number: 8.01.13

Related Policies
None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

When using radiation therapy after breast-conserving surgery (BCS) for early stage breast cancer:

Accelerated whole breast irradiation (AWBI) may be MEDICALLY NECESSARY for patients who meet the following conditions:
- Invasive carcinoma of the breast. Exclude disease involving the margins of excision; tumors >5 cm in diameter; breast width >25 cm at posterior border of medial and lateral tangential beams, AND
- Negative lymph nodes, AND
- Technically clear surgical margins.

Interstitial or balloon brachytherapy may be MEDICALLY NECESSARY 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.

AWBI is INVESTIGATIONAL in all other situations involving treatment of early stage breast cancer after BCS.

Accelerated partial breast irradiation (APBI), including interstitial APBI, balloon APBI, external beam APBI, noninvasive brachytherapy using Accubost®, and intra-operative APBI, is INVESTIGATIONAL.
Noninvasive brachytherapy using Accuboost® 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 BCS and whole-breast external-beam radiotherapy is INVESTIGATIONAL.

Prior Authorization Information
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
<th>Inpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
<td>n/a</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>No</td>
<td>n/a</td>
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<tr>
<td>Medicare PPO Blue℠</td>
<td>No</td>
<td>n/a</td>
</tr>
</tbody>
</table>

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>19296</td>
<td>Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radionuclide application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy</td>
</tr>
<tr>
<td>19297</td>
<td>Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radionuclide application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>19298</td>
<td>Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radionuclide application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance</td>
</tr>
<tr>
<td>77776</td>
<td>Interstitial radiation source application; simple</td>
</tr>
<tr>
<td>77777</td>
<td>Interstitial radiation source application; intermediate</td>
</tr>
<tr>
<td>77778</td>
<td>Interstitial radiation source application; complex</td>
</tr>
<tr>
<td>77785</td>
<td>Remote afterloading high dose rate radionuclide brachytherapy; 1 channel</td>
</tr>
<tr>
<td>77786</td>
<td>Remote afterloading high dose rate radionuclide brachytherapy; 2-12 channels</td>
</tr>
<tr>
<td>77787</td>
<td>Remote afterloading high dose rate radionuclide brachytherapy; over 12 channels</td>
</tr>
<tr>
<td>77261</td>
<td>Therapeutic radiology treatment planning; simple</td>
</tr>
<tr>
<td>77262</td>
<td>Therapeutic radiology treatment planning; intermediate</td>
</tr>
<tr>
<td>77263</td>
<td>Therapeutic radiology treatment planning; complex</td>
</tr>
<tr>
<td>77280</td>
<td>Therapeutic radiology simulation-aided field setting; simple</td>
</tr>
<tr>
<td>77285</td>
<td>Therapeutic radiology simulation-aided field setting; simple</td>
</tr>
<tr>
<td>77290</td>
<td>Therapeutic radiology simulation-aided field setting; complex</td>
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<tr>
<td>77295</td>
<td>3-dimensional radiotherapy plan, including close volume histograms</td>
</tr>
<tr>
<td>77326</td>
<td>Brachytherapy isodose plan; simple (calculation made from single plane, 1 to 4 sources/ribbon application, remote afterloading brachytherapy, 1 to 8 sources)</td>
</tr>
<tr>
<td>77327</td>
<td>Brachytherapy isodose plan; intermediate (multiplane dosage calculations, application involving 5 to 10 sources/ribbons, remote afterloading brachytherapy, 9 to 12 sources)</td>
</tr>
<tr>
<td>77328</td>
<td>Brachytherapy isodose plan; complex (multiplane isodose plan, volume implant</td>
</tr>
</tbody>
</table>
calculations, over 10 sources/ribbons used, special spatial reconstruction, remote afterloading brachytherapy, over 12 sources)

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1717</td>
<td>Brachytherapy source, nonstranded, high dose rate iridium-192, per source</td>
</tr>
<tr>
<td>C9726</td>
<td>Placement and removal (if performed) of applicator into breast for radiation therapy</td>
</tr>
<tr>
<td>Q3001</td>
<td>Radioelements for brachytherapy, any type, each</td>
</tr>
</tbody>
</table>

**HCPCS Codes**

**Description**

Radiation therapy is the standard 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 approximately 25 treatments delivered over 5 to 6 weeks. Nonetheless, 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.
- Accelerated partial-breast irradiation (APBI).

Breast Conservation Therapy (BCT) is a multimodality treatment that consists of BCS to excise the tumor with adequate margins, followed by whole-breast external-beam radiation therapy. 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.

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. 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). 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 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.

There are a variety of radiotherapy modalities that have been approved or cleared for marketing by the U.S. Food and Drug Administration (FDA). All radiotherapy modalities for AWBI or APBI are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

**Summary**

The overall body of evidence on accelerated whole-breast irradiation (AWBI) compared to conventional whole-breast irradiation suggests local recurrence rates with accelerated whole-breast radiotherapy were
not worse than conventional whole-breast irradiation in patients meeting the criteria of the Canadian trial, when applying a noninferiority margin of 5%. Similar results were published in 2013 on the START B trial, although that study included some patients who had a mastectomy rather than breast-conserving surgery (BCS) before radiotherapy. Patient selection is important, and at this point, only patients similar to those in the Canadian trial should be considered for this therapy. Thus, accelerated whole-breast irradiation may be considered medically necessary for these patients with clinical characteristics noted in the medically necessary policy statement. Outcomes could vary in women with other disease characteristics.

For patients treated with whole-breast external-beam radiation and BCS, local boost irradiation via interstitial or balloon brachytherapy is likely to result in equivalent outcomes compared to local boost given by external beam. This is based on results on nonrandomized, comparative studies, a TEC Assessment, and specialty society guidelines. As a result, interstitial or balloon brachytherapy may be considered medically necessary for these patients when used as local boost irradiation.

Overall, the body of evidence on interstitial accelerated partial-breast irradiation (APBI) compared to conventional whole-breast irradiation is weak; and it is extremely weak (ie, no comparative studies) for balloon brachytherapy. There is 1 small study that compared external-beam APBI to whole-breast radiotherapy, and a second larger study that reported on cosmesis and toxicity after a median of 3 years. The strongest published evidence is on intraoperative radiotherapy, but 5- or 10-year follow-up of the remainder of the subjects would be informative for the TARGIT trial. While the results after 5 years for the ELIOT trial satisfy the prespecified equivalence criterion, the recurrence rate for intraoperative radiotherapy patients after treatment with electrons is statistically significantly larger than for whole-breast irradiation patients. Furthermore, it is becoming increasingly clear that each type of APBI should be judged on its own merits, and studies comparing different APBI techniques to each other, as well as to whole-breast irradiation, are needed. Fortunately, a number of large RCTs are underway.

The evidence on noninvasive breast brachytherapy using Accuboost to provide the boost radiation to the tumor bed is very weak, therefore this technique is considered investigational.

Given the available evidence, interstitial or balloon brachytherapy may be considered medically necessary for these patients when used as local boost irradiation. Otherwise, APBI is considered investigational for treatment of early stage breast cancer after BCS.

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2014</td>
<td>BCBSA National medical policy review</td>
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<tr>
<td></td>
<td>New investigational indications described. Effective 5/1/2014.</td>
</tr>
<tr>
<td>6/2013</td>
<td>BCBSA National medical policy review</td>
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<tr>
<td></td>
<td>Policy statement on criteria for accelerated whole breast radiation</td>
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<tr>
<td></td>
<td>changed from “negative surgical margins” to “technically clear surgical</td>
</tr>
<tr>
<td></td>
<td>margins”; no change to intent of policy statement. Effective 6/1/2013.</td>
</tr>
<tr>
<td>4/2012</td>
<td>No changes to policy statements.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>New policy, effective 12/1/2011, describing covered and non-covered</td>
</tr>
<tr>
<td></td>
<td>indication.</td>
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</tbody>
</table>

### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines
References


