Breast Brachytherapy

Policy # 00201
Original Effective Date: 12/01/2006
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider brachytherapy for the initial treatment of stage I or stage II breast cancer as local boost irradiation when used in conjunction with breast-conserving surgery (BCS) and whole breast external beam radiotherapy (EBRT) to be eligible for coverage.

Based on review of available data, the Company may consider brachytherapy for the treatment of stage I or stage II breast cancer as the sole form of radiotherapy after surgical excision of the tumor to be eligible for coverage if the patient selection criteria are met.

Patient Selection Criteria
Coverage eligibility for the use of breast brachytherapy for the treatment of stage I or stage II breast cancer as the sole form of radiotherapy after surgical excision of the tumor is considered to be eligible for coverage when all of the following criteria are met:

- Age 45 years old or greater; and
- Invasive carcinoma or ductal carcinoma in situ (DCIS) and
- Total tumor size (invasive and DCIS) less than or equal to 3 cm in size; and
- Negative microscopic surgical margins of excision; and
- Axillary lymph nodes/sentinel lymph node negative.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers interstitial or balloon brachytherapy for treatment of stage I or II breast cancer to be investigational* when patient selection criteria are not met.

Based on review of available data, the Company considers interstitial or balloon brachytherapy to be investigational* for local boost irradiation when combined with whole breast radiotherapy but without surgical excision.

Based on review of available data, the Company considers noninvasive brachytherapy with AccuBoost® and intra-operative brachytherapy to be investigational*.
Background/Overview

BREAST CONSERVATION THERAPY

For patients diagnosed with stage I or II breast tumors, survival after breast conservation therapy (BCT) is equivalent to survival after mastectomy. Breast conservation therapy is a multimodality treatment that initially comprised BCS to excise the tumor with adequate margins, followed by whole-breast EBRT 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 (WBI) 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 have demonstrated that the addition of radiotherapy after BCS reduces recurrences and mortality. In an expanded update of an individual patient data 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=7287), 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=1050), 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, radiotherapy is generally recommended following BCS. A potential exception is for older women at low risk of recurrence. For example, current National Comprehensive Cancer Network guidelines state that women ages 70 or older may omit radiotherapy if they are estrogen-receptor positive, have T1 tumors, have clinically negative lymph nodes, and plan to take adjuvant endocrine therapy. However, agreement is not universal.

Controversy continues on the length of follow-up needed to determine whether accelerated partial-breast irradiation (APBI) is equivalent to WBI (see the 2013 Technology Evaluation Center (TEC) Assessment on accelerated radiotherapy after BCS for early-stage breast cancer for details). Because recurrences are relatively rare among low-risk early breast cancer patients, it may take considerable time for enough recurrences to occur to provide sufficient power for comparing recurrence rates across radiotherapy approaches. Additionally, radiation-induced adverse cardiovascular effects and radiation-induced non-breast cancers tend to occur 10 or more years after treatment. For accelerated whole-breast irradiation (AWBI), some 10-year data are available. However, for newer approaches, the issue may be resolved by statistical issues rather than biological ones. For example, in the large NSABP-39/RTOG 0413 trial comparing WBI and APBI (NCT00103181), enrollment has reached the revised target of 4216. Trial duration (barring early termination) is determined by the occurrence of a prespecified number (175) of in-breast recurrences. Researchers expect that reaching that number of recurrences will take approximately 10 years.

Currently, most patients diagnosed with stage I or II breast cancer are offered a choice of BCT or mastectomy, but BCT is selected less often than expected. Studies have shown that those living farthest from treatment facilities are least likely to select BCT instead of mastectomy and most likely to forgo radiotherapy after BCS.
ALTERNATIVE RADIOTHERAPY REGIMENS

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 WBI 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 radiation is delivered to the tumor bed in fewer fractions at larger doses per fraction. Third, radiation dose is intrinsically less uniform within the target volume when APBI uses brachytherapy (ie, the implantation of radioactive material directly in the breast tissue).

The major types of radiotherapy used after BCS are outlined in Table 1. They differ by technique, instrumentation, dose delivery, and possibly outcomes.

<table>
<thead>
<tr>
<th>Radiation Type</th>
<th>Accelerated?</th>
<th>Whole or Partial Breast</th>
<th>EBRT or Brachytherapy</th>
<th>Treatment Duration</th>
<th>Published RCTs</th>
<th>Length of Follow-Up</th>
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<td>Yes</td>
<td>Partial</td>
<td>Not applicable</td>
<td>1 d</td>
<td>1</td>
<td>5 y</td>
</tr>
</tbody>
</table>

APBI: accelerated partial-breast irradiation; EBRT: external-beam radiotherapy; RCT: randomized controlled trial; WBI: whole-breast irradiation.

a Noninvasive breast brachytherapy using AccuBoost has been described by the manufacturer as capable of delivering APBI, but no studies for this indication were found.

b Interstitial brachytherapy entails placement of multiple hollow needles and catheters to guide placement of the radioactive material by a remote afterloading device. It is more difficult to perform than other types of brachytherapy and has a steep learning curve.

c Balloon brachytherapy (eg, MammoSite®) entails inserting a balloon into the tumor bed, inflating the balloon, confirming its position radiographically, and then using a remote afterloader to irradiate the targeted area. Some brachytherapy systems combine aspects of interstitial and balloon brachytherapy.

d External-beam APBI is delivered in the same way as conventional or accelerated whole-breast radiotherapy but to a smaller area. All 3 external-beam regimens can use 3-dimensional conformal radiotherapy or intensity-modulated radiotherapy.

e Intraoperative APBI is performed during breast-conserving surgery with a single dose of radiation delivered to the exposed tumor bed.
Breast Brachytherapy

Policy # 00201
Original Effective Date: 12/01/2006
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To appreciate the differences among radiotherapy techniques, it is useful to understand attributes of radiation delivery. The goals of cancer radiotherapy are to provide the tumor or tumor bed with a high dose of homogeneous radiation (ie, all parts of the tumor cavity receive close to the targeted dose). Areas adjacent to the tumor may be given a lower dose of radiation (eg, with WBI) to treat any unobserved cancerous lesions. Radiation outside the treatment area should be minimal or nonexistent. The goal is to target the tumor or adjacent areas at risk of harboring unseen cancer with an optimum dose, while avoiding healthy tissues.

BRACHYTHERAPY BOOST WITH WBI
Brachytherapy also can be used as an alternative to EBRT to deliver boost radiotherapy combined with whole-breast EBRT. Most studies of local boost brachytherapy use temporarily implanted needles, wires, or seeds after patients have recovered from surgery and completed whole-breast radiotherapy.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
In 2002, the MammoSite Radiation Therapy System (Proxima Therapeutics; Alpharetta, GA), the first device specifically designed for breast brachytherapy, was cleared for marketing by the FDA through the 510(k) process. Its intended use is “to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.”

Since 2002, several other devices for breast brachytherapy have been cleared for marketing by FDA through the 510(k) process. FDA determined that several devices (eg, Axxent Electronic Brachytherapy System [Xoft; San Jose, CA], Strut-Adjusted Volume Implant [SAVI™] Applicator Kit [Biolucent (now Cianna Medical); Aliso Viejo, CA], Contura Multi-Lumen Balloon Source Applicator for Brachytherapy [SenoRx; Aliso Viejo, CA], ClearPath™ Adjustable Multi-Catheter Source Applicator [North American Scientific; Chatsworth, CA], Intrabeam System [Carl Zeiss Surgical; Oberkochen, Germany]) were substantially equivalent to predicate devices. Each includes an FDA-required warning that the safety and effectiveness of the device “as a replacement for whole-breast irradiation in the treatment of breast cancer has not been established.”

Although the Intrabeam System (discussed in the Intraoperative Brachytherapy subsection) is subject to FDA regulation, it does not fall under the regulatory purview of the U.S. Nuclear Regulatory Commission. In some states, participation of radiation oncologists in delivering radiation is not required.

Centers for Medicare & Medicaid Services (CMS)
There is no national coverage determination.

Rationale/Source
ACCELERATED PARTIAL-BREAST IRRADIATION
A number of randomized controlled trials (RCTs) and nonrandomized comparative studies have evaluated interstitial, external-beam, or intraoperative APBI compared with conventional WBI. Several meta-analyses have evaluated evidence on APBI, with various methods grouped in same review. Conclusions cannot be
drawn from these meta-analyses because methods vary and need to be evaluated individually. This evidence is reviewed next.

**Interstitial Brachytherapy**

In 2016, Strnad et al published findings of the GEC-ESTRO multicenter noninferiority RCT. The trial included patients ages 40 and older with stage 0 to II breast cancer and lesions of 3 cm or less in diameter. Patients had undergone BCS with clear margins of at least 2 mm in any direction and no lymph or blood vessel invasion. Patients were randomized to conventional WBI at 50 Gy in daily fractions of 1.8 to 2.0 Gy over 5 weeks (n=551) or APBI using interstitial brachytherapy (n=633). The primary study end point was the first event of local ipsilateral breast cancer recurrence within the 5-year observation period and the noninferiority margin was a difference of 3%. At 5 years, 5 of 551 women in the conventional WBI group and 9 of 633 women in the APBI group had a local recurrence. The associated cumulative incidence of local recurrence was 0.92% (95% CI, 0.12% to 1.73%) in the conventional WBI group and 1.44% (95% CI, 0.51% to 2.38%) in the APBI group (risk difference, 0.52%; 95% CI, -0.72% to 1.75%). The difference between groups was within the noninferiority margin. OS was not a primary end point and there was no prespecified noninferiority analysis on survival outcomes. However, trialists reported that, at the time of data analysis, 32 (6%) of 551 patients in the conventional WBI group and 27 (4%) of 633 in the APBI group had died. Trial limitations included outcomes data only being available up to 5 years, survival not being a primary end point, and the absolute number of women with local recurrences being small.

For a 2007 RCT, accrual was stopped before reaching the goal specified to evaluate differences in local recurrence, to allow patients to enroll in another trial. The randomization process was unclear; patients deemed “technically unsuitable” for interstitial brachytherapy were given EBRT APBI; and patient characteristics and outcomes for each type of APBI were not reported separately. Finally, the sample size (N=126) was relatively small; and longest reported follow-up was 66 months. Similar local and regional failure rates were found across treatment arms.

Ajkay et al (2015) reported retrospectively on 5-year adverse events in patients with early-stage breast cancer treated at a single center. Of 417 patients who received BCS and radiotherapy, 271 received intracavitary brachytherapy (34 Gy in 10 fractions; 90% MammoSite, 9% Contura, 1% strut-adjusted volume implant [SAVI]) and 146 received WBI using 3-dimensional conformal radiotherapy (3D-CRT; 45-50.4 Gy in 25-28 fractions with 10-16 Gy boost). Median follow-up was 4.8 years in the brachytherapy group and 4.1 years in the WBI group. Estimated 5-year overall incidence of any adverse event was greater in the brachytherapy group (72%) than in the WBI group (52%; p<0.001). For prespecified adverse events of interest, estimated 5-year incidences of infectious skin complications, abscess, telangiectasia, and breast pain were similar between groups. Estimated 5-year incidences of seroma (47% vs 19%, p<0.001) and fat necrosis (40% vs 24%, p<0.001) were greater in the brachytherapy group, respectively.

**Section Summary: Interstitial Brachytherapy**

The 2015 GEC-ESTRO RCT reported 5-year follow-up data and found that interstitial brachytherapy was noninferior to WBI on rates of local breast cancer recurrence, when applying a noninferiority margin of 3%. Ten-year follow-up data are needed and at least 1 additional trial confirming these findings.
Intraoperative Brachytherapy

One RCT compared intraoperative radiotherapy (IORT) with WBI in 2232 women. Radiotherapy was delivered to the tumor bed using the Intrabeam device, which provides a point source of 50 kV energy x-rays at the center of a spherical applicator, for 20 to 45 minutes. It was specifically developed for IORT. The TARGIT-A (Risk-adapted Targeted Intraoperative Radiotherapy) trial was a noninferiority study at 28 centers in 9 countries and a sample size of 3451. (In 2010, the trial was extended for 2 more years to allow accrual in subprotocols.) An ITT approach was used. Patients were not blinded to treatment choice. As anticipated, 14% of those in the IORT arm received EBRT as well, because of unfavorable pathologic features determined after surgery (eg, lobular carcinoma). The predefined noninferiority margin was an absolute difference of 2.5% between groups for pathologically confirmed, ipsilateral local recurrence. The most recent report (2013) provided 5-year results, defined as results for patients with 5 years of follow-up or “if they were seen the year before database lock.” Median follow-up for all patients was 2 years and 5 months (IQR, 12-52 months), and 1222 (35%) patients had a median follow-up of 5 years. Estimated 5-year risks for ipsilateral local recurrence were 3.3% (95% CI, 2.1% to 5.1%) in the TARGIT group and 1.3% (95% CI, 0.7% to 2.5%; p=0.042) in the WBI group. Mortality was similar between the 2 groups (2.6% with TARGIT vs 1.9% with whole-breast radiotherapy; p=0.56). However, there were significantly fewer non-breast cancer deaths in the TARGIT group (1.4%; 95% CI, 0.8% to 2.5%) than in the WBI group (3.5%; 95% CI, 2.3% to 5.2%; p<0.001), with fewer deaths from cardiovascular causes and other cancers in the TARGIT group. In the group that received IORT plus whole-breast radiotherapy, the mortality rate was higher at 8% (95% CI, 3.7% to 17.5%), but the percentage of women with local recurrences (0.9%; 95% CI, 0.1% to 6.1%) was similar to those who received only IORT. Noninferiority was established for the whole intraoperative cohort and for those who received IORT alone, but not for those patients who underwent both types of radiotherapy. There was no significant difference between the IORT and WBI groups in predefined 6-month wound-related complications. However, grade 3 or 4 radiotherapy-related skin complications were more common in the WBI group (13/1730 vs 4/1731; p=0.029). Five- and 10-year follow-ups for the entire TARGIT-A cohort have yet to be accrued.

Another form of IORT, called electron intraoperative radiotherapy (ELIOT), uses electrons. The 2013 ELIOT trial compared IORT plus ELIOT to WBI. With a sample size of 1305 patients and median follow-up of 5.8 years (IQR, 4.1-7.7 years), 35 (4.4%) patients in the intraoperative group and 4 (0.4%) patients in the WBI group developed ipsilateral breast tumor recurrences (HR=9.3; 95% CI, 3.3 to 26.3; p<0.001). There was no statistically significant difference in 5-year OS. For women with data on adverse skin events (IORT=464, WBI=412), there were significantly fewer events among women who received IORT (p<0.001). This was an equivalence trial with a prespecified limit of 7.5% for local recurrence in the IORT group only. Therefore, although the criterion for equivalence was satisfied, ipsilateral breast recurrence rate was significantly higher in the IORT group. A subsequent review of the ELIOT trial noted that, of 69 women who had 4 or more positive lymph nodes, those randomized to WBI (n=38) received concurrent axillary radiation; for those randomized to ELIOT (n=31), axillary irradiation was delayed 6 to 12 weeks.7 These reviewers also characterized ELIOT data as “still early” and noted that long-term results are needed to assess net health benefit.
Section Summary: Intraoperative Brachytherapy
Several RCTs have been published, but they have not demonstrated that outcomes after intraoperative brachytherapy are noninferior to WBI. Five-year results from the TARGIT-A RCT showed increased ipsilateral local recurrence with APBI compared with whole-breast radiotherapy. In another RCT that used a different technology (ELIOT), recurrence rate with IORT was statistically greater than that with WBI.

BRACHYTHERAPY WITH LOCAL BOOST
A 1996 TEC Assessment concluded that net health outcomes with brachytherapy with local boost were equivalent to outcomes with EBRT with local boost in women who received BCS plus WBI as initial treatment for stage I or II breast cancer. No RCTs were identified. However, there were 7 nonrandomized studies comparing 2 types of local boost radiotherapy: brachytherapy (n=2033) and EBRT (n=1557); all patients also received BCS and WBI. The combination of brachytherapy with local boost, BCS, and WBI prevented local tumor recurrence and salvage mastectomy in 95% to 97% of patients at 5 years and 88% to 92% of patients at 10 years. Five-year survival in the 5 studies reporting this outcome ranged from 83% to 96%. Data from uncontrolled studies reported similar rates of local control and 5-year survival.

Section Summary: Brachytherapy With Local Boost
For women undergoing BCS plus WBI as initial treatment for stage I or II breast cancer, nonrandomized comparative studies have shown similar outcomes with brachytherapy with local boost and with EBRT with local boost.

NONINVASIVE BREAST BRACHYTHERAPY
AccuBoost for image-guided breast irradiation, also called noninvasive breast brachytherapy, has been used for local boost around the tumor bed. The AccuBoost system provides image-guided radiotherapy before each treatment to ensure that radiation is directed at the treatment target. The breast is placed between mammography paddles, where images are taken and radiation is delivered using a distinct applicator. The paddles prevent motion during treatment. Radiation is delivered from 1 side of the breast to the other or from the top of the breast to the bottom. This is proposed to reduce radiation exposure to adjacent tissues, including the heart and lung. No long-term studies are available to confirm this.

There is only 1 comparative study on noninvasive breast brachytherapy. This 2013 matched retrospective study assessed patients receiving the boost dose using AccuBoost or electron beams (a type of EBRT). Each of 47 AccuBoost patients was compared with 2 controls matched on age, stage, chemotherapy use, fractionation, and when possible, breast size, comorbidities, and smoking status. Main differences between the 2 treatment groups were in radiation doses received and timing of radiotherapy administration. The percentage of patients with a WBI dose (accompanying the boost dose) of 50 to 50.4 Gy was 68% in the AccuBoost group and 37% in the electron-treated group (p<0.001). Also, a greater proportion of patients in the electron-treated group received the boost dose after WBI, rather than during WBI or starting before and ending during WBI (99% for the electron-treated group vs 6% for the AccuBoost group). Approximately 60% of patients had stage I breast cancer, and approximately 25%, ductal carcinoma in situ. With median follow-up of 13.6 months, skin and subcutaneous tissue toxicity occurred less often among patients treated with AccuBoost than among those treated with electron beam (p=0.046). Locoregional control rates were 99% or
Breast Brachytherapy

Policy # 00201
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greater in both groups. Study limitations included the between-group differences in dose and timing of boost, as well as selection bias and the study’s retrospective design.

Section Summary: Noninvasive Breast Brachytherapy
No RCTs and only 1 nonrandomized comparative study were identified. The comparative study was retrospective matched comparison of noninvasive breast brachytherapy or electron-beam radiotherapy to provide boost radiation to the tumor bed. The study was subject to selection bias, relatively short follow-up, and use of a retrospective design.

SUMMARY

Accelerated Partial-Breast Irradiation
For individuals who have early-stage breast cancer who receive interstitial brachytherapy, the evidence includes 1 completed RCT. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The RCT reported 5-year follow-up data and found that interstitial brachytherapy was noninferior to WBI for rates of local breast cancer recurrence, when applying a noninferiority margin of 3%. Ten-year follow-up data are needed on local recurrence as well as at least 1 additional trial confirming these findings.

For individuals who have early-stage breast cancer who receive intraoperative brachytherapy, the evidence includes RCTs. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. Several RCTs have been published, but they have not demonstrated that outcomes after intraoperative brachytherapy are noninferior to WBI. Results of 2 RCTs (TARGIT-A, ELIOT) comparing intraoperative brachytherapy to WBI found higher rates of local recurrence with intraoperative brachytherapy than with WBI. The evidence is insufficient to determine the effects of the technology on health outcomes.

Brachytherapy
For individuals who have early-stage breast cancer who receive local boost brachytherapy with WBI, the evidence includes nonrandomized studies and a systematic review. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. A TEC Assessment concluded that, for women undergoing BCS plus WBI as initial treatment for stage 1 or 2 breast cancer, nonrandomized comparative studies have shown similar outcomes with brachytherapy local boost and with external-beam radiotherapy local boost. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

References
Breast Brachytherapy

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Breast Brachytherapy

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08/02/2006 Medical Director review
08/09/2006 Medical Policy Committee approval
07/18/2007 Medical Policy Committee approval. Brachytherapy in patients with stage I or II disease as the sole form of radiotherapy after surgical excision is now considered to be eligible for coverage with criteria. Rationale replaced.
05/07/2008 Medical Director review
05/21/2008 Medical Policy Committee approval. No change to coverage eligibility.
05/07/2009 Medical Director review
05/20/2009 Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010 Medical Policy Committee review
06/16/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2011 Medical Policy Committee review
05/18/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2012 Medical Policy Committee review
05/16/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2013 Medical Policy Committee review
05/22/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/01/2014 Medical Policy Committee review
05/21/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2015 Coding Update
05/07/2015 Medical Policy Committee review
05/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/01/2016 Coding update
05/05/2016 Medical Policy Committee review
05/18/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Investigational statement on accelerated partial breast irradiation using an electronic radiotherapy device removed and investigational statement added on Accuboost. Rationale, background, FDA section and references updated.

Coding

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Breast Brachytherapy

Policy # 00201
Original Effective Date: 12/01/2006
Current Effective Date: 06/01/2017

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) – Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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Breast Brachytherapy

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.