

**Policy terminated because coverage is provided under the combined
Medicaid and Health Choice policy 1K-6, Radiation Oncology**

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1.0 Description of the Procedure, Product, or Service

Breast conservation therapy (BCT) is a multi-modality alternative to mastectomy to treat early (stage I or II) breast cancer. In current practice, most conventional BCT includes breast-conserving surgical excision of the tumor (lumpectomy, segmentectomy, or quadrantectomy) and whole-breast radiotherapy (WBRT), delivered 5 days/week over 5–7 weeks using external beam radiation (EBR). For those at higher risk of recurrence (based on age younger than 50 years, tumor size greater than 2–3 cm, nodal involvement, inadequate tumor-free margins, etc.), "boost" radiotherapy narrowly directed to the tumor bed is included in WBRT. In randomized trials, WBRT reduced local (i.e., in-breast) recurrence, and meta-analysis showed it also improved survival compared with breast-conserving surgery alone. Other trials and meta-analysis showed that efficacy of BCT with WBRT is equivalent to mastectomy. The radiation is hypothesized to eliminate residual cancer near the surgical site and treat any undetected multicentric disease. Radiation alone (i.e., without resection) is not recommended in current guidelines to manage early breast cancer.

Breast brachytherapy uses radiation sources placed inside the breast. Interstitial brachytherapy uses multiple sources spaced in 2 or more planes through the breast, with computerized treatment planning to optimize dose homogeneity in the target. The number, spacing, and radiation strength of sources vary with the breast volume to be treated. Balloon brachytherapy uses a single source placed in an inflatable catheter inside the surgical cavity. It treats the cavity plus a surrounding margin of 1–2 cm, with radiation dose declining as a function of distance from the source.

Differences between interstitial and balloon brachytherapy in geometry and target dose homogeneity are of less concern for boost therapy, since the target volume is limited to the tumor bed close to the radiation source. External beam radiation separate from the boost adequately treats breast tissue outside the tumor bed.

However, when brachytherapy is used alone without EBR to the remaining breast, i.e., for partial breast irradiation (PBI), target volume extends beyond the tumor bed, and these differences may have greater impact on outcomes. For PBI, it is thus uncertain whether outcomes of interstitial brachytherapy could be used to reliably predict outcomes of balloon brachytherapy.

Methods other than brachytherapy are also used for PBI, such as several types of external beam therapy. They are not discussed in this policy.

This policy separately addresses use of interstitial or balloon brachytherapy as alternatives to external beam radiation therapy in two settings:

- a. To replace external beam for boost radiation therapy, combined with whole-breast external-beam radiation therapy and breast-conserving surgery.
- b. Alone, for accelerated partial breast radiation therapy after breast-conserving surgery.

This second, more recent application of brachytherapy methods is based partly on the observation that most ipsilateral breast recurrences after breast-conserving surgery and radiation therapy occur near the tumor bed, with only a minority of recurrences located elsewhere in the breast. In addition, in trials of breast-conserving surgery with versus without radiation therapy, most

recurrences also occurred near the tumor bed, suggesting that undetected multicentric disease may not be common. Together these findings suggested that tumor bed irradiation may provide the major benefit from whole-breast external beam radiation therapy. Also, the extended treatment course for WBRT may be difficult for some recipients, for example, those living in remote locations, or the elderly or disabled.

Both methods of brachytherapy usually are delivered over a week. This shortened, more convenient treatment course, which has been termed accelerated partial-breast irradiation (APBI), may increase the proportion of recipients choosing breast-conserving surgery. On the other hand, APBI may sacrifice some or all of the radiobiological advantage associated with fractionated doses and the slower repair of sublethal radiation damage in tumor versus normal cells.

Various interstitial brachytherapy techniques have been investigated. They differ in the timing of implantation relative to other components of breast-conserving therapy, the radiation dose rate, the loading technique, the number and volumetric distribution of radioactive sources, and the radioisotopes used. Most of the older studies of local boost brachytherapy temporarily implanted needles, wires, or seeds after recipients recovered from surgery and completed whole-breast radiation therapy. Since the 1990s, investigators have perioperatively implanted hollow needles or catheters that guide placement of the radioactive material. This can be done during the initial lumpectomy if brachytherapy has been selected already or at re-excision if the lumpectomy specimen has positive surgical margins. Intraoperative implantation avoids the need for a separate surgical procedure with anesthesia for brachytherapy.

Both low- and high-dose rate interstitial techniques are used, with high-dose rate techniques increasing in popularity. In the low-dose rate technique, radioactive seeds are temporarily implanted in hospitalized recipients. They deliver radiation continuously over 4 days and then are removed. In the high-dose rate technique, a computer-controlled device loads highly radioactive isotope sources into catheters that have been placed into the tumor bed. The recipient is exposed to the radiation therapy for a brief period—e.g., 15 minutes—and then the radioactive sources are withdrawn. High-dose rate brachytherapy is typically administered to outpatients as 8 fractions given twice daily over 4 days.

A balloon catheter system (the Mammosite™ RTS device; Cytac Corp; Alpharetta, GA) is also available for brachytherapy. The device is implanted in the lumpectomy cavity during or shortly after breast-conserving surgery. The balloon is inflated with sterile solution of contrast media in saline solution, and its position is confirmed radiographically using computed tomography. A high-dose rate source of iridium-192 is then centrally positioned within the applicator by a remote afterloader. This system is used to deliver 34 Gy in 10 fractions over 5 days. Thus, balloon brachytherapy uses a single radioactive source that delivers radiation to a spherical or elliptical target volume. Like interstitial brachytherapy, it can be used to deliver local boost or accelerated partial-breast radiation therapy.

In December 2005, the U.S. Food and Drug Administration (FDA) cleared the Axxent Electronic Radiotherapy device (Xoft, Inc., Fremont, CA) via 510(k) as substantially equivalent to the Mammosite and other brachytherapy systems. The Axxent device is a balloon brachytherapy system that uses a disposable, microminiature radiation source to deliver the radiation rather than radioisotopes. Additional brachytherapy devices have received FDA 510(k) marketing clearance, e.g., the SenoRad multi-lumen balloon source applicator for brachytherapy (SenoRx, Inc., Aliso Viejo, CA, May 18 2007).

1.1 Medical Term Definitions

- a. Lumpectomy: the excision of a breast tumor (lump or mass), including a limited amount of surrounding tissue.
- b. Mastectomy: surgical removal of all or a part of the breast, generally performed for breast cancer or breast disease.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Brachytherapy treatment of breast cancer is covered under the NCHC Program when brachytherapy is used as local boost irradiation in recipients undergoing initial treatment for stage I or II breast cancer who are also treated with breast-conserving surgery and whole breast external beam radiotherapy.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Brachytherapy treatment of breast cancer is not covered in the following situations:

- a. When the criteria in Subsection 3.2 are not met
- b. Brachytherapy is considered investigational when used in recipients with Stage I or II diseases as the sole form of radiotherapy after surgical excision.
- c. Brachytherapy is considered investigational for local boost irradiation when combined with whole breast radiotherapy but without surgical excision.
- d. Accelerated partial breast irradiation using an electronic radiotherapy device is considered investigational.

4.3 Policy Guidelines

In review of the MammoSite® website in April 2009 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 and Axxent issued in 2005 requires of the manufacturer of the devices: "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."

"The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established."

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for brachytherapy treatment of breast cancer.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- e. meet NCHC qualifications for participation;
- f. be currently enrolled with NCHC; **AND**
- g. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
4/30/12	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)					
19296	19297	19298	77326	77776	77777
77778	77785	77786	77787		

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital

G. Co-payments(s)

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.