

Policy: MP120

Section: Medical Benefit Policy

Subject: Intracavitary Balloon Brachytherapy for Breast Cancer

I. Policy: Intracavitary Balloon Brachytherapy for Breast Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Intracavitary Balloon Brachytherapy for Breast Cancer

III. Responsibility:

- A. Medical Directors
- B. Medical Management Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

The MammoSite® Radiation Therapy System is a minimally invasive method of delivering internal radiation therapy following a lumpectomy for breast cancer. A small balloon catheter is inserted inside the tumor resection cavity. A tiny radioactive seed is inserted into the balloon and delivers the radiation therapy. This focuses the radiation dose on the area of the breast at highest risk for tumor recurrence.

The Axxent Electronic Brachytherapy System uses disposable miniature X-ray radiation sources to deliver electronically generated ionizing radiation directly to tumor beds. Electronic brachytherapy is intended to minimize exposure of the patient's healthy tissue to unnecessary radiation.

INDICATIONS:

The MammoSite Radiation Therapy System may be used independently as the sole monotherapy or as a brachytherapy boost in conjunction with whole-breast external irradiation following breast-conserving surgery.

MammoSite breast brachytherapy may be used as a sole monotherapy when **all** of the following criteria are met:

1. following breast conserving surgery with surgical margins free of tumor; **AND**
2. the pathology is identified as Stage 0, I, or II (stage II tumors 3cm in diameter or less); **AND**
histologically confirmed ductal carcinoma in situ or invasive adenocarcinoma of the breast; **AND**
3. no more than 3 positive axillary nodes
4. is 45 years or greater in age for invasive carcinoma and 50 years or older for ductal carcinoma in situ when accelerated partial breast irradiation is being used as the sole form of radiation therapy in lieu of whole breast irradiation
5. The sentinel lymph node is negative

CONTRAINDICATION:

The MammoSite Radiation Therapy System is contraindicated for patients in which the tumor location is in an area of insufficient tissue (i.e. inadequate device to skin ratio).

EXCLUSIONS:

The Plan does **NOT** provide coverage for the use Electronic Brachytherapy for any indication because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

CODING ASSOCIATED WITH : Intracavitary Balloon Brachytherapy for Breast Cancer

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 77263 Therapeutic radiology treatment planning; complex
- 77290 Therapeutic radiology simulation-aided setting; complex
- 77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician.
- 77370 Special medical radiation physics consultation
- 77470 Special treatment procedure (eg, total body irradiation, hemibody radiation, per oral, endocavitary or intraoperative cone irradiation)
- 77761 intracavitary radiation source application; simple
- 77762 intracavitary radiation source application; intermediate

77763 intracavitary radiation source application; complex
 77770 remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
 77771 2-12 channels
 77772 over 12 channels
 77767 remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel
 77768 remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions
 19296 Placement of radiotherapy after loading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
 19297 concurrent with partial mastectomy
 19298 Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent) partial mastectomy
 19499 Unlisted procedure, breast
 C9726 Placement and removal (if performed) of applicator into breast for radiation therapy
 A4650 Implantable radiation dosimeter, each
 A4648 tissue marker, implantable, any type, each
 C9728 placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple.

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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AMERICAN BRACHYTHERAPY SOCIETY BREAST BRACHYTHERAPY TASK GROUP
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February, 2007 accessed on August 24, 2011 at http://www.americanbrachytherapy.org/guidelines/abs_breast_brachytherapy_taskgroup.pdf

This policy will be revised as necessary and reviewed no less than annually

Devised: 11/03

Revised: 10/04, 10/05 (expanded criteria, updated coding and reference);11/06 (contraindication);11/07 (re-titled policy, added exclusions), 9/11 (added indications)

Reviewed: 11/08; 10/09; 09/10, 9/12, 9/13, 9/14, 9/15, 9/16, 8/17, 8/18