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.
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
3. histologically confirmed ductal carcinoma in situ or invasive adenocarcinoma of the breast; AND
4. no more than 3 positive axillary nodes
5. 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
6. 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.

77263  Therapeutic radiology treatment planning; complex
77290  Therapeutic radiology simulation-aided setting; complex
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.

Special medical radiation physics consultation

Special treatment procedure (e.g., total body irradiation, hemibody irradiation, per oral, endocavitary or intraoperative cone irradiation)

Placement of radiotherapy after loading balloon catheter into the breast for interstitial radionuclide application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy concurrent with partial mastectomy

Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radionuclide application following (at the time of or subsequent) partial mastectomy

Unlisted procedure, breast

Placement and removal (if performed) of applicator into breast for radiation therapy

Implantable radiation dosimeter, each


LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Winifred S. Hayes, Hayes Inc Online, Brachytherapy for Breast Cancer, April 2000. Update BRAC0201.14; 7/31/03.


Xoft. [website]. Freemont (CA): Xoft, INC; [Accessed on 09/14/07]. Available at: http://www.zoftmicrotube.com


AMERICAN BRACHYTHERAPY SOCIETY BREAST BRACHYTHERAPY TASK GROUP
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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