

**Policy: MP120**

**Section: Medical Benefit Policy**

**Subject: Intracavitary Balloon Brachytherapy for Breast Cancer**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

**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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- 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**.

#### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

#### **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](http://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.
- 0394T High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
- 0395T (E/I) High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed
- Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

#### **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 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.

Food and Drug Administration. FDA Talk Paper. FDA Clears New Device for Radiation treatment for Breast Cancer. May 6, 2002.

Zannis VJ, Walker LC, Barclay-White B, Quiet CA, "Postoperative ultrasound-guided percutaneous placement of a new breast brachytherapy balloon catheter", Am J Surg. 2003 Oct; 186(4):383-385.

Edmundson GK, Vicini FA, Chen PY, Mitchell C, Martinez AA., "Dosimetric characteristics of the MammoSite RTS, a new brachytherapy applicator", Int J Radiat Oncol Biol Phys. 2002 Mar 15; 52(4):1132-1139.

Keisch M, Vinici F, et. al., "Initial clinical experience with the MammoSite breast brachytherapy applicator in women with early-stage breast cancer treated with breast-conserving therapy", Int J Radiat Oncol Biol Phys. 2003 Feb 1;55(2):289-293.

Edmundson GK, Weed D, et. al., "Accelerated treatment of breast cancer: dosimetric comparisons between interstitial HDR brachytherapy, Mammosite balloon brachytherapy, and external beam quadrant radiation", Proceedings of the 45<sup>th</sup> ASTRO (American Society for Therapeutic Radiology and Oncology) Meeting.

Gittleman M, Vigneri P. et. al., "Clinical evaluation of the MammoSite breast brachytherapy catheter: an analysis of technical reproducibility, acute toxicity and patient demographics", Proceedings of the 45<sup>th</sup> ASTRO ( American Society for Therapeutic Radiology and Oncology) Meeting.

ECRI, HTAIS Target Database. Intracavitary balloon brachytherapy for early stage breast cancer. November 2003.

Keisch > "Thirty Month Results with the MammoSite Breast Brachytherapy Applicator: Cosmesis, Toxicity and Local Control in Partial Breast Irradiation", Proceedings of the 46<sup>th</sup> ASTRO ( American Society for Therapeutic Radiology and Oncology) Meeting. October 4, 2004.

Richards GM, Berson AM, Rescigno J, Sanghavi S, Siegel B, Axelrod D, Bernik S, Scarpinato V, Mills C. "Acute Toxicity of High-Dose-Rate Intracavity Brachytherapy with Mammosite Applicator in Patients with Early-Stage Breast Cancer." *Ann Surg Oncol*. 2004 Aug;11(8):739-46.

Gennari R, Perego E, Ballardini B, dos Santos G, Costa A. "Surgical Technique of mammosite RTS implant for Accelerated Radiation Delivery in Breast Conserving Surgery." *J Exp. Clin. Cancer Res*. 2004 Sep;23(3):411-5.

Vicini FA, Beitsch PD, Quiet CA, Keleher A, Garcia D, Snider HC, Gittleman MA, Zannis VJ, Kuerer H, Whitacre PW, Fine RE, Haffty BG, Arrambide LS. "First Analysis of Patient Demographics, Technical Reproducibility, Cosmesis, and Early Toxicity- *Results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial*". *Cancer* 15 Sept. 2005;104(6):1138-1148.

Polgar C, Sulyok Z et. al. "Sole Brachytherapy of the Tumor Bed After Conservative Surgery for T1 Breast Cancer: Five year results of a phase I and II study and initial findings of a randomized Phase III trial." *J Surg Oncol* 2002;80:121-128.

Polgar C, Major T et. al. "High-Dose Brachytherapy Alone Versus Whole Breast Radiotherapy With or Without Tumor Bed Boost After Breast-Conserving Surgery: Seven-Year Results of a Comparative Study." *Int J Radiation Oncology Biol. Phys* 2004; 60(4):1173-1181.

Benitez PR, Streeter O, Vicini F, Mehta V, Quiet C, Kuske R, Hayes MK, Arthur D, Kuerer H, Freedman G, Keisch M, Dipetrillo T, Khan D, Hudes R. Preliminary results and evaluation of MammoSite balloon brachytherapy for partial breast irradiation for pure ductal carcinoma in situ: a phase II clinical study. *Am J Surg*. 2006 Oct; 192(4):427-33.

Zannis V, Beitsch P, Vicini F, Quiet C, Keleher A, Garcia D, Snider H, Gittleman M, Kuere H, Whitacre E, Whitworth P, Fine R, Haffty B, Stolier A, Mabie J. Descriptions and outcomes of insertion techniques of a breast brachytherapy balloon catheter in 1403 patients enrolled in the American Society of Breast Surgeons Mammosite breast brachytherapy registry trial. *Am J Surg*. 2005 OCT;190(4):530-8.

Jeruss JS, Vicini FA, Beitsch PD, Haffty BG, Quiet CA, Zannis VJ, Keleher AJ, Garcia DM, Snider HC, Gittleman MA, Whitacre E, Whitworth PW, Fine RE, Arrambide S, Kuerer HM. Initial outcomes for patients treated on the American Society for Breast Surgeons MammoSite Clinical Trial for ductal carcinoma-in-situ of the breast. *Ann Surg Oncol* May 2006;13(7):967-976.

ECRI Institute. TARGET Report (online) Intracavitary balloon Brachytherapy for early-stage breast cancer. ECRI Institute. Current as of July 2007.

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

Smith BD, Arthur DW, Buchholz TA, Haffty BG, Hahn CA, Hardenbergh PH, et al. Accelerated partial breast irradiation consensus statement from the American Society for Radiation Oncology (ASTRO). *J Am Coll Surg*. 2009 Aug;209(2):269-77. Epub 2009 Apr 24.

Mehta VK, Algan O, et. Al. Experience with an electronic brachytherapy technique for intracavitary accelerated partial breast irradiation. [Am J Clin Oncol](#). 2010 Aug;33(4):327-35.

The American Society of Breast Surgeons, Consensus Statement for Accelerated Partial Breast Irradiation Revised, August 15, 2011 Accessed on August 24, 2011 at [http://www.breastsurgeons.org/statements/PDF\\_Statements/APBI.pdf](http://www.breastsurgeons.org/statements/PDF_Statements/APBI.pdf)

AMERICAN BRACHYTHERAPY SOCIETY BREAST BRACHYTHERAPY TASK GROUP

Martin Keisch, M.D., Douglas Arthur, M.D., Rakesh Patel, M.D., Mark Rivard, PhD., Frank Vicini, M.D.

February, 2007 accessed on August 24, 2011 at  
[http://www.americanbrachytherapy.org/guidelines/abs\\_breast\\_brachytherapy\\_taskgroup.pdf](http://www.americanbrachytherapy.org/guidelines/abs_breast_brachytherapy_taskgroup.pdf)

Wadasadawala T, et al. A prospective comparison of subjective and objective assessments of cosmetic outcomes following breast brachytherapy. *J Contemp Brachytherapy* 2019;11:207-214.

Shah C, et al. The American Brachytherapy Society consensus statement for accelerated partial-breast irradiation. *Brachytherapy* 2018 Jan-Feb;17(1):154-170

Polgár C, et al. Late side-effects and cosmetic results of accelerated partial breast irradiation with interstitial brachytherapy versus whole-breast irradiation after breast-conserving surgery for low-risk invasive and in-situ carcinoma of the female breast: 5 year results of a randomised, controlled, phase 3 trial. *Lancet Oncol* 2017 Feb;18(2):259-268

Tagliaferri L, et al. Cosmetic assessment in brachytherapy (interventional radiotherapy) for breast cancer: a multidisciplinary review. *Brachytherapy* 2019 Sep-Oct;18(5):635-644.

National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology, breast cancer. v4.2022

Polgar C, Major T, Takacs-Nagy Z, et al. Breast-Conserving Surgery Followed by Partial or Whole Breast Irradiation: Twenty-Year Results of a Phase 3 Clinical Study. *Int J Radiat Oncol Biol Phys*. Mar 15 2021; 109(4): 998-1006

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, 8/19, 8/20, 8/21, 8/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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