



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Brachytherapy for Breast Cancer**

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Cryoablation of Breast Lesions
 Inpatient Admission for Radiation Therapy
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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers brachytherapy (e.g., multicatheter interstitial, intracavitary) for the treatment of early-stage breast cancer as medically necessary when used in conjunction with external whole breast radiation therapy following breast-conserving surgery.

CIGNA covers brachytherapy (e.g., multicatheter interstitial, intracavitary) as the sole method of breast radiation therapy for the treatment of breast cancer following breast-conserving surgery as medically necessary when ALL of the following criteria are met:

- age greater than or equal to 45 years OR postmenopausal
- individual has invasive ductal carcinoma or ductal carcinoma in situ (DCIS)
- total tumor size (invasive and DCIS) is less than or equal to 3 centimeters in size
- microscopic surgical margins of excision are negative
- sentinel lymph nodes are negative

CIGNA does not cover brachytherapy for breast cancer for any other indication because it is considered experimental, investigational or unproven.

CIGNA does not provide separate reimbursement for the temporary implantation of a cavity evaluation device (CED)/cavity maintenance catheter performed at the same time as a breast-conserving surgery in anticipation of brachytherapy because it is considered to be incidental to the breast-conserving surgery.

CIGNA does not cover electronic/kilovoltage brachytherapy for the treatment of breast cancer because it is considered experimental, investigational or unproven.

General Background

Breast-conserving therapy (BCT) or breast-conserving surgery (BCS) has been shown to be an effective option for the treatment of early-stage breast cancer compared to mastectomy. Using external-beam radiation therapy to the whole breast, excellent local recurrence rates have been achieved in prospective, randomized studies with follow-up of 20 years. More recently, internal (brachytherapy) partial breast radiation therapy is also offered after BCS. Accelerated partial breast irradiation (APBI) is a technique in which the portion of the breast at the highest risk of recurrence (the tissue surrounding the lumpectomy cavity) receives a shortened course of high dose radiation therapy.

There are several techniques that can deliver breast brachytherapy including multiple catheters placed through the breast, a balloon catheter inserted into the lumpectomy cavity, bead or seed implants, single dose intraoperative treatment and others. Regardless of which technique of APBI is employed, the scientific justification for APBI is that the vast majority of recurrences after standard breast conserving treatment occur in the vicinity of the tumor bed. Following WBRT or APBI, the patient may also be treated with adjuvant therapy for several months after surgery to reduce the risk of recurrence. Adjuvant treatments may include various types and combinations of additional 'boost' radiation therapy, hormonal manipulation and chemotherapy.

The APBI technique that has been in use the longest is interstitial brachytherapy, which requires a clinician to insert 10 to 20 catheters through multiple incisions on either side of the affected breast. The catheters allow delivery of a radiation source to the tissues that surround the malignancy. Less invasive and less technically difficult APBI methods have emerged in the last five years, and are replacing older methods. Intracavitary brachytherapy is popular among clinicians because it is less invasive than interstitial brachytherapy and simpler to administer. This technique requires a clinician to insert a single catheter applicator during the lumpectomy procedure (open cavity placement) or up to 10 weeks after surgery (closed cavity placement) through a single incision lateral to the lumpectomy site or in the crease under the breast. Typically, the catheter remains in place for the duration of treatment, which allows delivery of a radiation source directly into the lumpectomy cavity twice daily for five days. Most intracavitary brachytherapy techniques require a remote computer-controlled, high-dose rate (HDR) afterloader to insert and retract the radiation source into and from the single-use catheter that delivers the radiation. Also required are accessories to implant and explant the device. Intracavitary brachytherapy techniques vary by catheter type (i.e., single balloon-tipped, single with multiple lumens, multiple catheters housed within a single applicator), implantation timing, and radiation source (i.e., isotopes, radioactive seeds, miniature electronic x-ray tubes) (ECRI, 2009).

A cavity evaluation device (CED) or cavity maintenance catheter or preparation device is a balloon catheter temporarily implanted in the lumpectomy cavity as a placeholder until it is exchanged for a brachytherapy delivery device after final pathologic confirmation. Its proposed advantages include better cavity conformity, assurance of adequate skin spacing before leaving the operating room, and ease of replacement for the brachytherapy device in the office.

U.S. Food and Drug Administration (FDA)

Interstitial: Numerous interstitial (multiple catheter) brachytherapy devices exist. As part of the interstitial treatment plan, mapping templates (e.g., Kuske Breast Applicator Set, MammoTest[®]) may be used to guide the manual (low-dose rate) or remote loading (high-dose rate) of the cannulas for a precise delivery of brachytherapy. The FDA approved the Kuske Breast Template (Nucletron Corporation, U.S. subsidiary of Netherlands Delft Instruments) in 2002 and MammoTest (Fischer Imaging Corp., Denver, CO) in 2004.

Intracavitary: Numerous intracavitary brachytherapy devices have also been approved by the FDA for the same intended use; to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer. Some of these devices include:

- MammoSite® Radiation Therapy System (Hologic, Marlborough, MA) (formerly Proxima)
- ClearPath HDR Breast Brachytherapy System (NAS Medical, Chatsworth, CA) (formerly North American Scientific)
- Contura Multi-Lumen Balloon (SenoRx, Inc., Irvine, CA)
- Strut-Adjusted Volume Implant (SAVI) (Cianna Medical, Inc., Aliso Viejo, CA)

Cavity Evaluation Device/Cavity Maintenance Catheter: The MammoSite Cavity Evaluation Device (CED) received FDA approval in May 2008, based on the predicate device the MammoSite Radiation Therapy System. According to the FDA, the MammoSite Cavity Evaluation Device is a balloon catheter intended to be placed in the lumpectomy cavity and inflated with sterile saline or contrast solution for the purposes of:

- assessing the size and shape of the lumpectomy cavity in order to choose the appropriate MammoSite RTS applicator
- assessing skin spacing (between outer skin surface and balloon surface)
- assessing cavity conformance (fit between cavity walls and balloon surface)
- maintaining the size and shape of the cavity (acting as a placeholder) until it is exchanged for a MammoSite RTS applicator (FDA, 2008).

Additional examples of FDA-approved Cavity Maintenance Catheters include:

- The Contura Cavity Maintenance Catheter: Received FDA approval August 2009, based on the predicate device MammoSite Cavity Evaluation Device. The FDA indication for use states “the Contura Cavity Maintenance Catheter is temporarily implanted in the lumpectomy cavity as a placeholder until it is exchanged for the Contura MLB Applicator” (FDA, 2009).
- The SAVI Preparation device (Cianna Medical, Inc., Aliso Viejo, CA): Received FDA approval July 2010, based on the predicate devices of MammoSite and Contura (FDA, 2010). The intended use states the device “is temporarily implanted in the lumpectomy to access the lumpectomy cavity, aid in the selection of the appropriate SAVI brachytherapy applicator and serve as a placeholder until it is exchanged for the SAVI brachytherapy applicator.”

Electronic: Axxent Electronic Brachytherapy System (Xoft, Inc., Sunnyvale, CA). The intended use of this electronic brachytherapy system is “when a physician chooses to deliver intracavitary or interstitial radiation to the surgical margins after lumpectomy for breast cancer”. In February 2008, FDA granted marketing clearance for upgrades to the system as an HDR brachytherapy device for use with Axxent applicators to treat lesions, tumors, and conditions in or on the body where radiation is indicated. In February 2009, FDA granted marketing clearance for the Axxent Surface Applicator for use with the Axxent Brachytherapy System to deliver surface brachytherapy (ECRI, 2009).

Literature Review

Interstitial Brachytherapy: Interstitial brachytherapy studies have shown excellent control of disease with ipsilateral breast tumor recurrence (IBTR) rates of <5% at ≥5 years follow-up (Arthur, et al., 2008; Vicini, et al., 2007; Polgar, et al., 2007; Polgar, et al., 2004; Vicini, et al., 2003; King, et al., 2000). Additionally, there were no statistically significant differences in the five-year recurrence rates found between WBRT and interstitial brachytherapy (Polgar, et al., 2007; Polgar, et al., 2004; Vicini, et al., 2003). Antonucci et al. (2009) updated information previously reported by Vicini et al. (2003); noting the cumulative incidence of IBTR at 10 years was 5%; producing 10-year local control rates comparable to those from WBRT in selected low-risk patients (stages I/II breast cancer included infiltrating ductal carcinomas with diameter <3.0 centimeters [cm], negative surgical margins [≥2 millimeters, mm], age >40-50 years, and negative lymph nodes).

Intracavitary Brachytherapy: Although there are no direct comparison studies with WBRT and currently there are fewer longer-term studies for intracavitary brachytherapy as exist for interstitial brachytherapy, results

demonstrate excellent local recurrence rates, generally less than 5% at 2-5 years (Vicini, et al., 2010; Israel, et al., 2010; Harper, et al., 2010; Nelson, et al., 2009; Patel, et al., 2008; Benitez et al. 2007).

Cavity Evaluation Device (CED)/Cavity Maintenance Catheter: Although a temporary device is commonly used by some providers, there is insufficient evidence in the peer-reviewed scientific literature demonstrating any impact the use of a temporary device has on clinical outcomes.

Electronic/Kilovoltage Brachytherapy: In electronic brachytherapy, radioactive isotopes are not required. Miniature electronic x-ray tubes are used, requiring a minimally shielded treatment room and enabling clinicians to remain in the treatment room during therapy. Only a few small projected dosimetric comparison reports or toxicity reports have been published. There are no studies in the current peer-reviewed scientific literature reporting recurrence rates over time with the use of electric brachytherapy. There is insufficient evidence within the literature to support the use of electronic/kilovoltage brachytherapy in the treatment of patients with breast cancer.

Technology Assessments

Updated October 2008, the California Technology Assessment Forum (CTAF) reviewed current studies that have been conducted on the use of brachytherapy as a primary source of radiation therapy. The CTAF concluded that “the use of breast brachytherapy does not meet Technology Assessment Criteria 4 or 5 for safety, effectiveness and improvement in health outcomes when used as primary radiation therapy following breast conserving surgery for localized breast cancer.” CTAF criteria and results include:

- the technology must have the appropriate regulatory approval: met
- the scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes: met
- the technology must improve the net health outcomes:
 - met for interstitial brachytherapy
 - not met for balloon brachytherapy
- the technology must be as beneficial as any established alternatives: not met
- the improvement must be attainable outside the investigational setting: not met

The National Institute for Health and Clinical Excellence (NICE) (2008) in their guidance for brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision, stated “Current evidence on brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision raises no major safety concerns. Current evidence on its efficacy is limited in quantity and there is little information on long-term outcomes (5 years or more). Therefore, this procedure should be used only in the context of research, which should address control of local disease with a minimum of 5 years of follow-up.” This document addressed both interstitial and balloon brachytherapy.

Professional Societies/Organizations

American Society of Breast Surgeons (ASBS): The ASBS Consensus Statement for Accelerated Partial Breast Irradiation (October, 2008) stated that several single-institution, non-randomized studies using the multicatheter technique have shown low local recurrence rates that are comparable to standard external beam radiation therapy. Based on the available data the American Society of Breast Surgeons acknowledges the following:

1. Patients should be carefully selected for APBI and properly informed of the benefits and risks of this type of radiation treatment. The American Society of Breast Surgeons recommends the following selection criteria when considering patients for treatment with APBI, as a sole form of radiation therapy, in lieu of whole breast irradiation:
 - age 45 years old or greater
 - invasive ductal carcinoma or ductal carcinoma in situ
 - total tumor size (invasive and DCIS) less than or equal to 3 cm in size
 - negative microscopic surgical margins of excision
 - sentinel lymph node negative

2. Surgeons, radiation oncologists and physicists who will be utilizing the various APBI techniques should be adequately trained to allow for optimum radiation therapy planning and treatment.
3. All patients should be monitored regularly to identify adverse events as well as local recurrences.
4. The published data for APBI supports the recommendations summarized above. Continuous, long-term, outcomes-based monitoring of APBI is desirable. The ASBS maintains an ongoing Mammosite® Registry (registration completed in 2004) collecting data on more than 1400 patients treated via the balloon catheter technique. As is the case with all cancer treatments, participation in multi-institutional clinical studies, or in single site protocols, or in the context of data-gathering registries, is desirable, if available.

American Society for Radiation Oncology (ASTRO): ASTRO published a consensus statement on APBI (Smith, et al., 2009). Some of the included statements are as follows:

- All patients considered for APBI should be candidates for breast-conserving therapy (no earlier radiation therapy, no history of certain collagen vascular diseases, and not pregnant) and should be committed to long term follow-up to evaluate for recurrence, second primary cancers, and treatment toxicity. The Task Force's consensus defined the following: a "suitable" group, for whom treatment with APBI is considered acceptable outside of a clinical trial; a "cautionary" group, for whom caution and concern in the use of APBI should be exercised at this point in time because of limited data; and an "unsuitable" group, for whom APBI is not generally considered warranted outside of a clinical trial. A subset of the factors addressed includes:

Factors	Suitable	Cautionary
Age	≥60	50-59
Size of the invasive tumor	≤ 2	2.1–3.0
T N stage	T1, pN0	T0 or T2, n/a
Margins	Negative by at least 2 mm	Close (<2 mm)
Grade	Any	N/A
Estrogen receptor	Positive	Negative (Encouraged to enroll in RTOG 04-13 clinical trial)
Multicentricity	Unicentric only	N/A
Multifocality	Clinically unifocal with total size ≤2 cm*	Clinically unifocal with total size 2.1 to 3.0 cm*
Extensive intraductal component	Not allowed	≤3 cm in size
Histology	Invasive ductal or other favorable subtypes (mucinous, tubular, and colloid).	Invasive lobular

* Microscopic multifocality allowed, provided the lesion is clinically unifocal (a single discrete lesion by physical examination and ultrasonography/ mammography) and the total lesion size (including foci of multifocality and intervening normal breast parenchyma) does not exceed 2 cm for the "suitable" group and 3 cm for the "cautionary" group.

- Patients who choose treatment with APBI should be informed that WBI is an established treatment with a much longer track record, which has documented longterm effectiveness and safety. In contrast, APBI is a relatively new method with a limited track record, so its longterm effectiveness and safety are not fully known.
- Interstitial brachytherapy is the technique with the longest followup reported; followup data for other APBI techniques remain limited. Currently, there are insufficient clinical and dosimetric data to determine the optimal technique for APBI delivery (Smith, et al., 2009).

American Brachytherapy Society (ABS): The ABS recognizes the following patient selection criteria when using brachytherapy for the treatment of patients with breast cancer:

- age 50 years old or greater (age recommendation has been changed to reflect the uncertainty as to the influence of menopausal status and in recognition that most women treated in reported experiences with greater than five-year follow-up were postmenopausal and had a median age of 60 years or older)

- infiltrating ductal carcinoma only
- tumor size of less than or equal to three centimeters (cm) in size
- no distant metastasis (Keisch, et al., 2007).

American College of Radiology (ACR): The ACR has published practice guidelines for the management of ductal carcinoma in situ (DCIS) and invasive breast carcinoma (2006; 2006). For the management of DCIS and invasive breast carcinoma, they recommend “at the present time, patients with invasive or noninvasive breast cancer undergoing breast conserving treatment, and interested in APBI should be made aware of the status of data exploring this treatment approach and given the option of participation in Phase III trials. Data from the National Surgical Adjuvant Breast and Bowel Project (NSABP) and Radiation Therapy Oncology Group (RTOG) Phase III trial will be critical in helping to determine the long-term efficacy of APBI and the patients most suitable for its application.”

National Comprehensive Cancer Network Guidelines™ (NCCN®): The NCCN Clinical Practice Guideline for Breast Cancer (v.2.2010) states the use of whole breast irradiation with boost (by photons, brachytherapy or electron beam) to the tumor bed is recommended to maximize local control, especially in patients 50 years of age or younger. The NCCN states that partial breast radiation (PBR) should be performed only as part of a prospective trial. If no trial eligible, PBI should be reserved for patients with a low risk of recurrence (NCCN, 2010).

Summary

For early-stage breast cancer, breast-conserving surgery followed by radiation therapy is the standard treatment of choice. Radiation therapy may be administered via whole-beam (WBRT) or brachytherapy methods. The use of brachytherapy as an adjunct to chemotherapy or WBRT, and also as the sole radiotherapy after breast-conserving surgery has become a standard of care within the armamentarium of breast cancer treatments. Although there are fewer longer-term studies for intracavitary brachytherapy as exist for interstitial brachytherapy as the sole radiotherapy after breast-conserving surgery, overall results demonstrate excellent local recurrence rates; rates comparable with WBRT.

There is insufficient evidence in the published, peer-reviewed scientific literature to support the use of brachytherapy as the sole radiotherapy after breast-conserving surgery for any woman not meeting the American Society of Breast Surgeons (ASBS) 2008 selection criteria for accelerated partial breast irradiation.

The use of a cavity evaluation device or cavity maintenance catheter is considered to be incidental to the breast-conserving surgery.

There is insufficient evidence within the literature to support the use of electronic/kilovoltage brachytherapy as an adjunct to or for the sole treatment of patients with breast cancer.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®*	Description
19296	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19297	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following

	(at the time of or subsequent to) partial mastectomy, includes imaging guidance
19499 [†]	Unlisted procedure, breast
77326	Brachytherapy isodose plan; simple (calculation made from single plane, one to four sources/ribbon application, remote afterloading brachytherapy, 1 to 8 sources)
77327	Brachytherapy isodose plan; intermediate (multiplane dosage calculations, application involving 5 to 10 sources/ribbons, remote afterloading brachytherapy, 9 to 12 sources)
77328	Brachytherapy isodose plan; complex (multiplane isodose plan, volume implant calculations, over 10 sources/ribbons used, special spatial reconstruction, remote afterloading brachytherapy, over 12 sources)
77761	Intracavitary radiation source application; simple
77762	Intracavitary radiation source application; intermediate
77763	Intracavitary radiation source application; complex
77776	Interstitial radiation source application; simple
77777	Interstitial radiation source application; intermediate
77778	Interstitial radiation source application; complex
77785	Remote afterloading high dose rate radionuclide brachytherapy 1 channel
77786	Remote afterloading high dose rate radionuclide brachytherapy; 2-12 channels
77787	Remote afterloading high dose rate radionuclide brachytherapy; over 12 channels
77790	Supervision, handling, loading of radiation source

[†]Note: Separate reimbursement will not be provided for the temporary implantation of a cavity evaluation device (CED)/cavity maintenance catheter performed at the same time as a breast-conserving surgery in anticipation of brachytherapy because it is considered to be incidental to the breast-conserving surgery.

ICD-9-CM Diagnosis Codes	Description
174.1	Malignant neoplasm of central portion of female breast
174.2	Malignant neoplasm of upper-inner quadrant of female breast
174.3	Malignant neoplasm of lower-inner quadrant of female breast
174.4	Malignant neoplasm of upper-outer quadrant of female breast
174.5	Malignant neoplasm of lower-outer quadrant of female breast
174.6	Malignant neoplasm of axillary tail of female breast
174.8	Malignant neoplasm of other specified sites of female breast
174.9	Malignant neoplasm of breast (female), unspecified site
198.81	Secondary malignant neoplasm of breast
233.0	Carcinoma in situ of breast

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0182T	High dose rate electronic brachytherapy, per fraction

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0204	Brachytherapy for Breast Cancer

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.