



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 Breast Biopsy Procedures including Sentinel Node Biopsy

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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 minimally invasive breast biopsy procedures as medically necessary to confirm the diagnosis of breast cancer.

CIGNA covers sentinel lymph node biopsy (SLNB) as medically necessary to diagnose lymph node involvement in individuals with breast cancer.

CIGNA does not cover radioactive seed localization because it is experimental, investigational or unproven.

General Background

The presence or absence of carcinoma in a suspicious clinically or mammographically detected abnormality can only be reliably determined by tissue sampling. A biopsy remains the standard technique for diagnosing both palpable and nonpalpable breast abnormalities and is the preferred initial method of evaluating almost all breast masses (Conzen, 2008). Studies have shown that the combination of a physical examination, radiographic

imaging and cyto/histo/pathological confirmation, also referred to as “the triple-test,” can produce accuracy levels of over 90% when all three components are concordant for benign or malignant disease (Singhal, 2008).

The American College of Radiology ([ACR], 2009a) has developed a standard way of describing mammogram findings known as the Breast Imaging Reporting and Data System (BI-RADS). Indications for breast biopsy include BI-RADS category four (i.e., suspicious abnormality) and category five (i.e., highly suggestive of malignancy) lesions. Under certain circumstances when a mass or radiographic abnormality is categorized as probably benign in the presence of high patient anxiety, family history of breast cancer, or poor likelihood of compliance with recommended six-month follow-up imaging, a breast biopsy may be recommended for category three lesions (American Cancer Society, [ACS], 2009; National Comprehensive Cancer Network® [NCCN®], 2010).

A number of well-designed studies have demonstrated the safety and clinical utility of minimally invasive breast biopsy methods relative to open surgical biopsy. Advantages include less discomfort for the patient, a reduction in scarring and cosmetic defect, less invasive procedure, and quicker patient recovery. Several techniques may be used to obtain tissue samples, including fine needle aspiration biopsy, core-needle biopsy with ultrasound or stereotactic (e.g., conventional core), vacuum-assisted core (e.g., automated or by the Advanced Breast Biopsy Instrumentation [ABBI®] system), automated excisional biopsy, and wire localization. Radioactive seed localization has also been proposed as a means to facilitate the operative excision of nonpalpable breast lesions.

Fine-Needle Aspiration or Biopsy (FNA, FNB or FNAB): Fine-needle aspiration or biopsy is a simple, minimally invasive technique used to obtain a sample of cellular tissue or fluid from palpable lesions. The main advantages of FNA are that it does not require an incision and that in some cases it is possible to make a diagnosis the same day. The disadvantage is that sometimes this needle cannot remove enough tissue for a definite diagnosis (ACS, 2009). Complications from the procedure are minimal, and may include mild pain, hematoma, infection, and fainting. The sensitivity of FNA ranges from 80% to 95%, and false-positive aspirates are seen in <1% of cases in most series. False-negative results are seen in 4% to 10% of cases and are most common in fibrotic or well-differentiated tumor (Conzen, 2008). In a large retrospective study of 730 consecutive patients who underwent FNA, accuracy was 95%, and specificity was 100%. Using histology or clinical follow-up, PPV was 100% and NPV was 99% (Florentine, 2006).

Divergent opinions persist about the reliability of the FNA and its role in clinical management. It is best used as an adjunctive diagnostic tool used to complement, not supplant, the clinical, radiographic, and laboratory findings (Westra, 2008).

Core-Needle Biopsy (CNB): Core cutting needle biopsy, also called percutaneous core breast biopsy, has many of the advantages of FNA. It is less invasive, has shorter recovery time, and is less deforming than open surgical excision. In addition, it causes minimal to no scarring on mammogram (Lieberman, 2001). It provides a histologic specimen suitable for interpretation by any pathologist, which is vital to the planning of subsequent surgery and treatment of the patient, and can be used to detect in situ as well as invasive malignancy. In addition, estrogen and progesterone receptor status and the presence of HER-2 overexpression can be routinely determined from core biopsy specimens, making core needle biopsy the diagnostic technique of choice for patients who will receive preoperative systemic therapy (Conzen, 2008). CNB may be performed using several guidance modalities (e.g., stereotaxis, ultrasound) and different tissue acquisition devices (e.g., automated needles or vacuum-assisted biopsy probes) (Lieberman, 2001). A stereotactic approach is preferred when areas of micro-calcification require biopsy, and for masses that are detected on radiographic imaging, but cannot be palpated.

The sensitivity and specificity of CNBs have been reported as 90.5%-96% and 88.1-100%, respectively (Schueller, 2008; Singhal, 2008; Ciatto, 2006; Topal, 2005). In a retrospective study of 4035 women who underwent core biopsy, positive and negative predictive values were reported as 84.8% and 95.6%, respectively (Ciatto, 2006). False-negative results due to sampling error may also occur with CNB. If concordance between the core biopsy diagnosis and the clinical and imaging findings is not present, additional tissue should be obtained, usually by excisional biopsy. Stereotactic CNB is a viable option to a needle or wire-localized open excisional biopsy for diagnosing breast cancer.

Vacuum-Assisted Core Biopsy (VACB): Vacuum-assisted breast biopsy is performed as an alternative to core-needle biopsy or open surgical biopsy. Concerns about the false-negative rate of image-guided core biopsy have been resolved with the availability of large, vacuum-assisted biopsy devices that increase the extent of lesion sampling (Conzen, 2008).

There are three forms of vacuum-assisted core biopsy (VACB): minimally invasive breast biopsy (MIBB), semi-automated, and fully-automated. There are several design and clinical advantages of this procedure over a fine needle biopsy. These include that the vacuum can be used to suction blood from the biopsy cavity during the procedure, the probe can be inserted once with multiple specimens obtained from a single insertion, and that the specimens are larger than those obtained with the fine-needle aspiration (FNA). Additionally, the device allows the placement of a localizing clip to mark the biopsy site (Lieberman, 2001). Clinical advantages include the ability of the pathologist to make a definitive diagnosis, to differentiate most in situ carcinomas from invasive carcinomas, and greater probability that the tissue sample will be of adequate size for this diagnostic process to occur. In a retrospective study of 1152 women with 1280 lesions who underwent stereotactic vacuum-assisted needle breast biopsy, Jackman et al. (2009) reported false negative diagnoses were made in 25% (one of four) of cases in which specimen radiographs showed no calcifications and 0.67% (two of 300) of cases in which they did show calcifications. False-negative diagnoses were made in 1.2% (three of 248) of cases of calcification lesions and 0.8% (two of 260) of cases of mass lesions.

The National Institute for Clinical Excellence for the United Kingdom (NICE, 2006) completed an analysis of several case series concerning image-guided vacuum-assisted excision biopsy of benign breast lesions. NICE concluded that the current evidence on the safety and efficacy of image-guided vacuum-assisted excision biopsy of benign breast lesions appears to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

Food and Drug Administration (FDA) 510(k) approved devices include:

- Mammotome® System (Ethicon Endo-Surgery of Johnson & Johnson). Although the sample(s) may partially or completely remove imaging evidence of abnormality, this device is to be used for diagnosis and is not indicated for therapeutic use.
- Advanced Breast Biopsy Instrumentation (ABBI®) (United States Surgical Corp., Norwalk, CT).

Excisional Biopsy: According to the NCCN (2010), “Excisional needle biopsy involves the removal of the entire breast mass or suspicious area of the breast by a surgeon in an operating room setting. Needle or wire localization is performed by the radiologist immediately prior to an excisional biopsy to direct surgical excision” (NCCN, 2010). Excisional biopsy is indicated in the following situations: for a nondiagnostic core biopsy, when atypical ductal hyperplasia is found, when ductal cancer in situ (DCIS) is present, when the patient has a radial scar, and when calcifications cannot be sampled (Abeloff, 2008).

“The current standard of practice for patients diagnosed with early-stage breast cancer via core biopsy is to undergo an open surgical excision or surgical lumpectomy, with histopathological confirmation of clear surgical margins” (NCCN, 2010). Researchers and device manufacturers have proposed the use of automated excision/extraction devices in lieu of open surgical excision; however, they have not been approved for use as early breast cancer treatment modalities. The use of these devices is not intended to eliminate the need for surgical intervention but may assist in determining the timing and extent of treatment that may be needed to care for a patient when results are suspicious, or malignancy is noted. The various devices may also allow real-time imaging to occur for the precise localization of the lesion for sampling; the biopsy sites can be marked (e.g., inked or clipped) for additional radiological study or for surgical excision. At this time the role of these systems for the treatment of breast cancer has not been established.

FDA 510(k) approved devices include:

- Automated Tissue Excision and Collection (ATEC)® Breast Biopsy System (Hologic, Inc., (Bedford, MA.) formerly Suros Surgical Systems, Inc., (Indianapolis, IN).
- The Intact™ Breast Lesion Excision System (BLES) (formerly known as the en-bloc Biopsy System™ [Neothermia Corp.], manufactured by Intact Medical Corporation (Natick, MA).

Wire-Localization: Wire-localization biopsy is an outpatient, surgical procedure, performed under local anesthesia, in which the wire serves as a guide to perform an excisional surgical biopsy. It has been in use for >25 years and is considered the “gold-standard” technique for the surgical excision of non-palpable breast lesions. Wire localized excisional biopsy is highly accurate and results in good to excellent cosmetic outcome (Abeloff, 2008). Radiographic films of the breast are taken and a wire-lock needle is inserted either to the side of the lesion, or in the case of small calcifications, into the center of the microcalcified clusters. Additional mammography, flat radiographs, or ultrasound may be used to visualize the lesion and insert the wire guide. According to the NCCN (2010), “Wire localization may bracket a lesion that had a clip placed at the time of core needle biopsy.”

Radioactive Seed Localization (RSL): This approach has been proposed as an alternative to wire localization prior to excisional breast biopsy or breast conservation surgery. It involves the introduction of a radioactive titanium seed containing 3.7 to 10.7 MBq of ¹²⁵Iodine (I) which has a half-life of 60 days and emits 27 keV of gamma radiation as a point source for localization. Using ultrasound or mammographic guidance to locate the breast lesion the radioactive seed is introduced into the breast parenchyma through an 18 gauge needle. An intraoperative handheld gamma probe is used to localize the ¹²⁵I seed by scanning the breast for a focus of intense uptake. The gamma probe is also used to confirm that the seed is contained within the resected specimen and removed when the lesion is extracted (Jakub, 2010).

Researchers propose several advantages of this procedure compared with the use of wire localization: because of the long half-life of the seed, it can, in theory, be placed several weeks before the surgical procedure, which may allow more flexibility in scheduling of surgical times. It is suggested that incision placement is improved because the surgeon has precise knowledge regarding the location of the radiologic marker and target lesion. Additionally, the number of radiographs required to identify lesions may be reduced (Jakub, 2010). Disadvantages include the necessity of the radioactive marker to be contained within a lead container and returned after use to the appropriate department for long-term decay. Care must also be taken during specimen processing that the seed not be cut; if this occurs the ¹²⁵I could become airborne or solubilized. Additionally, protocols must be in place for tracking the marker.

Randomized clinical trial data regarding the safety, effectiveness and clinical utility of radioactive seed localization are limited. Gray et al. (2001) initially randomized 106 women with non-palpable breast lesions to RSL or wire localization. Ninety-seven women were assessable in the final study group: RSL (n=51), wire localization (WL) (n=46). Fifty-six patients (58%) underwent localization for excisional biopsy and forty-one patients (42%) underwent localization for lumpectomy. RSL was carried out with a titanium seed containing .29 mCi of ¹²⁵I. Both RSL and WL utilized mammographical or ultrasound guidance. The lesion was retrieved in 100% of patients in both groups. No significant migration of the localization device was observed in either group. No significant differences were reported for mean times associated with radiographical localization or operative excision between the groups. Twenty-six percent of patients undergoing RSL had pathologically involved margins of excision compared with 57% of those undergoing WL. The sentinel lymph node was identified in 97% of the RSL group compared with 100% in the WL group. Metastatic breast cancer was identified in 10% of the RSL patients compared with 18.2% of WL patients. The authors noted that a benefit to the use of RSL was a reduction in the incidence of involved margins of excision and a reduction in scheduling conflicts. The study was limited by a small patient population, and a lack of data regarding short or long-term outcomes, including safety outcomes associated with the use of the radioactive seed.

In another study by Gray (2004), 200 consecutive patients underwent WL (n=100) or RSL (n=100). No significant differences were noted between groups for retrieval rates of the localization device or lesion. All WL procedures were performed the day of surgery while 68% of patients received RSL at least one day prior to the day of surgery. Six percent of patients undergoing WL required two wires to bracket a lesion; 7% of patients undergoing RSL required two radioactive seeds for localization. Patients undergoing RSL had a 35% relative improvement in the rate of negative margins in the first specimen as compared to the WL patients (p=0.01) and a 62% relative improvement in the rate of reoperation for positive margins (p=0.01). Limitations to the study include uncontrolled design, and a lack of data regarding long-term outcomes.

Cox et al. (2003) reported outcomes of a trial of a prospective case series study of 146 women with nonpalpable breast lesions requiring biopsy or lumpectomy. One hundred and thirty-four women underwent RSL using .20 to .29 mCi of ¹²⁵I. One hundred and twenty-four women were evaluable. Eighteen patients either had ≥2 lesions or required ≥2 seeds to bracket the lesion requiring placement of 146 seeds. The lesion was grossly identified in

73.9% of cases. Specimen radiographs were performed to identify pathologic lesions in 22.5% of 142 lesions; 77.5% of lesions did not require a radiograph for identification. Study limitations include uncontrolled design, including lack of comparator, and a lack of data regarding long-term outcomes.

Although promising, there is insufficient evidence to support the safety, effectiveness and clinical utility of RSL for the localization of nonpalpable breast lesions. At this time, the role of RSL has not been established for this indication.

Sentinel Lymph Node Biopsy: Sentinel lymphadenectomy or sentinel lymph node biopsy (SLNB) identifies the first, or “sentinel”, lymph node (SLN) or nodes in the lymph node chain that receives drainage from the breast. Individuals diagnosed with breast cancer as a result of breast biopsy procedures may be referred for a sentinel node biopsy to further assist in strategic planning for surgical and/or adjunctive interventions of care. This procedure and lymphatic mapping may be used instead of full axillary dissection to stage early breast cancer, which carries with it additional morbidity (Abeloff, 2008; Sukunivanich, 2008; Kell, 2004; Kelley, 2004).

A negative sentinel lymph node (SLN) biopsy suggests that cancer has not spread to the lymph nodes. It is considered sufficient to rule out metastasis in other nodes, which leads to reduced short-term morbidity and improved quality of life (Canavese, 2009). A positive result indicates that cancer is present in the sentinel lymph node (SLN) and may be present in other lymph nodes in the same regional area. Several prospective randomized controlled trials, systematic reviews, and case studies have demonstrated the benefit of sentinel lymph node biopsy (SLNB) compared with axillary lymph node dissection (Canavese, 2009; Gill, 2009; Kelly, 2009; Heuts, 2007; Langer, 2007; Wilke, 2006). Sensitivity ratings of SLNB when compared to axillary node biopsies have yielded results of 93% accuracy, 77.1–>96% sensitivity, 91.1–98% negative predictive value and a false-negative rate of 5.5–8%, respectively, for SLNB, versus 97.3% sensitivity, negative predictive value of 98.5% with a false-negative rate of 2.7%, respectively, for axillary node biopsy.

Although large prospective multi-institutional studies are in progress to establish the precise clinical utility of this technique, SLNB has largely replaced axillary dissection for patients with clinically negative axillae and is becoming the standard surgery for staging cancers, including women with clinically negative lymph nodes (Abeloff, 2008; Sukunivanich, 2008; Heuts, 2006; Wood, 2005; Kell, 2004; Muss, 2004). There is emerging consensus that complete axillary dissection could be safely omitted in SLN-negative patients, thus sparing them the known immediate sequelae of axillary surgery (Canavese, 2009).

Professional Societies/Organizations

American Cancer Society (ACS, 2009): The ACS supports the use of various biopsy techniques, including excisional biopsy, wire localization, fine needle aspiration, core needle biopsy, stereotactic needle biopsy, stereotactic core needle biopsy, and vacuum-assisted breast biopsy.

American College of Radiology (ACR, 2009b, 2009c): The ACR published a practice guideline for the Performance of Stereotactically Guided Breast Interventional Procedures which notes that image-guided core needle biopsy has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis, including microcalcifications, masses, asymmetries, and architectural distortions. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, less cost, and similar accuracy.

American Society of Breast Surgeons (ASBS): The ASBS published Performance and Practice Guidelines for Stereotactic Breast Procedures which notes the following indications for breast biopsy:

- Primary diagnosis
 - Highly suspicious microcalcifications or densities (Breast Imaging Reporting and Data System [BI-RADS] 5) to confirm the diagnosis and facilitate treatment planning
 - Suspicious microcalcifications or densities (BI-RADS 4).
 - Probably benign microcalcifications or densities (BI-RADS 3) when there are valid clinical indications
 - Multifocal or multicentric lesions to facilitate treatment planning
- Rebiopsy
 - Stereotactic biopsy is an option for repeat biopsy when the initial biopsy results are discordant with the imaging assessment (2007, updated 2010).

The ASBS (2006) Percutaneous Needle Biopsy for Image Detected Breast Abnormalities guideline notes that image guided percutaneous needle biopsy is the diagnostic procedure of choice for image-detected breast abnormalities. Percutaneous histologic tissue-acquisition techniques include large-core biopsy, vacuum-assisted biopsy, and larger tissue-acquisition methods. In general, stereotactic guidance using vacuum-assisted devices with larger (11 gauge or greater) needles is the preferred approach for lesions presenting as microcalcifications without a mass. The Guideline also notes for smaller lesions (1 cm or less,) percutaneous excision using a vacuum-assisted device with clip placement is desirable. For larger (greater than 1 cm) BI-RADS 4 or 5 masses, 14-gauge core needle biopsy is sufficient. While fine-needle aspiration cytology is useful for lymph node evaluation, it is less desirable than histologic tissue-acquisition techniques for evaluation of primary breast lesions. Regardless of the instrument used, correlation of histologic and imaging findings is essential.

American Society of Clinical Oncology (ASCO) (Lyman, 2005): ASCO published recommendations for the use of sentinel lymph node biopsy (SLNB) in patients with early-stage breast cancer which include:

- the use of SLNB in most women with clinically negative axillary lymph nodes
- performing an axillary lymph node dissection (ALND) in patients with a failed or technically unsatisfactory sentinel node biopsy (SNB) procedure, or the presence of clinically suspicious nodes in the axilla palpable at the time of surgery
- an ALND in patients with a positive SLN according to routine pathological examination

National Comprehensive Cancer Network Guidelines™ (NCCN Guidelines™): The NCCN Guidelines “support the use of tissue diagnosis using needle biopsy (preferred) or needle localization excisional biopsy for BI-RADS categories 4 and 5 lesions.” The Guidelines “recommend breast biopsy if diagnostic mammogram and/or ultrasound findings are suspicious or highly suggestive of malignancy.” The Guidelines also note “Performance of sentinel lymph node biopsy can be considered in patients with clinically negative axillary nodes and large clinical stage IIA , IIB, ad T3N1M0 tumors. For those with clinically suspicious axillary lymph nodes, the panel recommends either a core biopsy or FNA of these nodes, along with a sentinel node biopsy if FNA or core biopsy results are negative.” The Guidelines note “sentinel node biopsy should not be offered to pregnant women who are under 30 weeks gestation” (2010).

Summary

The published, peer-reviewed literature supports the clinical utility of minimally invasive breast biopsies, including sentinel node biopsy in the evaluation of breast cancer. However, data regarding the safety, effectiveness, and clinical utility of radioactive seed localization are limited. At this time the role of RSL prior to excisional biopsy or breast conservation surgery has not been established.

The clinical utility of all automated tissue excision systems when used as early therapeutic modalities for the treatment of breast cancer has not been demonstrated through well-designed clinical trials. There is insufficient evidence in published, peer-reviewed scientific literature to support the use of these automated, excision breast biopsy systems, as their long-term safety and efficacy has not yet been determined.

Coding/Billing Information

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

Covered when medically necessary:

CPT®*	Description
10021	Fine needle aspiration; without imaging guidance
10022	Fine needle aspiration; with imaging guidance
19100	Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)
19102	Biopsy of breast; percutaneous, needle core, using imaging guidance
19103	Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance

19290	Preoperative placement of needle localization wire, breast
19291	Preoperative placement of needle localization wire, breast; each additional lesion (List separately in addition to code for primary procedure)
19295	Image guided placement, metallic localization clip, percutaneous, during breast biopsy
38500	Biopsy or excision of lymph node(s);open, superficial
38505	Biopsy or excision of lymph node(s); by needle, superficial (e.g.: cervical, inguinal, axillary)

ICD-9-CM Diagnosis Codes	Description
174	Malignant neoplasm of nipple and areola of female breast
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
217	Benign neoplasm of breast
233.0	Carcinoma in situ of breast
238.3	Neoplasm of uncertain behavior of breast
239.3	Neoplasm of unspecified nature of breast
175.0	Malignant neoplasm of nipple and areola of male breast
175.9	Malignant neoplasm of other and unspecified sites of male breast
610.0	Solitary cyst of breast
610.1	Diffuse cystic mastopathy
610.2	Fibroadenosis of breast
610.3	Fibrosclerosis of breast
610.8	Other specified benign mammary dysplasias
611.0	Inflammatory disease of breast
611.72	Signs and symptoms of the breast, lump or mass in breast
793.80	Unspecified abnormal mammogram
793.81	Mammographic microcalcification
793.89	Other abnormal findings on radiological examination of breast

Experimental/Investigational/Unproven/Not Covered when used to report radioactive seed localization:

CPT* Codes	Description
19499	Unlisted procedure, breast

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

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
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