Cigna Medical Coverage Policy

Subject **Emerging Breast Localization/Biopsy Procedures**

Effective Date **11/15/2014**
Next Review Date **11/15/2015**
Coverage Policy Number **0205**

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Coverage Policy

Cigna does not cover tomosynthesis-guided localization/biopsy 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 (Burstein, 2011). 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, 2011).

The American College of Radiology ([ACR], 2011) 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 (National Comprehensive Cancer Network® [NCCN®], 2014).

The advantages of minimally invasive breast biopsy methods relative to open surgical biopsy 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. Wire localization is the standard of care for the localization of nonpalpable breast lesions prior to excisional surgical biopsy. Radioactive seed localization has also been proposed as a means to facilitate the operative excision of non-palpable breast lesions. Image guidance is also used for preoperative needle localization.

Tomosynthesis–Guided Biopsy
The use of tomosythesis to guide breast procedures such as localization/biopsy is currently under investigation. Breast tomosynthesis, also called three-dimensional (3D) breast imaging, is a mammography system where the x-ray tube moves in an arc over the breast during the exposure. It creates a series of thin slices from which numerous projection images are obtained. Data from these projection images are then manipulated using reconstruction algorithms similar to computed tomography (CT) scans to produce thin-slice cross-sectional images through the breast. The manufacturer of the Affirm Breast Biopsy Guidance System (Hologic, Inc., Danbury, CT) states that this biopsy option allows a radiologist to locate and target areas of interest for biopsy using tomosynthesis (Hologic, 2014). However, the published peer-reviewed scientific literature has not demonstrated the accuracy and clinical utility of three-dimensional (3D) digital tomosynthesis.

U.S. Food and Drug Administration (FDA): The Affirm Breast Biopsy Guidance System (Hologic, Inc., Danbury, CT) was granted approval by the FDA via the 510(k) process on January 11, 2013. The Affirm Breast Biopsy Guidance System is considered substantially equivalent to another device already on the market which is used with the Selenia Full Field Digital Mammography X-ray system to provide location of areas of concern and pre-surgical localization for performance of breast biopsies on an upright mammography system. The Affirm system is “intended to provide guidance for interventional purposes (e.g., biopsy, pre-surgical focalization or treatment devices)” (FDA, 2013).

Literature Review: There is a paucity of studies in the published peer-reviewed scientific literature evaluating tomosythesis-guided breast procedures. Few evaluation studies consisting of patient populations ranging from 39-118 have been conducted (Tucker, et al., 2014; Viala, et al., 2013). Reported adverse events have included hematoma (n=8), hemorrhage (n=5), and infection (n=1) (Viala, et al., 2013; n=118 biopsies). Although results of these preliminary studies suggest that 3D digital tomosynthesis may improve visualization of breast lesions over conventional two-dimensional (2D) imaging, insufficient evidence exists to demonstrate safety and effectiveness and to determine the role of this technology in breast biopsy or pre-surgical localization.

Professional Societies/Organizations
The National Comprehensive Cancer Network (NCCN) guidelines Breast Cancer Screening and Diagnosis support the use of tissue diagnosis using needle biopsy (preferred) or needle localization excisional biopsy for BI-RADS categories 4 and 5 lesions. According to the NCCN, breast biopsy is recommended if a suspicious malignancy is identified by diagnostic mammogram and/or ultrasound (NCCN, 2014). The NCCN does address tomosynthesis-guided breast interventions.

The American Cancer Society (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 (ACS, 2014a). The ACS states that the role of breast tomosynthesis in screening and diagnosing breast cancer is still unclear (ACS, 2014b).

Use Outside of the US
No relevant information.

Summary

Evidence in the published, peer-reviewed medical literature investigating tomosythesis-guided breast interventions is limited. Overall, there is insufficient evidence from which to draw conclusions regarding the effectiveness and clinical utility. As such, tomosynthesis for breast interventional procedures is unproven.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered when used to report tomosynthesis–guided localization/biopsy:

CPT* Codes	Description
76499	Unlisted diagnostic radiographic procedure
77061	Digital breast tomosynthesis; unilateral (Code effective 01/01/2015)
77062	Digital breast tomosynthesis; bilateral (Code effective 01/01/2015)

***Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.**

References

1. American Cancer Society (ACS). Breast Cancer: Types of biopsy procedures. Updated 2014(a) Jul 21. Accessed Oct 5, 2014. Available at URL address: http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/forwomenfacingabreastbiopsy/breast-biopsy-biopsy-types

2. American Cancer Society (ACS). Mammograms and other breast imaging procedures. Updated 2014(b) Jun 10. Accessed Oct 5, 2014. Available at URL address: http://www.cancer.org/acs/groups/cid/documents/webcontent/003178-pdf.pdf

3. American Society of Breast Surgeons (ASBS). Position Statement on Breast Cancer Lumpectomy Margins. Jan 2013. Accessed Oct 6, 2013. Available at URL address: http://www.breastsurgeons.org/statements/Performance_Practice_Guidelines_Stereo.pdf

4. Burstein HJ, Harris JR, Morrow M. Malignant tumors of the breast. In: DeVita VT, Lawrence TS, Rosenberg S, editors. Devita, Hellman & Rosenberg's Cancer: Principles & Practices of Oncology.9th ed. Philadelphia, PA: Lippincott, Williams & Wilkins;2011.

5. Hologic, Inc. Affirm breast biopsy guidance system. © 2014 Accessed Oct 5, 2014. Available at URL address: http://www.hologic.com/products/intervention-and-treatment/breast-biopsy/affirm-breast-biopsy-guidance-system

6. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™: Breast Cancer Screening and Diagnosis. Version 1.2014. © National Comprehensive Cancer Network, Inc 2012, All Rights Reserved. Accessed October 5, 2014. Available at URL address: http://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf

7. Singhal H, Lai LM, Teh W, Lewin JM, Coombs BD, Azavedo E, et al. Breast, stereotactic core biopsy/fine needle aspiration. Updated Jan 20, 2011. Accessed Sep 11, 2011. Available at URL address: http://www.emedicine.com/radio/topic768.htm

8. Tucker AW, Calliste J, Gidcumb EM, Wu J, Kuzmiak CM, Hyun N, et al. Comparison of a Stationary Digital Breast Tomosynthesis System to Magnified 2D Mammography Using Breast Tissue Specimens.

Acad Radiol. 2014 Aug 27. pii: S1076-6332(14)00271-2. doi: 10.1016/j.acra.2014.07.009. [Epub ahead of print]

9. U.S. Food and Drug Administration. Center for Devices and Radiologic Health. 510K database. Modified Affirm Breast Biopsy Guidance System: 510(k) Summary. Accessed 2013 Sep 14. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf12/k122836.pdf

10. Viala J, Gignier P, Perret B, Hovasse C, Hovasse D, Chancelier-Galan MD, et al. Stereotactic vacuum-assisted biopsies on a digital breast 3D-tomosynthesis system. Breast J. 2013 Jan-Feb;19(1):4-9. doi: 10.1111/tbj.12044. Epub 2012 Dec 17.