# **Medical Coverage Policy**



## **Digital Breast Tomosynthesis**

Device/Equip	ment 🗌 Drug 🗌 I	Medical 🗌 Surgery	Test Other
Effective Date:	2/07/2011	Policy Last Updated:	3/5/2013

### Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

## Prospective review is not required.

#### **Description:**

Digital breast tomosynthesis uses existing digital mammography equipment to obtain additional radiographic data that are used to reconstruct cross-sectional "slices" of breast tissue. Tomosynthesis may improve the accuracy of digital mammography by reducing problems caused by overlapping tissue. Tomosynthesis involves some additional imaging time and radiation exposure.

To acquire the three-dimensional (3D) DBT images, the x-ray tube head is moved in a 15 degree arc over the stationary breast acquiring 11 to 21 (typically 15) x-ray projection images. The projection images are reconstructed to produce cross-sectional "slices" through the breast. The nominal thickness of the slices can vary from 0.5 to 10 mm, with 1 mm being the "normal" thickness.

The same detector and x-ray tube are used to acquire both the 2D and 3D images. Images can be acquired in any orientation of the gantry, including the standard cranio-caudal (CC) and mediolateral oblique (MLO) mammography views, which may be useful in comparing new images with older mammography results. The 2D and 3D images can be acquired during a single breast compression, or they can be acquired separately.

Digital breast tomosynthesis (DBT) is being developed as an approach to generate images that may improve the sensitivity and specificity of mammography. Current radiographic approaches to mammography produce two-dimensional (2D) images. These 2D systems can have limitations due to overlapping tissue in the breast that may hide lesions (cancers) or cause benign masses to appear suspicious. DBT may be utilized along with full-field digital mammography (FFDM) in screening for breast cancer and may also be used as a technique for the diagnosis of breast cancer in helping to clarify equivocal mammographic findings.

In evaluating DBT, studies must consider test accuracy (sensitivity and specificity), as well as recall rates. In addition, the incremental value of DBT might be compared to using additional views from traditional mammography. Radiation exposure is also a very important consideration. Finally, issues such as the duration of the examination (breast compression) are also important.

There are no studies currently published that provide adequate information about outcomes (sensitivity, specificity, accuracy, recall rate) when DBT is used in clinical practice. The use of digital breast tomosynthesis in generating images for screening or diagnosis of breast cancer is considered not medically necessary. Studies of outcomes (including accuracy and recall rate) with use in clinical practice are needed. In addition, there are unanswered questions about the number of images needed as well as concerns about radiation dose and time for interpretation.

#### **Medical Criteria:**

None.

#### Policy:

Digital breast tomosynthesis is considered not medically necessary in the screening or diagnosis of breast cancer as there is insufficient evidence in published, peer-reviewed literature to support its efficacy.

#### Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for laboratory testing/not medically necessary services.

#### Coding:

At this time, there are no specific CPT codes for this test. Tests should be reported with the appropriate breast mammography code (77055-77057) along with an unlisted code (e.g., 76499) for the additional views.

The following codes are covered and medically necessary:

77055 77056 77057

Digitial breast tomosynthesis is not medically necessary and should be filed with the following unlisted code. 76499

Related Topics: None

Also known as: None

Published:

Provider Update, May 2013 Provider Update, April 2012

#### **References:**

Blue Cross and Blue Shield Association Medical Policy Reference Manual, Policy No. 6.01.53.

Poplack, SP., Tosteson, TD., Kogel, CA., Nagy, HM. Digital breast tomosynthesis: initial experience in 98 women with abnormal digital screening mammography. American Journal of Roentgenology;2007;189(3):616-623.

Spangler ML, Zuley ML, Sumkin JH, et al. Detection and classification of calcifications on digital breast tomosynthesis and 2D digital mammography: a comparison. American Journal of Roentgenology; 2011 Feb;196(2):320-4.

Teertstra HJ, Loo CE, van den Bosch MA, et al. Breast tomosynthesis in clinical practice: initial results. European Radiology;2010 Jan;20(1):16-24.

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