

Corporate Medical Policy

Digital Breast Tomosynthesis

File Name: digital_breast_tomosynthesis
Origination: 3/2011
Last CAP Review: NA
Next CAP Review: 3/2012
Last Review: 3/2011

Description of Procedure or Service

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.

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.

Regulatory Status

On February 11, 2011, the FDA approved Hologic, Inc. to market its Selenia Dimensions 2D Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) system. This DBT is the first mammography system that provides 3D images of the breast for breast cancer screening and diagnosis. The FDA approved the 2D modality of this system two years ago. Since then, a number of facilities in the U.S. have been using the Selenia Dimensions 2D (with the DBT locked). Facilities that have an accredited (or have applied to be accredited) Selenia Dimensions 2D unit can activate the DBT modality of the unit after applying to and obtaining FDA approval to extend its certificate to include the DBT modality.

Because DBT is a new mammographic modality, facilities wanting to use DBT on patients must meet all MQSA (Mammography Quality Standards Act) applicable requirements: (1) personnel must obtain at least 8 hours of DBT training; (2) the unit must undergo a mammography equipment evaluation prior to use; and (3) the facility must follow the manufacturer's recommended quality control procedures.

Currently, the Accreditation Bodies (ABs) do not have the capability to review DBT images, and thus, cannot accredit the DBT modality portion of the unit. Therefore, a facility wanting to use the DBT modality of its accredited (or have applied to be accredited) Selenia Dimensions 2D unit will need to apply to FDA to

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extend its certification to include the DBT modality.

The Selenia Dimensions 3D DBT is a hardware and software upgrade to the Selenia Dimensions 2D FFDM system, which is FDA approved for conventional mammography imaging (P010025/S013, approved December 22, 2008).

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Digital breast tomosynthesis is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Digital Breast Tomosynthesis is covered

Not applicable.

When Digital Breast Tomosynthesis is not covered

Digital breast tomosynthesis is considered **investigational** in the screening or diagnosis of breast cancer. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

There are no studies currently published that provide adequate information about outcomes (sensitivity, specificity, accuracy, recall rate) when DBT is used in clinical practice. This contrasts to other breast imaging technologies such as computer aided detection (CAD) and full-field digital mammography (FFDM) where large clinical studies have demonstrated effectiveness in clinical care. The reader studies described here should be viewed as hypothesis-generating. There also are concerns about determining the impact on recall rates when studies with enriched numbers of cancers are used.

In addition, there still seem to be open questions about the number of DBT views that are needed. A related question is how the impact of using additional views from standard mammography would compare with the impact from digital breast tomosynthesis. Questions also still remain about the impact of calcifications on interpretation. Finally, more information is needed about the learning curve regarding interpretation of these studies. (Two of 14 radiologists were not able to participate in Reading Study 1.)

In summary, the use of digital breast tomosynthesis in generating images for screening or diagnosis of breast cancer is considered investigational. 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.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: No specific CPT code

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

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Executive Summary for FDA Advisory Panel available at:
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM226757.pdf>. Last Accessed March 2, 2011.

Gir D, Abrams GS, Chough DM et al. Digital breast tomosynthesis: Observer performance study. *AJR Am J Roentgenol* 2009; 193(2):586-91.

Medical Director review 3/2011.

Policy Implementation/Update Information

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| 4/12/11 | New policy issued. Digital breast tomosynthesis is considered investigational in the screening or diagnosis of breast cancer. (lpr) |
| 7/19/11 | Specialty Matched Consultant Advisory Panel review 6/29/11. Policy accepted as written. (adn) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.