

Corporate Medical Policy

Digital Breast Tomosynthesis

File Name:	digital_breast_tomosynthesis
Origination:	3/2011
Last CAP Review:	6/2016
Next CAP Review:	6/2017
Last Review:	11/2016

Description of Procedure or Service

Conventional mammography produces two-dimensional (2D) images of the breast. Overlapping tissue on a 2D image can mask suspicious lesions or make benign tissue appear suspicious, particularly in individuals with dense breast tissue which may result in recalls for additional mammographic spot views. Inaccurate results may lead to unnecessary biopsies and emotional stress, or to a potential delay in diagnosis. The spot views are often used to evaluate microcalcifications, opacities or architectural distortions or to distinguish masses from overlapping tissue, as well as to view possible findings close to the chest wall or in the retro-areolar area behind the nipple. The National Cancer Institute (NCI) reports that approximately 20% of cancers are missed at mammography screening. Average recall rates are approximately 10%, with an average cancer detection rate of 4.7 per 1,000 screening mammography examinations. The Mammography Quality Standards Act audit guidelines anticipate 2-10 cancers detected per 1,000 screening mammograms. Interval cancers, which are detected between screenings, tend to have poorer prognoses.

Digital breast tomosynthesis was developed to improve the accuracy of mammography by capturing three-dimensional (3D) images of the breast, further clarifying areas of overlapping tissue. Developers proposed that its use would result in increased sensitivity and specificity, as well as fewer recalls due to inconclusive results. Digital breast tomosynthesis produces a 3D image by taking multiple low-dose images per view along an arc over the breast. During breast tomosynthesis, the compressed breast remains stationary while the x-ray tube moves approximately 1 degree for each image in a 15-50 degree arc, acquiring 11-49 images. These images are projected as cross-sectional "slices" of the breast, with each slice typically 1-mm thick. Adding breast tomosynthesis takes about 10 seconds per view. In one study in a research setting, the mean time to interpret the results was 1.22 (standard deviation [SD]=1.15) minutes for digital mammography and 2.39 (SD=1.65) for combined digital mammography and breast tomosynthesis.

With conventional 2D mammography, breast compression helps decrease tissue overlap and improve visibility. By reducing problems with overlapping tissue, compression with breast tomosynthesis may be reduced by up to 50%. This change could result in improved patient satisfaction.

A machine equipped with breast tomosynthesis can perform 2D digital mammography, 3D digital mammography, or a combination of both 2D and 3D mammography during a single compression. The radiation exposure from tomosynthesis is roughly equivalent to a mammogram. Therefore, adding tomosynthesis to mammography doubles the radiation dose, although it still is below the maximum allowable dose established in the U.S. Mammography Quality Standards Act.

Studies typically compare one- or more commonly, two-view breast tomosynthesis alone or combined with standard 2D mammography to standard 2D mammography alone. The assessment focuses on two-view tomosynthesis. According to the U.S. Food and Drug Administration (FDA) Radiological Devices Panel, which reviewed this new modality: "2D [full-field digital mammography] plus a single [digital breast tomosynthesis] view (3D MLO) could be another exam option, but the full 2-view [digital breast

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tomosynthesis] protocol (MLO [mediolateral oblique view] and CC [cranio-caudal view]) would be recommended.”

In May 2013, the FDA approved new tomosynthesis software that will permit creation of a 2D image (called C view) from the tomosynthesis images. As a result, the 2D mammography may become unnecessary, thereby lowering the radiation dose. In other words, only the tomosynthesis procedure will be needed and both 2D and 3D images will be created from them. It is too early to gauge how traditional mammography plus tomosynthesis compares to the C view plus tomosynthesis.

Regulatory Status

The Selenia® Dimensions® 3D System manufactured by Hologic, Inc. achieved FDA approval on February 11, 2011 through the premarket application (PMA) approval process. This system is a software and hardware upgrade of the Selenia® Dimensions 2D full-field digital mammography system, which the FDA approved in 2008. The SenoClaire™ breast tomosynthesis system from GE Healthcare (Waukesha, WI), received FDA approval on August 26, 2014, through the PMA process. SenoClaire is an imaging option for the Senographe™ Essential Full-Field Digital Mammography system. A screening examination using this system may consist of either a 2-view mammogram or a 1-view craniocaudal mammogram with a 1-view MLO oblique tomosynthesis image. On April 21, 2015, FDA approved Mammomat™ Inspiration® mammography platform with tomosynthesis option by Siemens Medical Solutions (Malvern, PA).

Facilities using a digital breast tomosynthesis system must apply to the FDA for a certificate extension covering the use of the breast tomosynthesis portion of the unit. The Mammography Quality Standards Act requires the interpreting physicians, radiologic technologists, and medical physicists to complete 8 hours of digital breast tomosynthesis training and mandates a detailed mammography equipment evaluation prior to use.

In May 2013, the FDA also approved Hologic's C-View 2D imaging software. This software is used to create 2D images from the tomosynthesis results, rather than performing a separate mammogram.

*****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.

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Policy Guidelines

Digital breast tomosynthesis uses modified 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 typically involves additional imaging time and radiation exposure, although recent improvements may change this.

The evidence for DBT for individuals who are asymptomatic at average risk of breast cancer includes results from 3 studies in which women served as their own controls and separate observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, change in disease status, and treatment-related morbidity. Norse and Italian screening studies published in 2013 provide the strongest evidence available to date on the use of mammography plus DBT versus mammography alone for screening women for breast cancer. Partial results (50% of anticipated enrollment) from the Malmö Breast Tomosynthesis Screening Trial (MBTST) using 1-view DBT offers similar evidence. This evidence suggests that use of mammography plus breast tomosynthesis may modestly increase the number of cancers detected, with a decrease in the number of women who undergo unnecessary recalls or biopsies. For example, in interim analysis of the Norse screening trial, the ratio of cancer detection rates per 1000 screens for mammography plus breast tomosynthesis versus mammography alone was 1.27 (98.5% confidence interval [CI], 1.06 to 1.53; $p=0.001$). The ratio of false positive rates for mammography plus breast tomosynthesis versus mammography alone was 0.85 (98.5% CI, 0.76 to 0.96; $p<0.001$). Results from half the anticipated sample of the MBTST demonstrated improved sensitivity with 1-view DBT, but not lower recall rates. A decrease in the false-positive rate would reduce unnecessary diagnostic workups and their consequences. However, the potential for overdiagnosis cannot be ascertained because of the study designs and interval cancer rates are not yet available. Other studies were retrospective case reviews; patients had mixed or unclear indications for screening. More recently, prospective and large retrospective studies have reported cancer detection rates with reduced false-recall rates. The nonrandomized designs lack long-term follow-up to assess false-negative results. Long-term effects of additional radiation exposure also are unknown. Adding tomosynthesis to mammography may increase the radiation dose depending on the specific equipment and protocols used, although it still is below the maximum allowable dose established in the U.S. Mammography Quality Standards Act. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for DBT in individuals who have abnormal findings on breast imaging or clinical exam includes multiple observational studies and 1 meta-analysis. Relevant outcomes are test accuracy and validity, and treatment-related morbidity. Studies show either a similar diagnostic performance between breast tomosynthesis and other approaches or an advantage for breast tomosynthesis, with 2-view DBT having better performance characteristics than 1-view DBT. Some concerns have been raised regarding classification of microcalcification clusters with DBT alone. Mixed patient populations, differences in reference standards, use of different imaging tests being compared with breast tomosynthesis, and variations in follow-up make it difficult to draw conclusions from these studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

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: 77061, 77062, 77063, G0279

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Effective 1/1/2015, there are specific CPT codes for this testing, however the unlisted code 76499 could still be reported.

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.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 3/10/11

Specialty Matched Consultant Advisory Panel 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 7/12/12

Specialty Matched Consultant Advisory Panel 7/2013

National Comprehensive Cancer Network (NCCN). Breast Cancer Screening and Diagnosis. NCCN Guidelines Version 2.2013.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 7/11/13

Specialty Matched Consultant Advisory Panel 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 7/10/14

U.S. Preventive Services Task Force. Screening for breast cancer (2002).
<http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening-2002>. Accessed April, 2015.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: breast cancer screening and diagnosis, version 1.2015 (discussion update in progress).

American College of Radiology (ACR). ACR, SBI Statement on Skaane et al. -- Tomosynthesis Breast Cancer Screening Study. News Releases 2013; <http://www.acr.org/About-Us/Media-Center/Press-Releases/2013-Press-Releases/20130110ACR-SBI-Statement-on-Skaane-et-al>. Accessed April, 2015.

American College of Radiology. Position statements: ACR statement on breast tomosynthesis, 11/24/2014. <http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/20141124-ACR-Statement-on-Breast-Tomosynthesis>. Accessed June 11, 2015.

U.S. Preventive Services Task Force. Screening for Breast Cancer.
<http://www.uspreventiveservicestaskforce.org/Page/SupportingDoc/breast-cancer-screening1/more-information-on-the-update-in-progress>. Accessed June, 2015.

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Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Use of digital breast tomosynthesis with mammography for breast cancer screening. TEC Assessments 2015; Volume 29, Tab TBA.

Specialty Matched Consultant Advisory Panel 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 6/11/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 12/10/15

U.S. Preventive Services Task Force. Screening for Breast Cancer.
<http://www.uspreventiveservicestaskforce.org/Page/SupportingDoc/breast-cancer-screening1/more-information-on-the-update-in-progress>. Accessed December, 2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.53, 10/13/16

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) |
| 7/10/12 | Specialty Matched Consultant Advisory Panel review 6/20/12. Policy accepted as written. (sk) |
| 7/30/13 | Reference added. Paragraph added to Regulatory Status regarding GE Healthcare. Policy guidelines updated. Specialty Matched Consultant Advisory Panel review 7/17/13. No change to policy statement. (sk) |
| 10/1/13 | References added. Description and Policy Guidelines sections extensively revised. Medical Director review. No change to Policy statement. (sk) |
| 8/12/14 | Specialty Matched Consultant Advisory Panel review 7/29/14. No change to Policy statement. (sk) |
| 9/30/14 | Reference added. Policy Guidelines updated. Senior Medical Director review. No change to Policy statement. (sk) |
| 12/30/14 | Added CPT codes 77061, 77062, 77063, and HCPCS code G0279 to the Billing/Coding section for effective date 1/1/2015. (lpr) |
| 7/28/15 | Specialty Matched Consultant Advisory Panel review 6/24/2015. Updated Policy Guidelines section and Regulatory Status. References added. No change to policy statement. (lpr) |
| 1/26/16 | Updated Policy Guidelines section. References added. No change to policy statement. (lpr) |
| 7/26/16 | Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (an) |

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11/22/16 Reference added. (an)

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.