Digital Breast Tomosynthesis

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 women with dense breast tissue. As a result, women may be recalled 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 tomosynthesis] protocol (MLO [mediolateral oblique view] and CC [cranio-caudal view]) would be
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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. It is currently the only tomosynthesis system with FDA approval on the market. This system is a software and hardware upgrade of the Selenia® Dimensions 2D full-field digital mammography system, which the FDA approved in 2008. 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.

GE Healthcare is seeking FDA premarket approval (PMA) for breast tomosynthesis, specifically as an add-on option for the Senographe™ Essential mammography device. The FDA has agreed to a modular PMA submission, which means that GE Healthcare will submit the request in a different section. The first of 4 sections was submitted in November 2011. Three completed trials sponsored by GE are listed at online site clinicaltrials.gov. They focus on the use of breast tomosynthesis in routine screening (NCT00535678), in women undergoing diagnostic mammography (NCT00535327), and in women referred for breast biopsy (NCT00535184). The results do not appear to have been published to date.

***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

The screening studies published in 2013 provide the strongest evidence available to date on the use of mammography plus digital breast tomosynthesis versus mammography alone for screening women for breast cancer. This evidence suggests that the use of the mammography plus breast tomosynthesis may modestly increase the number of cancers detected, while having a large impact on decreasing the number of women who undergo unnecessary recalls or biopsies. Even if adding breast tomosynthesis simply maintained the same sensitivity as for mammography, a decline in the false-positive rate would reduce the substantial number of unnecessary diagnostic work-ups in the U.S. and spare women the psychological stress these engender.

Additional studies generally have supported these findings, with no observed differences in test performance across subgroups defined by age or breast density. However, all studies were nonrandomized. Lack of long-term follow-up prevents assessment of false negative results and full assessment of test performance. Further, overall impacts on health outcomes are unknown. Long-term effects of additional radiation exposure also are unknown. For these reasons, digital breast tomosynthesis is considered investigational. A trial that randomizes women to digital mammography with or without tomosynthesis, or performs both screening methods in the same woman, is required to demonstrate that improvements in screening are due to tomosynthesis and not to confounding variables, eg, patient characteristics or radiologist experience in tomosynthesis interpretation.

The configuration of mammography and breast tomosynthesis used in these studies roughly doubled the radiation dose of mammography alone, but the exposure was still lower than the guideline established in the Mammography Standards and Quality Act. On May 20, 2013, the U.S. Food and Drug Administration approved new tomosynthesis software from Hologic that creates a 2d image from the tomosynthesis images obviating the need for a separate mammogram. This approach reduces the radiation dose of the combination. Two studies reported comparable performance with digital mammography plus breast tomosynthesis, which reduces radiation exposure. Results warrant replication.

The potential of digital breast tomosynthesis, as an addition to diagnostic mammography (such as spot views), is primarily to reduce the number of women who are biopsied by screening out some fraction of women with false-positive results. The body of evidence on the use of breast tomosynthesis to evaluate women who are recalled for a diagnostic work-up after a suspicious finding on screening mammography is weaker than that on adding breast tomosynthesis to mammography for screening. Confounding this analysis is the fact that diagnostic mammography is not the only imaging modality used during the diagnostic work-up. Ultrasound is also commonly used and less often, MRI. As a result, the study designs are more complicated in terms of how they incorporate ultrasound into the comparison between diagnostic mammography and breast tomosynthesis. A different research design would be needed to assess the incremental value of tomosynthesis compared to the set of diagnostic tests currently used. In addition, some of the studies focused on one type of finding, e.g., masses versus calcification. They do not provide data on the accuracy of breast tomosynthesis for the full range of findings.

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

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


Medical Director review 3/2011.


Policy Implementation/Update Information

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)


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)
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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)

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