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Digital Breast Tomosynthesis

Policy # 00293
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Based on review of available data, the Company considers digital breast tomosynthesis in the screening or diagnosis of breast cancer to be **investigational.***

Background/Overview

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 a recently improved modification may change this.

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.

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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 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 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 3D images. The study submitted to the FDA was a noninferiority trial that compared the combined C view and 3D reconstruction to digital tomosynthesis alone, so it does not provide information on the comparison of greater interest.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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.

Several other manufacturers are working toward FDA approval of their digital breast tomosynthesis systems. GE Healthcare is seeking FDA 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 different sections. The first of 4 sections was submitted in November 2011. Three completed trials sponsored by GE are listed at online site

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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.

Rationale/Source

The primary outcomes to be examined include the number of cancers detected and the number of unnecessary recalls and biopsies. Improvement in sensitivity and specificity of testing is an intermediate outcome that will impact the ultimate health outcomes, but is not by itself sufficient to establish that outcomes are improved. If the sensitivity of breast cancer detection is improved by tomosynthesis, then the number of cases detected will increase. If the specificity of cancer detection is improved, then the number of recalls and biopsies for patients without cancer will decreased. If tomosynthesis is performed during screening, the number of unnecessary recalls may decline, with the attendant anxiety and inconvenience for the patient. If tomosynthesis is performed as part of the diagnostic workup, after a woman is recalled for questionable findings during screening, then a lower false-positive rate could prevent unnecessary biopsies.

Screening: Four studies addressed the use of mammography with or without digital breast tomosynthesis for screening. The strongest evidence for using mammography and breast tomosynthesis for screening women for breast cancer comes from the interim results of a large trial in Norway. The sample consisted of 12,621 women with 121 screening-detected cancers who underwent routine screening. The cancer detection rate was 6.1 per 1000 screenings for mammography alone and 8.0 per 1000 screenings for mammography plus digital breast tomosynthesis. After adjusting for reader differences, the ratio of cancer detection rates for mammography versus mammography plus breast tomosynthesis was 1.27 (98.5% confidence interval [CI]: 1.06 to 1.53; p = 0.001). The authors note that they did not ascertain any improvement in detecting ductal carcinoma in situ (DCIS) by adding breast tomosynthesis; the additional cancers detected were largely invasive. The false-positive rate was 61.1 per 1,000 screenings for mammography alone and 53.1 per 1,000 screenings for mammography plus breast tomosynthesis. A reduction in the false-positive rate would decrease the number of women recalled after screening for additional imaging or biopsy. In Norway, as in much of Europe, women are screened every other year, and 2 readers independently interpret the images, which differs from usual practice in the U.S. After adjusting for differences across readers, the ratio of false-positive rates for mammography alone versus mammography plus breast tomosynthesis was 0.85 (98.5% CI: 0.76 to 0.96; p < 0.001). The authors note that for this interim analysis, only limited data were available about interval cancers so they could not estimate “conventional absolute sensitivity and specificity.” Additional information will be available when the trial is completed.

The second study examined comparative cancer detection for traditional mammography with or without breast tomosynthesis in a general Italian, asymptomatic screening population of 7,292 women. The reference standard was pathology for women undergoing biopsies; women with negative results on both mammography and breast tomosynthesis were not followed up, so neither the sensitivity nor specificity could be calculated. Mammography plus breast tomosynthesis revealed all 59 cancers, while 20 of them were missed by traditional mammography (p < 0.0001). The incremental cancer detection of using both modalities was 2.7 cancers per 1,000 screens (95% CI: 1.7 to 4.2). There were 395 false-positive results: 181 were false positive using either mammography or both imaging modalities together; an additional 141

occurred using mammography only and 73 occurred using mammography and breast tomosynthesis combined ($p < 0.0001$). In preplanned analyses, the researcher found that the combined results of mammography and digital breast tomosynthesis yielded more cancers in both age groups (< 60 versus $\geq$ 60 years) and breast density categories (1, least dense, and 2 versus 3 and 4, most dense).

Another study compared the results of mammography alone versus breast tomosynthesis plus mammography among 997 subjects with mixed indications: 780 were women undergoing routine screening, and 217 were women scheduled for biopsy. Two retrospective reader studies were conducted. Some of these results were included in the submission to the FDA for premarketing application approval of Hologic, Inc.'s Selenia Dimensions tomosynthesis system. Readers were trained in interpreting tomosynthesis images, and the training was augmented between the first and second reader studies to emphasize how to read certain lesions that were often misinterpreted in the first reader study. In both reader studies, the area under the ROC curve for mammography plus breast tomosynthesis was greater than for mammography alone; the difference for the second study was 6.8% (95% CI: 4.1% to 9.5%, $p < 0.001$). For noncancer cases, adding breast tomosynthesis to mammography changed the mean recall rate across readers for study 2 from 48.8% (95% CI: 28.2% to 69.1%; SD = 12.3%) to 30.1% (95% CI: 19.8% to 41.3%; SD = 7.6%) for the combined modalities. Almost all of the improvement among readers was attributable to noncalcification cases, including masses, asymmetries, and architectural distortions.

All of these studies had a medium risk of bias using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies; available online at: www.quadas.org) tool, except for the fourth screening study, which had a high risk of bias. One of the 3 related articles on this study reported that the recall rate among noncancer cases was 0.42 (95% CI: 0.38 to 0.45) for digital mammography alone and 0.28 (95% CI: 0.25 to 0.31) for digital mammography plus breast tomosynthesis ($p < 0.0001$). The analogous rates for cancer cases were 0.88 (95% CI: 0.84 to 0.91) for digital mammography alone and 0.93 (95% CI: 0.90 to 0.96) for digital mammography plus breast tomosynthesis. The sensitivity of digital mammography alone was 60% and increased to 72% when breast tomosynthesis was added ($p = 0.034$, but the authors note the small number of positive findings). These articles did not describe the sample, the time between digital mammography and breast tomosynthesis, or how the reference standard was verified.

These studies provide some evidence that adding breast tomosynthesis to mammography may increase the accuracy (and possibly the sensitivity) of screening while reducing the number of women who are recalled unnecessarily. Two of the studies took place in a routine screening environment and did not have adequate follow-up of women with negative screening results; the larger study provided interim results. The other two studies were retrospective reviews of cases; the sample for one had a mixed indications, while it is unclear for the other study.

Diagnosis: Six studies address the use of breast tomosynthesis in the diagnostic setting, i.e., if there are suspicious findings on screening mammography or if the woman is symptomatic. The studies vary considerably in the types of suspicious mammographic findings (e.g., calcifications versus noncalcifications); the patient population; and the comparators to breast tomosynthesis, e.g., two-view mammography, mammographic spot views, ultrasound. One study had a medium risk of bias; the remainder, a high risk of bias using the QUADAS-2 tool.

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In a study of 158 women consecutively recalled after screening mammography, breast tomosynthesis was evaluated as a possible triage tool to reduce the number of false-positive results. The results of the diagnostic assessment (including ultrasound and needle biopsy where performed) were used as the reference standard. Breast tomosynthesis eliminated 102 of the 158 recalls, all of which were unnecessary (i.e., false-positive results on mammography). No cancers were missed on breast tomosynthesis. The performance of breast tomosynthesis did not vary by breast density or age group, but the reduction in recalls was greater for asymmetric densities and distortions, and nodular opacities with regular margins. The authors note that the decline in recall rates following the use of breast tomosynthesis was higher in this study than in blinded comparisons of digital mammography and breast tomosynthesis.

Another study compared the performance of mammographic spot views versus tomosynthesis among 52 consecutive recalled women with a BI-RADS rating on initial screening of 0 (which means “Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison”). Women with calcifications were excluded. The study was designed as a noninferiority analysis for areas under the receiver operating characteristic (ROC) curve, sensitivity, and specificity, with a noninferiority margin of delta = 0.05, so that if breast tomosynthesis were noninferior to mammographic spot views, breast tomosynthesis could be performed right after screening mammography to avoid a recall. The sensitivity and specificity were extremely high for both modalities, and there was no statistically significant difference between them.

A third study compared diagnostic mammography to breast tomosynthesis among women with abnormalities on screening mammography with no calcifications in a “simulated clinical setting.” The breast tomosynthesis rating was based on both readers’ ratings and their confidence that no additional studies were needed, as well as ultrasound results in some cases. The reference standard was either the results of the entire clinical workup, including biopsy if performed, or follow-up for women not undergoing biopsy (86.1% of entire sample).There was not a statistically significant difference between diagnostic mammography and breast tomosynthesis in sensitivity or specificity.

Two of the these 3studies found no difference in sensitivity and specificity between breast tomosynthesis and a clinical workup that consisted of diagnostic mammographic images or a more comprehensive diagnostic work-up. The third study examined the use of breast tomosynthesis to triage women recalled after screening and substantially reduced the recall rate.

Another study evaluated 738 women with 759 lesions recalled after screening with film mammography. In this unblinded study, the incremental value of breast tomosynthesis added to film and digital mammography was assessed. The reference standard consisted of pathology results or follow-up for 18 to 36 months. Adding breast tomosynthesis to film and digital mammography results increased the area under the ROC curve from 0.895 (0.871-0.919) to 0.967 (0.957-0.977) (p = 0.001). The complete sensitivity (counting ratings of 3-5 as positive) increased from 39.7% for digital mammography to 58.3% when breast tomosynthesis was added; no CIs or *p* values were reported. The specificity increased from 51% to 74.2% when breast tomosynthesis was added to digital mammography. The difference in areas under the ROC curve after the addition of breast tomosynthesis was statistically significant for soft-tissue lesions, but not for microcalcifications.

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One study compared diagnostic mammography images to dual-view breast tomosynthesis in 217 lesions (72 [33%] malignant) among 182 women. In this retrospective study, women who had undergone diagnostic mammography and breast tomosynthesis were included. The sample included women with clinical symptoms such as a palpable lump, or findings on mammograms, ultrasound, or magnetic resonance imaging (MRI). Women with only calcifications were excluded. The area under the ROC curve for diagnostic mammography was 0.83 (95% CI: 0.77 to 0.83; range across readers = 0.74-0.87), while for tomosynthesis, it was 0.87 (95% CI: 0.82 to 0.92; range across readers = 0.80-0.92; $p < 0.001$). .

The authors of the Norse trial also wrote another article on their initial experience with digital breast tomosynthesis in a clinical setting.

This mixed set of articles provides evidence of either a similar diagnostic performance between breast tomosynthesis and other approaches or an advantage for breast tomosynthesis. The mixed patient populations, differences in references standard, use of different imaging tests to compare to breast tomosynthesis, and variations in follow-up make it difficult to draw a conclusion from these studies.

Conclusions
Screening: The Norse and Italian 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. For example, the interim results of the Norway screening trial reported that the ratio of cancer detection rates per 1,000 screens for mammography versus mammography plus breast tomosynthesis was 1.27 (98.5% CI: 1.06 to 1.53; $p = 0.001$). The ratio of false-positive rates for mammography alone versus mammography plus breast tomosynthesis was 0.85 (98.5% CI: 0.76 to 0.96; $p < 0.001$). 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.

Completion of the Norse trial and additional studies are needed to confirm these findings, as well as studies that indicate whether the use of breast tomosynthesis should be targeted at certain subgroups, e.g., by age and breast density. 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 FDA approved new tomosynthesis software from Hologic that would create a 2d image from the tomosynthesis images and obviate the need for a separate mammogram. This approach would reduce the radiation dose of the combination, but studies are needed to compare its performance to traditional mammography plus breast tomosynthesis, since the study submitted to the FDA only compared C view and 3D tomosynthesis to tomosynthesis alone.

Diagnosis: 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 tomosysnthesis 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.

Ongoing Research

Digital breast tomosynthesis continues to be an active field of investigation. According to online site clinicaltrials.gov (http://clinicaltrials.gov/ct2/results?term=breast+tomosynthesis), as of May 18, 2013, there were 15 trials on breast tomosynthesis enrolling subjects and 7 that were active but not recruiting. All but 2 of the studies had sample sizes larger than 100, and 6 studies were larger than 1,000—e.g., studies had estimated sample sizes of 10,000 (NCT01569802); 15,000 (NCT01091545); and 25,000 (the study whose interim analysis is reported by Skaane et al; NCT01248546). A study comparing screening recall rates for digital mammography versus breast tomosynthesis is being conducted by the American College of Radiology Imaging Network (ACRIN) and has a sample size of 550 (NCT01236781). One large study with target enrollment of 12,000 was suspended due to funding unavailability (NCT01593384).

Several studies have also been conducted using different breast tomosynthesis equipment, including one using the Siemens Inspiration Digital Breast Tomosynthesis system (NCT01373671) and 3 completed studies sponsored by GE Healthcare that have not yet been published (NCT NCT00535184, NCT NCT00535327, NCT00535678).

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Code Type	Code
CPT	76499, 77055, 77056, 77057
HCPCS	G0202, G0204, G0206
ICD-9 Diagnosis	174.0 thru 174.9, 175.0 thru 175.9, 198.81, 233.0, 611.72, V10.3, V16.3, V84.01
ICD-9 Procedure	No codes

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07/25/2014 Coding update: codes G0202, G0204, G0206 included for this policy due to coding guidelines.
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