Effective January 1, 2015
Check Medicare's Preventive Care site for coverage related to digital breast tomosynthesis

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Digital Breast Tomosynthesis

Policy #:252
Category: Radiology

Latest Review Date: July 2015
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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 involves some 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 two to ten 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 one 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 one-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 with standard 2D mammography alone. A 2014 TEC assessment (updated in 2015) focuses on two-view tomosynthesis. The FDA Radiological Devices Panel, which reviewed this new modality in 2011, recommended that two-view breast tomosynthesis is preferable to one-view tomosynthesis (both used in combination with full-field digital mammography).

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.

Policy:

Effective for dates of service on and after January 1, 2015:
Note: Check Medicare's Preventive Care site for coverage related to digital breast tomosynthesis.

Effective for dates of service on or after May 31, 2011 and prior to January 1, 2015:
Blue Advantage will treat **Digital Breast Tomosynthesis** as a **non-covered benefit** and as **investigational** in the screening or diagnosis of breast cancer**.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

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 decrease. 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

The 2014 TEC Assessment identified four studies that 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. Cancers missed by digital breast tomosynthesis were missed due to reading errors, either detection or interpretation. 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 two 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 >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 U.S. Food and Drug Administration (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 receiver operating characteristic 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 two 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 non-calcification 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 three 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.

Several studies assessing digital breast tomosynthesis for breast cancer screening have been published subsequent to the TEC Assessment. These studies are summarized in Table 1. Studies by Friedewald et al and Rose et al were retrospective; all others were prospective. Studies consistently showed improved breast cancer detection rates (sensitivity) with addition of tomosynthesis to digital mammography. Improvements were not always statistically significant or statistical significance was not reported. Reduction in noncancer recall rate was observed in two studies, but reduction in noncancer biopsy rate was observed in only one of two studies. The smallest study reported the largest improvements in performance with the addition of tomosynthesis. Performance of breast tomosynthesis did not vary by breast density or age group in four studies that examined these variables. The largest study by Friedewald et al reported no difference in DCIS detection rates between screening methods (1.4 per 1000 examinations [95%CI, 1.2 to 1.6] for both methods). Table 1 includes a study by Skaane et al of 2D images reconstructed from digital tomosynthesis (C view or synthesized 2D mammography). In another study of C view tomosynthesis (N=236), Zuley et al compared diagnostic accuracy of synthesized 2D mammography and digital mammography, both alone and in combination with 3D breast tomosynthesis. Area under ROC was 0.894 and 0.889 for synthesized and digital mammography, respectively; with the addition of 3D tomosynthesis, values increased to 0.916 and 0.939, respectively. In the second half of the Skaane et al study (after improvements to 2D image processing were made), there was no statistical difference in cancer detection rates, positive predictive values (PPV), and false positive rates (noncancer recall rates) between synthesized and digital mammography (both in combination with tomosynthesis). Mean glandular radiation dose for a single mammographic view was 45% less in the synthesized mammography group compared with the digital mammography group (mean, 1.58 mGy vs 3.53 mGy, respectively.

Table 1. Studies of Digital Breast Tomosynthesis for Breast Cancer Screening

	Noncancer Recall Rate	Noncancer Biopsy Rate	CDR/1000	PPV
Digital Mammography vs Digital Mammography + Tomosynthesis				
Bernardi 2014 (STORM), N=7292				
DM	2.8%	NR	5.3	NR
DM + DBT	2.2%	NR	8.1	NR
Destounis 2014, N=1048				
DM	6.9%	1.9%	3.8	16.7%
DM + DBT	1.0%	0.6%	5.7	50.0%
Friedewald 2014, N= 454,850				
DM	10.1%	1.4%	4.2	4.3%
DM + DBT	8.4%	1.3%	5.4[a]	6.4%[a]
Greenberg 2014, N=59,617				
DM	NR	1.7%	4.9	23.8%
DM + DBT	NR	2.0%	6.3[a]	22.8%
Haas 2013, N=13,158				
DM	NR	NR	5.2	NR
DM + DBT	NR	NR	5.7	NR
Rose 2013, N=23,355				
DM	8.3%	4.9%	4.0	4.7%
DM + DBT	1.1%	0.8%	5.4	10.1%[a]
Digital Mammography + Tomosynthesis vs 2D Tomosynthesis +3D Tomosynthesis				
Skaane 2014, N=12,270[b]				
DM + DBT	4.6%	NR	7.8	32.1%
C view + DBT	4.5%	NR	7.7	34.9%

DBT, digital breast tomosynthesis (2-view unless noted otherwise); DM, digital mammography (2-view unless noted otherwise); NR,
not reported

[a] Statistically significant difference from DM

[b] Second of 2 sequential cohorts reported here.

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. However, the available studies have methodological limitations. Several studies did not have adequate follow-up of women with negative screening results; one larger study provided interim results. 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. This evidence is from nonrandomized designs with a lack of long-term follow-up to assess false negative results. Therefore, performance of digital breast tomosynthesis in the screening setting cannot be determined with certainty. Two studies of synthesized 2D mammography showed comparable diagnostic performance with digital mammography and lower radiation exposure. Replication of these findings is warranted.

Diagnosis

Lei et al conducted a systematic review with meta-analysis of seven studies (total number of patients, 2014; total number of lesions, 2666) that compared digital breast tomosynthesis with digital mammography in patients with Breast Imaging-Reporting and Data System (BI-RADS) two or higher breast lesions. All studies were rated high quality using the QUADAS tool. As shown in Table 2, compared with histologic diagnosis, performance of both imaging modalities was approximately similar; PPVs were low (57% for breast tomosynthesis and 50% for digital mammography), and negative predictive values (NPV) were high. Statistical heterogeneity in these analyses was considerable (I2 approximately 90%). Studies used both 1-view (n=4) and 2-view (n=3) breast tomosynthesis. Pooled sensitivity and specificity for only 1-view breast tomosynthesis studies were 81% and 77%, respectively; for 2-view studies, pooled sensitivity and specificity were 97% and 79% respectively.

Table 2. Side-by-Side Comparison of Digital Breast Tomosynthesis and Digital Mammography Diagnostic Performance Compared with Histologic Diagnosis: Pooled Results

	Digital Breast Tomosynthesis, pooled estimate (95% CI)	Digital Mammography, pooled estimate (95% CI)
Sensitivity	90% (87 to 92)	89% (86 to 91)
Specificity	79% (77 to 81)	72% (70 to 74)
PPV [a]	57% (53 to 61)	50% (46 to 53)
NPV [a]	96% (95 to 97)	95% (94 to 97)
DOR	26.04 (8.70 to 77.95)	16.24 (5.61 to 47.04)
LR+	3.50 (2.31 to 5.30)	2.83 (1.77 to 4.52)
LR–	0.15 (0.06 to 0.36)	0.18 (0.09 to 0.38)
AUC	0.867	0.856

AUC, area under the summary receiver operating characteristic curve; DOR, diagnostic odds ratio (ratio of the odds of positivity in cases to the odds of positivity in controls = [LR+] ÷ [LR–]); LR+, positive likelihood ratio (ratio of the probability of positivity in cases to the probability of positivity in controls = sensitivity ÷ [1-specificity]); LR–, negative likelihood ratio (ratio of the probability of a negative result in cases to the probability of a negative result in controls = [1-sensitivity] ÷ specificity); NPV, negative predictive value; PPV, positive predictive value

[a] Calculated by author

The 2014 TEC Assessment identified 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 non-calcifications); 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. These studies are summarized on the following pages.

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 non-inferiority analysis for areas under the receiver operating characteristic (ROC) curve, sensitivity, and specificity, with a non-inferiority margin of delta=0.05, so that if breast tomosynthesis were non-inferior 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 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 these three studies 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 three to five as positive) increased from 39.7% for digital mammography to 58.3% when breast tomosynthesis was added; no confidence intervals 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.

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). .

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

Several studies assessing diagnostic digital breast tomosynthesis have been published subsequent to the TEC Assessment. These studies are summarized in Table 3. These studies reported that addition of tomosynthesis to digital mammography increased diagnostic accuracy overall, with improvements in true positive rates (sensitivity) exceeding improvements in true negative rates (specificity). However, PPV remained low (approximately 50%). Differences in test performance between studies (ie, between Rafferty 2014 and Thibault 2013) are likely due to the difference in technologies studied (2-view digital mammography plus 1-view tomosynthesis vs 1-view digital mammography plus 1-view tomosynthesis, respectively), but also to differences in sample size (310 vs 130, respectively), setting (U.S. vs Europe, respectively), number of readers (15 vs 7, respectively), training (150 cases vs 20 cases, respectively).

Table 3. Studies of Diagnostic Digital Breast Tomosynthesis

	AUC	Sens	Spec	PPV	NPV
Rafferty 2014, N=310					
DM	0.828	63%	86%	47%	92%
DM + 1-view DBT	0.864[a]	71%[a]	86%	50%	94%
DM + 2-view DBT	0.895[a]	79%[a]	85%	50%	95%
Gennaro 2013, N=463					
DM	NR	76%	NR	NR	NR
1-view (CC) DM + 1-view DBT	NR	79%	NR	NR	NR
Thibault 2013, N=130					
DM	.0756	73%	53%	53%	74%
1-view (CC) DM + 1-view DBT	0.780	68%	64%	58%	73%
DM + 1-view DBT + US	0.763	81%	52%	55%	79%

AUC, area under the receiver operating characteristic curve; CC, cranio-caudal; DBT, digital breast tomosynthesis; DM, digital mammography (2-view unless noted otherwise); MLO, mediolateral-oblique; NR, not reported; US, ultrasound

Note: 1-view DBT is MLO unless noted otherwise.

[a] Statistically significant difference from DM

[b] Statistically significant difference from 1-view DBT

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.

Summary

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.

Additional studies generally have supported these findings, with no observed differences in test performance across subgroups, e.g., by age and 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, e.g., 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 exposure was still lower than the guideline established in the Mammography Standards and Quality Act. On May 20, 2013, FDA approved new tomosynthesis software from Hologic, Inc. that creates a 2D image from tomosynthesis images (C view), 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.

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 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.

Practice Guidelines and Position Statements

American College of Radiology

The American College of Radiology does not include digital breast tomosynthesis in its Appropriateness Criteria for screening or diagnostic breast imaging. However, in a joint news release with the Society of Breast Imaging following the release of the interim analysis by Skaane et al, discussed below, the organizations stated that "While the study results are promising, they do not provide adequate information to define the role of tomosynthesis in clinical practice." They also noted that while cancer detection was greater with tomosynthesis, it is not known whether the incremental benefit would be the same during a second round of screening. Furthermore, they note "[h]ow the technology will affect screening accuracy among women of different ages, risk profiles and parenchymal density is uncertain. In addition, how this technology would affect reader performance among U.S. radiologists with varying practice patterns and expertise is also uncertain. Other questions include whether computer aided detection will provide any further benefit, and if reconstructed images (presumably 2D) can be used, in lieu of standard full field digital images, to reduce radiation dose."

American College of Obstetricians and Gynecologists

In its 2011 practice bulletin on breast cancer screening, the American College of Obstetricians and Gynecologists notes that digital breast tomosynthesis is one of several screening techniques that were considered but not recommended for routine screening.

National Comprehensive Cancer Network

According to the National Comprehensive Cancer Network, "Early studies show promise for tomosynthesis mammography. Two large trials showing a combined use of digital mammography and tomosynthesis resulted in improved cancer detection and decreased call back rates; of note, this is double the dose of radiation and is a factor in recommending this modality. Definitive studies are still pending."

U.S. Preventive Services Task Force

In 2009, USPSTF updated its recommendations for breast cancer screening using film mammography and using methods other than film mammography. USPSTF recommends mammography and digital mammography but does not include digital tomosynthesis. However, the Department of Health and Human Services, in implementing the Affordable Care Act, utilizes USPSTF 2002 recommendations on breast cancer screening. These recommendations do not include digital breast tomosynthesis. USPSTF is in the process of updating its recommendations for breast cancer screening.

Key Words:

3D Mammography, Breast, Digital Tomosynthesis, Hologic, Selenia

Approved by Governing Bodies:

The Selenia® Dimensions® 3D System manufactured by Hologic, Inc. achieved U.S. Food and Drug Administration (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 eight 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 U.S. Food and Drug Administration (FDA) has agreed to a modular PMA submission, which means that GE Healthcare will submit the request in a different section. The first of four sections was submitted in November 2011. Three completed trials sponsored by GE are listed at the 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT Codes:

77061	Digital breast tomosynthesis; unilateral **(Effective 01/01/15)**
77062	Digital breast tomosynthesis; bilateral **(Effective 01/01/15)**
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) **(Effective 01/01/15)**

HCPC Codes:

G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to g0204 or g0206) **(Effective 01/01/15)**

Previous Coding:

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 or G0202-G0206) along with an unlisted code (e.g., 76499) for the additional views. **(Deleted 01/01/15)**

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Policy History:

Adopted for Blue Advantage, March 2011
Available for comment April 13 – May 30, 2011
Medical Policy Group, July 2012
Medical Policy Group, July 2013
Medical Policy Group, July 2014
Medical Policy Group, November 2014
Medical Policy Group, July 2015

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.