Digital Breast Tomosynthesis

Policy #       00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company considers digital breast tomosynthesis in the screening or diagnosis of breast cancer to be eligible for coverage.

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...
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

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 [mediolateral oblique view] MLO) could be another exam option, but the full 2-view [digital breast tomosynthesis] protocol MLO 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

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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 2 of 13
Several other manufacturers are working toward FDA approval of their digital breast tomosynthesis systems. GE Healthcare is seeking FDA approval 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 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.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
This policy was created in 2011 and updated annually with literature review. A Technology Evaluation Center (TEC) Assessment was published in 2014.

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 (95% 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-
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

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 (estimated study completion date, September 2015).

The second study (STORM) 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 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 (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
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 2 studies, but reduction in noncancer biopsy rate was observed in only 1 of 2 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 4 studies that examined these variables. The largest study by Friedewald et al reported no difference in DCIS detection rates between screening methods (1.4/1000 examinations [95% CI, 1.2 to 1.6] for both methods).

Table 1 includes a study by Skaane et al (2014) 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 (2014) 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 (2014) 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>
<thead>
<tr>
<th>Study</th>
<th>Noncancer Recall Rate, %</th>
<th>Noncancer Biopsy Rate, %</th>
<th>CDR/1000</th>
<th>PPV, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bernardi (2014) (STORM), N=7292</td>
<td>2.8</td>
<td>NR</td>
<td>5.3</td>
<td>NR</td>
</tr>
<tr>
<td>DM + DBT</td>
<td>2.2</td>
<td>NR</td>
<td>8.1</td>
<td>NR</td>
</tr>
<tr>
<td>Destounis (2014), N=1048</td>
<td>6.9</td>
<td>1.9</td>
<td>3.8</td>
<td>16.7</td>
</tr>
<tr>
<td>DM + DBT</td>
<td>1.0</td>
<td>0.6</td>
<td>5.7</td>
<td>50.0</td>
</tr>
<tr>
<td>Friedewald (2014), N=454,850</td>
<td>10.1</td>
<td>1.4</td>
<td>4.2</td>
<td>4.3</td>
</tr>
<tr>
<td>DM + DBT</td>
<td>8.4</td>
<td>1.3</td>
<td>5.4*</td>
<td>6.4*</td>
</tr>
<tr>
<td>Greenberg (2014), N=59,617</td>
<td>NR</td>
<td>1.7</td>
<td>4.9</td>
<td>23.8</td>
</tr>
<tr>
<td>DM + DBT</td>
<td>NR</td>
<td>2.0</td>
<td>6.3*</td>
<td>22.8</td>
</tr>
<tr>
<td>Haas (2013), N=13,158</td>
<td>NR</td>
<td>NR</td>
<td>5.2</td>
<td>NR</td>
</tr>
</tbody>
</table>
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

Digital Breast Tomosynthesis vs 2D Tomosynthesis +3D Tomosynthesis

**Rose (2013), N=23,355**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>DOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM + DBT</td>
<td>8.3</td>
<td>4.9</td>
<td>4.0</td>
<td>4.7</td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>1.1</td>
<td>0.8</td>
<td>5.4</td>
<td>10.1</td>
<td></td>
</tr>
</tbody>
</table>

**Skaane (2014), N=12,270**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>DOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM + DBT</td>
<td>4.6</td>
<td>NR</td>
<td>7.8</td>
<td>32.1</td>
<td></td>
</tr>
<tr>
<td>C view + DBT</td>
<td>4.5</td>
<td>NR</td>
<td>7.7</td>
<td>34.9</td>
<td></td>
</tr>
</tbody>
</table>

DBT: digital breast tomosynthesis (2-view unless noted otherwise); DM: digital mammography (2-view unless noted otherwise); NR: not reported; PPV: positive predictive value.

Statistically significant difference from DM.

Lei et al (2014) conducted a systematic review with meta-analysis of 7 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) 2 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 ($I^2 = 90\%$). 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

<table>
<thead>
<tr>
<th>Test</th>
<th>Digital Breast Tomosynthesis, Pooled Estimate (95% CI)</th>
<th>Digital Mammography, Pooled Estimate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>90% (87 to 92)</td>
<td>89% (86 to 91)</td>
</tr>
<tr>
<td>Specificity</td>
<td>79% (77 to 81)</td>
<td>72% (70 to 74)</td>
</tr>
<tr>
<td>PPV</td>
<td>57% (53 to 61)</td>
<td>50% (46 to 53)</td>
</tr>
<tr>
<td>NPV</td>
<td>96% (95 to 97)</td>
<td>95% (94 to 97)</td>
</tr>
<tr>
<td>DOR</td>
<td>26.04 (8.70 to 77.95)</td>
<td>16.24 (5.61 to 47.04)</td>
</tr>
<tr>
<td>LR+</td>
<td>3.50 (2.31 to 5.30)</td>
<td>2.83 (1.77 to 4.52)</td>
</tr>
<tr>
<td>LR–</td>
<td>0.15 (0.06 to 0.36)</td>
<td>0.18 (0.09 to 0.38)</td>
</tr>
<tr>
<td>AUC</td>
<td>0.867</td>
<td>0.856</td>
</tr>
</tbody>
</table>

AUC: area under the summary receiver operating characteristic curve; CI: confidence interval; 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.

The following formulas are used to calculate diagnostic performance:

- **Sensitivity** = True Positive / (True Positive + False Negative)
- **Specificity** = True Negative / (True Negative + False Positive)
- **PPV** = True Positive / (True Positive + False Positive)
- **NPV** = True Negative / (True Negative + False Negative)
- **DOR** = (True Positive / False Negative) / (False Positive / True Negative)
- **LR+** = (True Positive / False Negative) / (False Positive / True Negative)
- **LR–** = (False Negative / True Positive) / (True Negative / False Positive)
- **AUC** = Area under the ROC curve

©2017 Blue Cross and Blue Shield of Louisiana
The 2014 TEC Assessment identified 6 studies that addressed the use of breast tomosynthesis in the diagnostic setting, i.e., when there are suspicious findings on screening mammography or when the woman is symptomatic. Studies vary considerably in types of suspicious mammographic findings (e.g., calcifications vs noncalcifications); patient sample; and comparators to breast tomosynthesis (e.g., 2-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 next.

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 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 3 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 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.

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.

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 (~50%). Differences in test performance between studies (i.e., 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

<table>
<thead>
<tr>
<th>Study Description</th>
<th>AUC</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
<th>PPV, %</th>
<th>NPV, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rafferty (2014), N=310</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>0.828</td>
<td>63</td>
<td>86</td>
<td>47</td>
<td>92</td>
</tr>
<tr>
<td>DM + 1-view DBT</td>
<td>0.864a</td>
<td>71a</td>
<td>86</td>
<td>50</td>
<td>94</td>
</tr>
<tr>
<td>DM + 2-view DBT</td>
<td>0.895a</td>
<td>79a</td>
<td>85</td>
<td>50</td>
<td>95</td>
</tr>
<tr>
<td>Gennaro (2013), N=463</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>NR</td>
<td>76</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>1-view (CC) DM + 1-view DBT</td>
<td>NR</td>
<td>79</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Thibault (2013(36)), N=130</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>0.756</td>
<td>73</td>
<td>53</td>
<td>53</td>
<td>74</td>
</tr>
<tr>
<td>1-view (CC) DM + 1-view DBT</td>
<td>0.780</td>
<td>68</td>
<td>64</td>
<td>58</td>
<td>73</td>
</tr>
<tr>
<td>DM + 1-view DBT + US</td>
<td>0.763</td>
<td>81</td>
<td>52</td>
<td>55</td>
<td>79</td>
</tr>
</tbody>
</table>

Note: One-view DBT is MLO unless noted otherwise.
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

AUC: area under the receiver operating characteristic curve; CC: craniocaudal; DBT: digital breast tomosynthesis; DM: digital mammography (2-view unless noted otherwise); MLO: mediolateral-oblique; NPV: negative predictive value; NR: not reported; PPV: positive predictive value; US, ultrasound.

a Statistically significant difference from DM.
b Statistically significant difference from 1-view DBT.

Update September 2015

On 11/24/2014 The American College of Radiology released the “ACR Statement on Breast Tomosynthesis.” It states, in part, “A new digital technology, breast tomosynthesis, has shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. This is extremely important. The medical community has long sought ways to improve breast cancer screening accuracy. Better sensitivity will likely translate into more lives saved. Lower recall rates result in fewer patients who may experience short-term anxiety awaiting test results. To be clear: tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography. While the College encourages more studies to clarify the clinical roles of tomosynthesis and its long-term outcomes, it is clear that tomosynthesis represents an advance in breast imaging.” The American Society of Breast Disease has issued a similar supporting statement.

Based on a review of the latest evidence and these professional society statements, the use of digital breast tomosynthesis for either screening or diagnostic mammography is considered to be medically necessary.

References

Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017


©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017


Policy History
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017
04/07/2011 Medical Policy Committee review
04/12/2012 Medical Policy Committee review
04/25/2012 Medical Policy Implementation Committee approval. No change to policy coverage.
05/02/2013 Medical Policy Committee review
05/22/2013 Medical Policy Implementation Committee approval. No change to policy coverage.
05/01/2014 Medical Policy Committee review
05/21/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2015 Medical Policy Committee review
05/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
08/12/2015 Coding update
09/03/2015 Medical Policy Committee review
09/23/2015 Medical Policy Implementation Committee approval. Changed from investigational to eligible for coverage.
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017 Medical Policy Committee review

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

09/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2018 Coding update
Next Scheduled Review Date: 09/2018

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>76499, 77061, 77062, 77063</td>
</tr>
<tr>
<td>HCPCS</td>
<td>G0279</td>
</tr>
<tr>
<td>Code added eff 1/1/2018: G9899, G9900</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis</th>
<th>C50.011-C50.029</th>
<th>C50.111-C50.129</th>
<th>C50.211-C50.229</th>
<th>C50.311-C50.329</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C50.411-C50.429</td>
<td>C50.511-C50.529</td>
<td>C50.611-C50.629</td>
<td>C50.811-C50.829</td>
</tr>
<tr>
<td></td>
<td>C50.911-C50.929</td>
<td>C79.81</td>
<td>D05.00-D05.512</td>
<td>D05.80-D05.82</td>
</tr>
<tr>
<td></td>
<td>D05.90-D05.92</td>
<td>D07.39</td>
<td>N63</td>
<td>Z15.01</td>
</tr>
<tr>
<td></td>
<td>Z80.3</td>
<td>Z85.3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Digital Breast Tomosynthesis

Policy # 00293
Original Effective Date: 04/13/2011
Current Effective Date: 09/20/2017

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.