

Subject: Digital Breast Tomosynthesis (DBT) for Breast Cancer		Original Effective Date: 3/10/16
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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ³⁵

Digital breast tomosynthesis (DBT) is a breast imaging technique that provides 3-dimensional (3D) views of breast tissues. DBT was developed to improve the accuracy of mammography by capturing three-dimensional (3D) images of the breast and clarifying areas of overlapping tissue which may appear using conventional mammography that produces two-dimensional (2D) images of the breast. Digital breast tomosynthesis uses a rotating X-ray tube to acquire multiple thin-slice images of the breast and computer algorithms to reconstruct the image into a 3D volume of the entire breast. The patient's breast is placed on a digital flat-panel detector and lightly compressed while the x-ray tube rotates around the breast in an arc. Multiple X-ray exposures are taken every few degrees in the arc rotation. Images from the X-ray projections are then reconstructed by computer software to produce a 3D map of the breast. This allows the clinician to view the entire breast at once or view the cross-sectional slices individually, thereby lessening the problem of overlapping tissue. This technique is proposed to reduce the number of false-positive findings, better depict lesions in the breast, and may also be able to replace spot compression views.

RECOMMENDATION ³⁻²⁷

Digital breast tomosynthesis (DBT) is considered experimental, investigational and unproven. There is insufficient evidence in the peer reviewed medical literature to conclude that digital tomosynthesis of the breast is effective as a diagnostic test for breast cancer or will provide any additional clinical information that cannot be obtained from conventional mammography.

The peer reviewed medical evidence from a number of retrospective, controlled, comparison studies have demonstrated that there is insufficient evidence in the peer reviewed medical literature to conclude that digital tomosynthesis of the breast is effective for the screening or diagnosis of breast cancer. Moderate quality evidence in the literature shows that digital mammography (DM) combined with tomosynthesis provides better lesion detection than DM alone but there is lack of evidence that tomosynthesis reduces breast cancer mortality and there are concerns that adjunct tomosynthesis approximately doubles radiation dosage, increases time required for breast imaging and image reading, and has not been adequately compared with DM that includes supplemental views.

A very large retrospective analysis of screening performance metrics from 13 academic and nonacademic breast centers was conducted to determine if mammography combined with tomosynthesis is associated with better performance of breast screening programs in the United States. A total of 454,850 examinations (n=281,187 digital mammography; n=173,663 digital mammography + tomosynthesis) were evaluated. With digital mammography, 29,726 patients were recalled and 5056 biopsies resulted in cancer diagnosis in 1207 patients (n=815 invasive; n=392 in situ). With digital mammography + tomosynthesis, 15,541 patients were recalled and 3285 biopsies resulted in cancer diagnosis in 950 patients (n=707 invasive; n=243 in situ). Addition of tomosynthesis to digital mammography was associated with a decrease in recall rate and an increase in cancer detection rate; however the authors concluded that further studies are needed to assess the relationship to clinical outcomes.⁷

The TOMMY Trial compared the diagnostic accuracy of DBT in conjunction with two-dimensional (2D) mammography or synthetic 2D mammography, against standard 2D mammography and to determine if DBT improves the accuracy of detection of different types of lesions. Women (aged 47-73 years) recalled for further assessment after routine breast screening and women (aged 40-49 years) with moderate/high of risk of developing breast cancer attending annual mammography screening were recruited after giving written informed consent. All participants underwent a two-view 2D mammography of both breasts and two-view DBT imaging. Image-processing software generated a synthetic 2D mammogram from the DBT data sets. Data were available for 7060 subjects comprising 6020 (1158 cancers) assessment cases and 1040 (two cancers) family history screening cases. Overall sensitivity was 87% [95% confidence interval (CI) 85% to 89%] for 2D only, 89% (95% CI 87% to 91%) for 2D + DBT and 88% (95% CI 86% to 90%) for synthetic 2D + DBT. The specificity of DBT and 2D was better than 2D alone but there was only marginal improvement in sensitivity. The study concluded that the performance of synthetic 2D appeared to be comparable to standard 2D. If these results were observed with screening cases, DBT and 2D mammography could benefit to the screening programme by reducing the number of women recalled unnecessarily, especially if a synthetic 2D mammogram were used to minimize radiation exposure. Further research is required into the feasibility of implementing DBT in a screening setting, prognostic modelling on outcomes and mortality, and comparison of 2D and synthetic 2D for different lesion types.⁸

A subgroup analysis of the above study reported that the addition of digital breast tomosynthesis to conventional DM significantly increased sensitivity relative to conventional DM alone in patients with dense breasts (P=0.03) and younger women age 50 to 59 years (P=0.01). Specificity was significantly greater



following the addition of digital breast tomosynthesis to conventional DM relative to conventional DM alone for all patient subgroups (P<0.001).⁹

Another large study prospective comparison of DBT with full-field digital mammography (FFDM) was conducted in 738 women and found no significant difference between the modalities for detection of cancers in radiographically fatty, dense, or glandular breasts.¹⁵ A prospective comparison of DBT with FFDM in 513 women with abnormal screening mammograms also found that there were no significant differences in diagnostic accuracy between FFDM and DBT.²⁴ A smaller prospective evaluation of DBT as a triage method for additional workup after screening FFDM in 158 women confirmed breast cancer in 21 cases but the interpretation of DBT images indicated a need for additional assessment and there were no false-negatives.⁴ A prospective comparison of DBT and FFDM in 129 women requiring diagnostic mammography for palpable lumps, abnormal screening mammogram, or post-treatment surveillance showed that of the 50 cases evaluated for cancer conspicuity, FFDM images were scored higher in 2 but rated DBT images for all other cases as equal to or better than FFDM.²⁰

A multi-center trial to compare radiologists' diagnostic accuracy and recall rates for breast tomosynthesis combined with digital mammography versus digital mammography alone was conducted in 1192 women. Results reported that diagnostic accuracy for combined tomosynthesis and digital mammography was superior to that of digital mammography alone and recall rates for noncancer cases for all readers significantly decreased with addition of tomosynthesis. The authors noted that almost all the patients with cancer were scheduled for biopsy as they had been detected on conventional mammogram. Therefore these study results underestimate the potential gains in sensitivity that might occur in clinical practice.¹⁸

Professional Society Guidelines²⁸⁻³⁴

Several professional organizations have not endorsed breast tomosynthesis as a diagnostic or screening tool for breast cancer. The American College of Obstetricians and Gynecologists (2011) Guidelines on breast cancer screening considered, but did not recommend, breast tomosynthesis.²⁹ The Society of Breast Imaging (SBI) and the American College of Radiology (ACR) statement on Tomosynthesis Breast Cancer Screening Study states that “While the study results are promising, they do not provide adequate information to define the role of tomosynthesis in clinical practice”.³² The National Comprehensive Cancer Network's (NCCN) Breast Cancer Screening and Diagnosis Guidelines (2015) indicate that there are promising results for digital mammography combined with breast tomosynthesis but that definitive studies are still pending.³⁵ The 2016 USPSTF Breast Cancer Screening Guidelines concludes that the current evidence is insufficient to assess the benefits and harms of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer.³⁴

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CPT	Description
	N/A
HCPCS	Description

G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)
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