Digital Breast Tomosynthesis (DBT)

POLICY

Digital Breast Tomosynthesis is considered investigational for breast cancer screening or diagnosis (77061-77063).

RATIONALE

DBT is a three-dimensional (3D) breast imaging technology that uses a rotating X-ray source to acquire multiple image slices at several angles. The X-ray source rotates around the breast in an arc. Serial exposures are taken every few degrees in the arc rotation. These images are then reconstituted by software to produce a 3D image of the breast, similar to CAT scanning. It has been suggested that DBT will have a higher sensitivity and specificity than Full Field Digital Mammography (FFDM), resulting in fewer for false-positive results and missed cancers by eliminating overlapping breast tissue resulting in improved lesion border identification. DBT is intended as an adjunct and alternative to screen-film mammography or FFDM for the screening and diagnosis of breast cancer. Therefore, the potential patient population includes the millions of women who undergo annual screening mammography and follow-up diagnostic imaging. For screening, DBT is used in conjunction with FFDM. The results must be interpreted by a radiologist specialized in mammography. Tomosynthesis typically involves additional imaging time and radiation exposure, although recent improvements in software may change this.

A series of prospective studies have been conducted to evaluate the effectiveness of DBT versus flat screen and/or FFDM for routine screening and for further evaluation of suspicious lesions. The largest study by Mitchell et al included 738 patients found to have abnormalities on routine screening mammogram. No significant difference between the modalities was found for detection of cancers in radiographically fatty, dense, or glandular breasts. Skaane et al \(^2\) in a study (The Norse Study) funded by Hologic compared DBT with FFDM in 129 women requiring diagnostic follow-up imaging who were referred to a breast-imaging clinic for a palpable lump, abnormal screening mammogram, or surveillance after previous breast biopsy or breast cancer surgery. This study has been cited as the major justification for DBT. Tagliafico et al. \(^3\) compared the accuracy of DBT versus FFDM performed with DSCV in 52 consecutive women recalled after an abnormality was identified on screening mammography. Sensitivity and specificity were extremely high for both modalities, but there was no statistically significant difference between them. The Malmö Breast Tomosynthesis Screening Trial (MBTST) using 1-view DBT suggests that use of mammography plus breast tomosynthesis may modestly increase the number of cancers detected, with a decrease in the number of women who undergo unnecessary recalls or biopsies. \(^4\) Results from the MBTST demonstrated improved sensitivity with 1-view DBT, but not

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lower recall rates. A decrease in the false-positive rate would reduce unnecessary diagnostic workups and their consequences. However, the potential for over diagnosis cannot be ascertained because of the study designs and interval cancer rates are not yet available.

Teerststra et al.\(^5\) compared the diagnostic accuracy of a prototype DBT system with FFDM using a Hologic system in 513 women in the Dutch National Screening Program who had an abnormal screening mammogram, clinical symptoms, or were referred for a second opinion. Patients underwent standard FFD, followed by DBT. US, fine-needle aspiration biopsy, and/or core biopsy were performed after breast imaging when indicated. There were no significant differences in diagnostic accuracy between FFDM and No studies evaluated the accuracy of DBT used alone for screening mammography.

The 2015 Blue Cross Blue Shield TEC Assessment identified 12 studies that addressed the use of mammography with or without digital breast tomosynthesis (DBT) for screening in the ongoing Malmö Breast Tomosynthesis Screening Trial\(^6\)\(^7\)

“Current evidence on use of breast tomosynthesis plus mammography versus mammography alone for screening is insufficient to permit conclusions regarding the effect on health outcomes of adding breast tomosynthesis. Most available studies are retrospective and many did not use adequate reference standards. Also, most subjects did not serve as their own controls. The risk of bias for most of the studies was high. In addition, there is substantial variation across studies concerning (1) the magnitude of the impact of adding tomosynthesis on recall rates, and (2) whether any increases in cancer detection rates are statistically significant. Variations may be due to inadequate sample sizes, and the effect of other factors such as whether the screening is the initial or repeat examination. Adding tomosynthesis to mammography may also increase over detection and entails greater radiation exposure. Therefore, the available evidence does not permit conclusions regarding the effect of the tomosynthesis on health outcomes.”

A series of retrospective studies have been done to evaluate DBT. These included Good et al and Gur et al\(^8\)\(^9\)\(^10\). These studies claimed a reduction in recall events. However, the articles did not describe the sample, the time between FFDM and breast tomosynthesis, or how the reference standard was verified. Therefore, risk of bias is unknown. The British NHS conducted

\(^7\) Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Use of digital breast tomosynthesis with mammography for breast cancer screening. TEC Assessments 2015; Volume 29, 8
a reading study of DBT versus FFDM\textsuperscript{11}. Other retrospective studies\textsuperscript{12} and prospective comparison studies with paired data for each screen \textsuperscript{13,14} and a prospective study with a retrospective cohort comparing women screened with tomosynthesis plus digital mammography or digital mammography alone\textsuperscript{15} have shown that tomosynthesis have fewer recalls, decreased false positive findings and can detect more invasive cancers. In one study, 2-view tomosynthesis performed better than digital mammography only for less-experienced radiologists, but the two techniques had equivalent performance when interpreted by more experienced radiologists\textsuperscript{16}.

Therefore, randomized controlled trials are needed to compare integrated 2D and 3D mammography with 2D mammography for breast cancer screening.

The Tomosynthesis with digital Mammography (TOMMY) trial, concluding sensitivity but not specificity for each of the combined modalities studied were statistically greater compared with FFDM alone. Because the study included a mix of screening and diagnostic patients, case-selection bias limits extrapolation of the results to a screening population.

The evidence for DBT in individuals who have abnormal findings on breast imaging or clinical exam includes multiple observational studies and 1 meta-analysis. Relevant outcomes are test accuracy and validity, and treatment-related morbidity. Studies show either a similar diagnostic performance between breast tomosynthesis and other approaches or an advantage for breast tomosynthesis, with 2-view DBT having better performance characteristics that 1-view DBT. Some concerns have been raised regarding classification of macrocalcification clusters with

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DBT alone. Mixed patient populations, differences in reference standards, use of different imaging tests being compared with breast tomosynthesis, and variations in follow-up make it difficult to draw conclusions from these studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Although some of the evidence suggests that the improvements in image quality and enhanced visualization of lesions associated with DBT may increase the detection rate of certain breast cancers and potentially reduce the incidence of recalls for additional imaging and/or biopsy, these results were primarily related to diagnostic follow-up imaging, performed after an initial screening mammogram was acquired using FFDM or screen-film mammography i.e., in patients with a high suspicion of cancer. There were no significant differences in diagnostic accuracy between FFDM and but the authors concluded that combining FFDM and DBT detected more, but not all, cancers. No long-term, well-designed studies have been conducted to determine whether adding DBT to FFDM screening or whether its use at diagnostic follow-up provides health benefits in terms of clinical decision-making and treatment selection, or whether its use improves breast cancer survival and decreases mortality due to the disease. Published studies have not demonstrated that DBT provides an advantage for imaging women with dense breast tissue. Additional studies comparing the accuracy of DBT with FFDM and screen-film mammography for initial breast cancer screening are necessary to determine whether DBT will actually decrease recall rates for diagnostic workup in routine clinical practice. Acquisition of the imaging equipment is expensive without a statistically demonstrated improvement in patient outcomes.