Corporate Medical Policy

Digital Breast Tomosynthesis (DBT)

3D Mammography

Description of Procedure or Service

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 computed tomography (CT/CAT scanning). For screening, DBT is used in conjunction with full film digital mammography (FFDM). The results must be interpreted by a radiologist specialized in mammography. Tomosynthesis typically involves additional imaging time and radiation exposure.

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits.

Policy Statement

GEHA will provide coverage of Digital Breast Tomosynthesis (DBT) at 100% under the Preventive benefit, subject to age and frequency recommendations of the U.S. Preventive Services Task Force (USPSTF).

GEHA will provide coverage for non-routine digital breast tomosynthesis (DBT) when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

When Digital Breast Tomosynthesis is covered:

A. Annual mammography screening for women aged 40 years and older
B. Annual screening for women with a prior history of breast cancer
C. Annual screening for women younger than 40 who are considered high risk based on the following:
   a. BRCA1 & BRCA2 mutation carrier; or
   b. Woman with diagnosis of, or has first degree relative diagnosed with breast cancer or
   c. Woman who has a history of high dose thoracic irradiation (such as therapeutic radiation therapy)

Physician documentation

If requested, Providers must be able to demonstrate compliance with regulatory and/or contractual standards regarding the provision of this service. This includes but is not limited to:

A. Letter of support and/or medical necessity;
B. History and Physical completed within the year;
C. Previous mammogram or breast screening results;
D. Comparison to previous exams.

Policy Guidelines

Compared with conventional mammography, DBT requires more complex equipment, more time for image collection and analysis or reading of the final images, and may increase radiation exposure. These extra demands may or may not outweigh the advantages obtained from less tissue overlap in images, particularly when compared with modifications of digital mammography that involve spot compression and magnified and angled views.


- Women with an average risk of breast cancer – most women – should begin yearly mammograms at age 45.
- Women should be able to start the screening as early as age 40, if they want to. It’s a good idea to start talking to your health care provider at age 40 about when you should begin screening.
- At age 55, women should have mammograms every other year – though women who want to keep having yearly mammograms should be able to do so.
- Regular mammograms should continue for as long as a woman is in good health.
- Breast exams, either from a medical provider or self-exams, are no longer recommended.

The guidelines are for women at average risk for breast cancer. Women at high risk – because of family history, a breast condition, or another reason – need to begin screening earlier and/or more often. Talk to your medical provider to be sure.

American College of Radiology (ACR) (2014): The ACR Position Statement on Breast Cancer Screening in Women at Higher-Than-Average Risk in relationship to mammography:

- For women with genetics-based increased risk (and their untested first-degree relatives) or with a calculated lifetime risk of 20% or more, digital mammography (DM), with or without digital breast tomosynthesis (DBT), should be performed annually beginning at age 30.
- For women with histories of chest radiation therapy before the age of 30, DM, with or without DBT, should be performed annually beginning at age 25 or 8 years after radiation therapy, whichever is later.
- All women, especially black women and those of Ashkenazi Jewish descent, should be evaluated for breast cancer risk no later than age 30, so that those at higher risk can be identified and can benefit from supplemental screening.

In 2019 The American Society of Breast Surgeons released a recommendation that all women should have screening with 3D mammograms (also called digital breast tomosynthesis, digital tomosynthesis, or just tomosynthesis).

Background

Breast cancer is the second-leading cause of cancer death among women in the United States. In 2019, an estimated 268,600 women were diagnosed with the disease and 41,760 women died of it.
(Cancer.org, 2019). It is most frequently diagnosed among women aged 55 to 64 years, and the median age of death from breast cancer is 68 years.

Current studies provide reasonable evidence that DBT can improve accuracy for detection and diagnosis of lesions in women with suspected breast cancer and may potentially provide benefits, such as improved cancer detection and/or reduced recalls, in women undergoing routine breast cancer screening (Byun et. al., 2017; Ciatto, et. al., 2013). However, none of these studies have effectively evaluated the influence of DBT on breast cancer mortality and morbidity, treatment decision making, or patient quality of life, leaving open the possibility that the potential improvements with DBT would lead to over diagnosis rather than meaningful improvements in patient health.

In 2016, The United States Preventive Services Task Force (USPSTF) found insufficient evidence to assess the balance of benefits and harms of DBT as a primary screening method for breast cancer. The USPSTF summates that preliminary evidence suggests that DBT can reduce recall rates for false-positive results. The USPSTF also notes that DBT appears to increase the cancer detection rate compared with conventional digital mammography alone. However, the rate of over diagnosis associated with DBT is unknown; it is also unknown if there is an incremental benefit to finding these cancers earlier than with conventional digital mammography.

DBT is a promising technology, but additional studies are needed to determine whether its use improves health outcomes in women undergoing routine breast cancer screening or who have suspected breast cancer. The clinical impact of DBT is unclear for patients who have breast lesions detected during screening or as palpable lumps that developed in the interval between screening mammograms. Assessment of the literature shows that a large body of low-quality evidence has shown that DBT is likely more accurate than conventional DM in these patients, some large studies have also found that, as an adjunct to conventional DM, ultrasound has the same or somewhat better accuracy than DBT in women who have known or suspected breast cancer.

A small body of evidence suggests that DBT may provide benefits such as earlier cancer detection and/or fewer false-positive results during breast cancer screening. However, most of the studies of DBT for screening also found that it elevated biopsy rates, which raises the possibility that use of DBT results in over diagnosis, the detection and treatment of breast lesions that will not develop into symptomatic breast cancer. Since the available studies did not assess the influence of DBT screening on mortality or treatment-related morbidity, it is unclear whether screening with DBT will improve health outcomes. However, studies that assess practice patterns have found that clinicians relied on the information obtained with DBT to guide patient management as reflected in decisions concerning patient recall and lesion biopsy versus monitoring over time with routine imaging (Friedewald, et. al., 2014).

In 2012 Michell et. al. conducted a trial involving 738 women. Participants underwent bilateral, two-view FFDM and two-view DBT. Readers scored each lesion separately for probability of malignancy on screen-film mammography, FFDM, and then DBT. The scores were compared with the presence or absence of malignancy based on the final histopathology outcome. Following assessment 204 (26.8%) were diagnosed as malignant (147 invasive and 57 in-situ tumors), 286 (37.68%) as benign, and 269 (35.4%) as normal. The diagnostic accuracy was evaluated by using receiving operating characteristic (ROC) and measurement of area under the curve (AUC). The AUC values demonstrated a significant ($p = 0.0001$) improvement in the diagnostic accuracy with the addition of DBT combined with FFDM and film-screen mammography ($AUC = 0.9671$) when compared to FFDM plus film-screen mammography alone ($AUC = 0.7882$). The effect was significantly
greater for soft-tissue lesions [AUC was 0.9905 with the addition of DBT and AUC was 0.9201 for FFDM with film-screen mammography combined (p = 0.0001)] compared to microcalcification [with the addition of DBT (AUC = 0.7920) and for FFDM with film-screen mammography combined (AUC = 0.7843; p = 0.3182)]. It was concluded that the addition of DBT increases the accuracy of mammography compared to FFDM and film-screen mammography combined and film-screen mammography alone in the assessment of screen-detected soft-tissue mammographic abnormalities.

Skaane et al. (2013) compared digital mammography and DBT in a side-by-side feature analysis for cancer conspicuity, and to assess whether there is a potential additional value of DBT to standard state-of-the-art conventional imaging work-up with respect to detection of additional malignancies. A total of 129 women underwent 2D digital mammography including supplementary cone-down and magnification views and breast ultrasonography if indicated, as well as digital breast tomosynthesis. The indication for conventional imaging in the clinical setting included a palpable lump in 30 (23%), abnormal mammographic screening findings in 54 (42%), and surveillance in 45 (35%) of the women. The women were examined according to present guidelines, including spot-magnification views, ultrasonography, and needle biopsies, if indicated. The DBT examinations were interpreted several weeks after the conventional imaging without knowledge of the conventional imaging findings. In a later session, three radiologists performed a side-by-side feature analysis for cancer conspicuity in a sample of 50 cases. State-of-the-art conventional imaging resulted in needle biopsy of 45 breasts, of which 20 lesions were benign and a total of 25 cancers were diagnosed. The remaining 84 women were dismissed with a normal/definitely benign finding and without indication for needle biopsy. The subsequent DBT interpretation found suspicious findings in four of these 84 women, and these four women had to be called back for repeated work-up with knowledge of the tomosynthesis findings. These delayed work-ups resulted in two cancers (increasing the cancer detection by 8%) and two false-positive findings. The side-by-side feature analysis showed higher conspicuity scores for tomosynthesis compared to conventional 2D for cancers presenting as spiculated masses and distortions. It was concluded that clinical experience shows that there is a potential for increasing the sensitivity using DBT, especially for cancers manifesting as spiculated masses and distortions.

Clauser et al. (2016) selected 150 FFDM and DBT (50 benign and 50 malignant histologically verified microcalcifications, 50 cases classified as BI-RADS 1). Four radiologists evaluated, in separate sessions and blinded to patients’ history and histology, the presence of microcalcifications. Cases with microcalcifications were assessed for visibility, characteristics, and grade of suspicion using BI-RADS categories. Detection rate and diagnostic performance were calculated. Visibility, lesions' characteristics and reading time were analyzed. The results showed Detection rate and visibility were good for both FFDM and DBT, without intra-reader differences (P = 0.510). Inter-reader differences were detected (P < 0.018). Only two lesions were not detected by any reader on either FFDM or DBT. Diagnostic performance with DBT was as good as that of FFDM, but a significant inter-reader difference was found (P = 0.041). High inter-reader variability in the use of the descriptors was found. Reading time for DBT was almost twice that for FFDM (44 and 25 s, respectively). It was concluded that wide scan-angle DBT alone shows a high detection rate for microcalcifications. DBT and FFDM can characterize microcalcifications at a comparable level. Characterization is influenced by reader and by lesion type (benign vs malignant). DBT might be used as a stand-alone technique for the assessment of microcalcifications.

Lang et al. (2016) assessed the performance of one-view DBT in breast cancer screening. The Malmö Breast Tomosynthesis Screening Trial is a prospective population-based one-arm study with a planned inclusion of 15000 participants; a random sample of women aged 40-74 years eligible for the screening.
program. This is an explorative analysis of the first half of the study population (n = 7500). Participants underwent one-view DBT and two-view digital mammography (DM), with independent double reading and scoring. Primary outcome measures were detection rate, recall rate and positive predictive value (PPV). McNemar’s test with 95 % confidence intervals was used. Breast cancer was found in sixty-eight women. Of these, 46 cases were detected by both modalities, 21 by DBT alone and one by DM alone. The detection rate for one-view DBT was 8.9/1000 screens (95 % CI 6.9 to 11.3) and 6.3/1000 screens (4.6 to 8.3) for two-view DM (p < 0.0001). The recall rate after arbitration was 3.8 % (3.3 to 4.2) for DBT and 2.6 % (2.3 to 3.0) for DM (p < 0.0001). The PPV was 24 % for both DBT and DM. The results suggest that one-view DBT might be feasible as a stand-alone screening modality.

In 2016 Gilbert et. al. conducted a study to compare 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. Data was available for 7060 subjects comprising 6020 (1158 cancers) assessment cases and 1040 (two cancers) family history screening cases. The specificity of DBT and 2D was better than 2D alone but there was only marginal improvement in sensitivity. 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 minimise 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.

Sharpe, et. al. (2016) compared the recall and cancer detection rates (CDRs) at screening with digital breast tomosynthesis (DBT) with those at screening with two-dimensional (2D) mammography and to evaluate variations in the recall rate (RR) according to patient age, risk factors, and breast density and among individual radiologists at a single U.S. academic medical center. The study included 5703 (6.6%) DBT examinations and 80 149 (93.4%) 2D mammography examinations. The DBT subgroup contained a higher proportion of patients with risk factors for breast cancer and baseline examinations. DBT was used to detect 54.3% more carcinomas (+1.9 per 1000, P < .0018) than 2D mammography. The RR was 7.51% for 2D mammography and 6.10% for DBT (absolute change, 1.41%; relative change, -18.8%; P < .0001). The DBT subgroup demonstrated a significantly lower RR for patients with extremely or heterogeneously dense breasts and for patients in their 5th and 7th decades. It was concluded that implementing DBT into a U.S. breast cancer screening program significantly decreased the screening RR overall and for certain patient subgroups, while significantly increasing the CDR.

**Regulatory Status**

The Federal Drug Administration issues Mammography Quality Standards Act and Program (MQSA) compliant facility certification requirements for those facilities that utilize Digital Breast Tomosynthesis systems. Facilities with DBT units must apply to their accrediting bodies for the accreditation of the full field digital mammography portion of the DBT unit, and most then must apply to and be approved by the FDA for an extension of their certification to include the use of the DBT portion of the unit, prior to using the unit to image patients.

The following codes are for reference purposes only and do not imply that the service is covered or non-covered. Applicable codes include but are not limited to:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Origination Date: Dec 2016  Peer Reviewed: Dec 2019  Next Review Date: Dec 2020
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77061</td>
<td>Digital breast tomosynthesis; unilateral</td>
</tr>
<tr>
<td>77062</td>
<td>Digital breast tomosynthesis; bilateral</td>
</tr>
<tr>
<td>77063</td>
<td>Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>77065</td>
<td>Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral</td>
</tr>
<tr>
<td>77066</td>
<td>Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral</td>
</tr>
<tr>
<td>77067</td>
<td>Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed</td>
</tr>
<tr>
<td>G0279</td>
<td>Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)</td>
</tr>
</tbody>
</table>

**Scientific references**


**Policy implementation and updates**

Jan 2018 Update to coverage considerations.

Jan 2019 Coverage expanded based upon implementation of benefit changes.

Dec 2019 Reference updates, addition to background content. No benefit changes. Clarification of coverage wording

CM-WEB-0220-004