

Corporate Medical Policy

Digital Breast Tomosynthesis (DBT)

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 CAT scanning. 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.

Background

Breast cancer is the second-leading cause of cancer death among women in the United States. In 2015, an estimated 232,000 women were diagnosed with the disease and 40,000 women died of it. It is most frequently diagnosed among women aged 55 to 64 years, and the median age of death from breast cancer is 68 years. The USPSTF recommends biennial screening mammography for women aged 50 to 74 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. 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.

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 summarizes 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.

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.

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 for 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. Use of digital breast tomosynthesis (DBT) combined with conventional digital mammography (DM) for breast imaging in women with suspected or known breast cancer.
- B. Use of DBT for breast cancer screening in asymptomatic women.

When Digital Breast Tomosynthesis is not covered

Use of DBT for any other indication not expressly described above.

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.

Physician documentation

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.

Codes impacted by this policy include, but are not limited to:

77061 Digital breast tomosynthesis; unilateral

77062 Digital breast tomosynthesis; bilateral

77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)

77065 Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral

77066 Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral

77067 Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed

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

Scientific references

Final Recommendation Statement: Breast Cancer: Screening. U.S. Preventive Services Task Force. November 2016.

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Policy implementation and updates

Jan 2018 Update to coverage considerations.

Jan 2019 Coverage expanded based upon implementation of benefit changes.