Digital Breast Tomosynthesis (DBT)

Disclaimer:

Please note that Baptist Health Plan updates Coverage Guidelines throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare & Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website: http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

Digital Breast Tomosynthesis (DBT) is a digital mammography technique during which individual layers of breast tissue can be visualized as opposed to conventional digital mammography in which layers may be obscured by overlapping breast tissue.¹ Studies indicate that DBT may be of clinical importance as a breast cancer screening tool. DBT may offer improvements over conventional digital mammography in sensitivity and specificity. Also, DBT may contribute to a decrease in health care costs associated with less false positives and less follow up studies. Finally, DBT offers a potential reduction in screening barriers for women such as a decrease in the cost burden of screening with fewer follow-ups as well as the stress, anxiety and opportunity costs associated with the time used for the further evaluation of false positives.²

The Barco Mammo Tomosynthesis device received FDA 501(k) status on March 4, 2011 with the specific designation for displaying and viewing digital images of the breast for mammography screening and diagnostic purposes. The Selenis Dimensions Full Field Digital Mammography System, manufactured by Hologic, received premarket approval on February 11, 2011. This device is intended to offer tomosynthesis as a complement to conventional digital mammography, which incorporates both within this same system.³
**COVERAGE CRITERIA**

Digital breast tomosynthesis may be medically necessary to supplement diagnostic mammography in women with any anatomical condition such as dense breast tissue, making interpretation of traditional mammography difficult regardless of risk classification.  

Digital breast tomosynthesis may NOT be medically necessary, or may be experimental / investigational is experimental and investigational and is not considered medically necessary for any other population.

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**MEDICAL BACKGROUND**

The importance of screening mammography in the reduction of breast cancer mortality is indisputable.  One major study conducted in Sweden of nearly 163,000 women demonstrated a mortality reduction of 31% as a result of film mammography. Technology has improved since this study concluded in 1984 with the development of digital mammography.  As opposed to film mammography, digital mammography is more effective by better recognizing malignancies in women under the age of 50, premenopausal and perimenopausal women, and women with dense breast tissue.

Although digital mammography has improved the detection of malignancies in dense breast tissue as compared to film mammography, malignancies in dense tissue is still sometimes missed using both methods.  Digital breast tomosynthesis (DBT) penetrates overlapping breast tissue and illuminates the layers of the breast.  Conventional and film mammography records single images of the breasts whereas DBT records a series of images while moving over the breasts.

Published literature validating the efficacy and clinical utility of breast tomosynthesis left this technology largely unproven until recently.  A multi-center analysis of nearly 1200 subjects conducted by Rafferty and colleagues remained one of the strongest pieces of evidence.  Although this study was promising in its demonstration of increased sensitivity and specificity of DBT over conventional digital mammography, two of the study investigators disclosed significant financial ties to Hologic, the company that manufactures one of the two FDA approved DBT devices.

The majority of additional studies resembled that of Skaane, et al. in which 129 women were evaluated in a comparison study.  DBT seemed to produce higher sensitivity in screening over conventional digital mammography, but the authors stress that more studies are needed in order to understand the appropriate role of DBT in breast cancer screening.  Wallis and others found similar results in their study of 130 women, but also noted that some variation existed with the individual radiologists and their unique ability to read DBT images.  This learning curve associated with reading DBT images differently than conventional mammography is also acknowledged by Svane and researchers, who found that DBT delivered higher sensitivity and specificity in their study population of 144 women, but not enough to be statistically significant.  Svane and colleagues noted that women preferred the DBT method over conventional mammography for its lack of discomfort during the process.  Spangler and others compared DBT to digital mammography, finding digital mammography to be more sensitive in the detection of calcification while acknowledging the diagnostic potential of DBT if display fields
However, several recent studies have better established the diagnostic benefit of breast tomosynthesis as an adjunct screening tool to conventional mammography in some populations. The TOMMY trial evaluated more than 7000 moderate to high risk women aged 47-73 years in a retrospective blinded study in which subjects underwent breast tomosynthesis and digital mammography. Sensitivity was measurably better in this study when breast tomosynthesis was used as an adjunct screening tool. A meta-analysis comparing the two technologies across seven studies in more than 2000 patients also found higher diagnostic yield in breast tomosynthesis than digital mammography. In a 2014 position statement, the American College of Radiology asserted that breast tomosynthesis is no longer investigational and, in clinical practice, this technology will have a positive impact on long term outcomes including mortality. A position statement from the American Society of Breast Disease emphasizes the role of breast tomosynthesis particularly for dense breast tissue. Recent studies have demonstrated patients with dense breasts benefit the most from this technology.

A recently updated Hayes Technology report concluded that breast tomosynthesis is reasonably safe, noting that no complications have been identified in the current body of literature. The only safety implication is radiation exposure, which results in twice the dosage for women when used as an adjunct screening tool to mammography.

### REGULATORY INFORMATION

Kentucky – No legislative mandates were found for coverage of Digital Breast Tomosynthesis (DBT).

Indiana – No legislative mandates were found for coverage of Digital Breast Tomosynthesis (DBT).

Tennessee – No legislative mandates were found for coverage of Digital Breast Tomosynthesis (DBT).

### COVERAGE DETAIL

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

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<th>CPT® Codes</th>
<th>Description</th>
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<td>Digital breast tomosynthesis; unilateral</td>
<td>May NOT be medically necessary, or may be experimental / investigational</td>
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Effective 01/01/2015
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<th>Code</th>
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C50.111-C50.119 | Malignant neoplasm of central portion of breast, female
C50.121 | Malignant neoplasm of central portion of breast, male

REFERENCES


