MEDICAL POLICY

SUBJECT: MAMMOGRAPHY: DIGITAL BREAST TOMOSYNTHESIS	**EFFECTIVE DATE: 10/18/01** **REVISED DATE: 10/16/02, 10/15/03, 09/16/04, 11/03/04, 09/15/05, 02/16/06, 12/21/06, 11/15/12, 11/21/13, 11/20/14, 01/22/15, 02/18/16, 03/16/17** **(ARCHIVED DATE: 10/18/07** **EDITED DATE: 12/18/08, 11/19/09, 09/16/10, 09/15/11)**
POLICY NUMBER: 6.01.22 **CATEGORY: Technology Assessment**	**ARCHIVED DATE: 02/15/18** **PAGE: 1 OF: 6**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, digital breast tomosynthesis is considered a **medically appropriate** imaging option in the screening or diagnosis of breast cancer.

Refer to Corporate Medical Policy #6.01.23 regarding Mammography: Computer Aided Detection.

POLICY GUIDELINES:

This policy does not address *direct full field digital mammography (FFDM)*. A direct full field digital mammogram is a digitally formatted mammogram which can be manipulated by changing orientation, magnification, brightness and contrast to highlight lesion conspicuity as needed. The digital images can be stored and transferred electronically which facilitates their quick and easy retrieval as well as allowing remote evaluation by distant specialists. Advantages of FFDM include the potential to detect breast cancer at an earlier stage, reduce the number of patients recalled for additional mammograms, reduce the number of false-positive mammograms, decreased radiation dose to the breast, increased accuracy of images, facilitation of long distance consultations with mammography specialists, and ease of mammography storage.

This policy does not address *computer-aided detection (CAD) mammography*. CAD acts as a second reader of mammograms, and can utilize digital mammograms or can digitize screen-film mammograms. CAD provides computer analysis of digitized mammograms for patterns suggestive of abnormalities.

DESCRIPTION:

Digital breast tomosynthesis (DBT) uses existing digital mammography equipment with specialized software to obtain low dose images acquired in an arc (3-D acquisition) which are then reconstructed into slices which can be viewed on a workstation. This allows for visualization of the breast in layers and therefore reduces the issue of tissue overlap. Currently at most sites both a 2-D image as well as the 3-D acquisition is obtained for each patient. Potential advantages of DBT are similar to those for full field digital mammography; more accurate estimation BI-RADS classification of a lesion (improved conspicuity), reduction of distortions, reduction of false positives associated with glandular clusters, greater security in the study of dense breasts, and the reduction of the number of recalls. Tomosynthesis involves some additional imaging time and doubling of the radiation exposure. To reduce the increased radiation exposure when obtaining both 2D images along with DBT, C-view software has been developed which allows 2D images to be generated as a part of the breast tomosynthesis exam. The 2D images created from C-View software are reviewed together with the tomosynthesis slices to make a clinical decision or diagnosis.

RATIONALE:

On February 11, 2011, the U.S. Food and Drug Administration (FDA) approved Hologic, Inc. to market its Selenia Dimensions 2D Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) system. This DBT is the first mammography system that provides 3D images of the breast for breast cancer screening and diagnosis. Since the date of the FDA approval, a number of facilities in the U.S. have been using the Selenia Dimensions 2D (with the DBT locked). Facilities that have an accredited (or have applied to be accredited) Selenia Dimensions 2D unit can

activate the DBT modality of the unit after applying to and obtaining FDA approval to extend its certificate to include the DBT modality.

Because DBT is a new mammographic modality, facilities wanting to use DBT on patients must meet all Mammography Quality Standards Act (MQSA) applicable requirements: (1) personnel must obtain at least 8 hours of DBT training; (2) the unit must undergo a mammography equipment evaluation prior to use; and (3) the facility must follow the manufacturer's recommended quality control procedures.

The Selenia Dimensions 3D DBT is a hardware and software upgrade to the Selenia Dimensions 2D FFDM system, which is FDA approved for conventional mammography imaging (P010025/S013, approved December 22, 2008).

The FDA approved new tomosynthesis software (May 2013) that enables a 2D image (called C view) to be created from the tomosynthesis images. As a result, the radiation dose will be lowered since both the tomosynthesis and the 2D mammography can be created from one procedure versus two. Studies are still needed to determine if the combined C view and 3D reconstruction to digital tomosynthesis alone are comparable.

A 2014 Blue Cross Blue Shield TEC Assessment, "Use of digital breast tomosynthesis with mammography for breast cancer screening or diagnosis" concluded that recent studies have provided some evidence that adding breast tomosynthesis to mammography may increase the accuracy (and possibly the sensitivity) of screening while reducing the number of women who are recalled unnecessarily. However studies with longer follow-up of women with negative screening results are needed. Digital breast tomosynthesis as an addition to diagnostic mammography (such as spot views) has the potential to screen out some women with false-positive results. As a consequence the number of women who are biopsied may be reduced. The body of evidence on the use of breast tomosynthesis to evaluate women who are recalled for a diagnostic work-up after a suspicious finding on screening mammography is weaker than that on adding breast tomosynthesis to mammography for screening. In addition, diagnostic mammography is not the only imaging modality used during the diagnostic work-up. Thus assessing the value of tomosysnthesis compared to the available set of different diagnostic tests (e.g., ultrasound, MRI) is problematic.

The American College of Obstetricians Technical Assessment (2013) on digital breast tomosynthesis concluded clinical data suggest that digital mammography with tomosynthesis produces a better image, improved accuracy, and lower recall rates compared with digital mammography alone. Further study will be necessary to confirm whether digital mammography with tomosynthesis is a cost-effective approach capable of replacing digital mammography alone as the first-line screening modality of choice for breast cancer screening.

The American College of Radiology (ACR) released a statement on digital breast tomosynthesis (11/24/2014). A new digital technology, breast tomosynthesis has shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. This is extremely important. The medical community has long sought ways to improve breast cancer screening accuracy. Better sensitivity will likely translate into more lives saved. Lower recall rates result in fewer patients who may experience short-term anxiety awaiting test results. As this technology is used in clinical practice, we anticipate that further studies will clarify its impact on long-term clinical outcomes, including reduced mortality. It will also be important to further elucidate which subgroups of women might benefit most from these exams (by age, breast density, frequency of examination, etc.). To facilitate such large scale outcome data collection, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The College applauds the decision by the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these exams by covering beneficiaries for tomosynthesis and urges private payers to do the same. To be clear: tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography. While the College encourages more studies to clarify the clinical role(s) of tomosynthesis and its long-term outcomes, it is clear that tomosynthesis represents an advance in breast imaging.

While there is strong evidence that tomosynthesis will have an important role in breast imaging, further studies are needed to assess tomosynthesis' relationship to long-term clinical outcomes, including reduced mortality. It will also be important to learn which subgroups of women might benefit most from these exams (by age, breast density, frequency of examination, etc.). To facilitate such large scale research, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The College urges the Centers for Medicare and Medicaid Services (CMS) and private insurers to facilitate access to these exams by covering beneficiaries for tomosynthesis - now that it has been shown to improve key screening parameters compared to digital mammography. While the College encourages more studies to clarify the clinical role(s) of tomosynthesis and its long-term outcomes, it is fairly clear that tomosynthesis represents an important advance in breast imaging. The ACR will continue to monitor this technology.

The National Comprehensive Cancer Network (2016) guidelines state early studies show promise for tomosynthesis mammography. Two large trials showing a combined use of digital mammography and tomosynthesis resulted in improved cancer detection and decreased call back rates; of note this is double the dose of radiation. The radiation dose can be minimized by synthetic 2-D reconstruction.

NCCN also suggests that tomosynthesis be considered whenever an annual screening mammogram is recommended.

The U.S. Preventive Services Task Force (USPSTF) updated its recommendations for breast cancer screening using film mammography and methods other than film mammography in 2016. USPSTF recommends mammography, but concluded that there is insufficient evidence to conduct a risk-benefit assessment of digital breast tomosynthesis as a primary screening strategy. USPSTF also stated that there is insufficient evidence to conduct a risk-benefit assessment of DBT as adjunctive screening for breast cancer in women who are identified as having dense breast tissue in an otherwise negative screening mammogram.

CODES:	Number	Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	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)

HCPCS:	G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral
	G9899	Screening, diagnostic, film, digital or digital breast tomosynthesis (3D) mammography results documented and reviewed (Effective 1/1/2018)
	G9900	Screening, diagnostic, film, digital or digital breast tomosynthesis (3D) mammography results were not documented and reviewed, reason not otherwise specified (Effective 1/1/2018)
ICD10:	C50.011-C50.019	Malignant neoplasm of nipple and areola, female (code range)

C50.111-C50.119	Malignant neoplasm of central portion of breast, female (code range)
C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of breast, female (code range)
C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of breast, female (code range)
C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of breast, female (code range)
C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of breast, female (code range)
C50.611-C50.619	Malignant neoplasm of axillary tail of breast, female (code range)
C50.811-C50.819	Malignant neoplasm of overlapping sites of breast, female (code range)
C50.911-C50.919	Malignant neoplasm of breast of unspecified site, female (code range)
C79.81	Secondary malignant neoplasm of breast
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
D05.00-D05.92	Lobular carcinoma in situ of breast (code range)
D48.60-D48.62	Neoplasm of uncertain behavior of other and unspecified sites (code range)
D49.3	Neoplasm of unspecified behavior of breast
N63	Unspecified lump in breast
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z12.39	Encounter for other screening for malignant neoplasm of breast
Z15.01- Z15.03	Genetic susceptibility to malignant neoplasm (code range)
Z80.3	Family history of malignant neoplasm of breast
Z85.3	Personal history of malignant neoplasm of breast

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KEY WORDS:

Digital breast tomosynthesis.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, Digital Breast Tomosynthesis is not addressed in a National or Local Medicare coverage determination or policy. However, Digital Breast Tomosynthesis is addressed in the CMS Manual System – Medicare Claims Processing. Please refer to the following website for Medicare Members: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3160CP.pdf.