

MP.201.MH – Digital Breast Tomosynthesis

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Digital Breast Tomosynthesis (DBT)** medically necessary for the following indications:

Screening Indications:

1. Annually for women 40 and over

Note: Surveillance may be indicated at an earlier age in women with high risk factors. DBT is not indicated as a screening tool for women over the age of 75, only diagnostic.

Diagnostic Indications:

1. There are signs or symptoms suggestive of malignancy (e.g., mass, some types of spontaneous nipple discharge, skin changes, unilateral breast pain, or unilateral axillary lymph nodes)
2. There are radiographic abnormalities detected on screening mammography;
3. DBT is performed in a member with metastatic disease of undetermined etiology, in whom the source is suspected to be breast;
4. DBT is performed on a member with axillary lymphadenopathy of undetermined etiology; or
5. There is short interval follow-up (at six month intervals, for two years) necessary for unresolved clinical/radiographic concerns;
 - a. A personal history of breast malignancy exists.
 - b. Benign, biopsy-proven breast disease.

Background

The Centers for Medicare and Medicaid Services (CMS) define screening mammography as the radiological procedure furnished to a women without signs or symptoms of breast disease, for the purpose of early detection of breast cancer. The minimum requirements of a screening mammogram are cranio-caudal (CC) and medio-lateral oblique (MLO) views. A diagnostic mammography subsequent to a suspicious screening mammography may include extra views without repeating the cranio-caudal (CC) and medio-lateral oblique (MLO) views, when the two tests are performed within a reasonable proximity of time of each other. Diagnostic mammography is the specific evaluation of a patient with signs or symptoms of a breast disorder, or with screening-detected abnormalities.

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Peppard et al define DBT as an emerging technology used in diagnostic breast imaging to evaluate potential abnormalities. In DBT, the compressed breast tissue is imaged in a quasi-three-dimensional manner by performing a series of low-dose radiographic exposures and using the resultant projection image dataset to reconstruct cross-sectional in-plane images in standard mammographic views. Additional studies are needed, but initial single-institution studies have shown that adding tomosynthesis to mammography increases cancer detection and reduces false-positive results.

The following breast tomosynthesis systems have received FDA premarket approval (PMA):

- Selenia Dimensions Full Field Digital Mammography System (Hologic Inc. cleared February 11, 2011; approved with modifications as the Selenia Dimensions 3D System on May 16, 2013)
- SenoClaire System (GE Healthcare, cleared August 26, 2014).
- Mammomat Inspiration with Tomosynthesis (Siemens Medical Solutions USA Inc. cleared April 21, 2015)

Codes:

CPT/HCPCS Codes	
Code	Description
77065	Diagnostic mammography, including (CAD) when performed; unilateral
77066	Diagnostic mammography, including (CAD) when performed; bilateral
+ G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066, NO ICD requirement)
NOTE: Breast tomosynthesis should be reported using the applicable mammography code along with the applicable add-on tomosynthesis code	
77061	Digital breast tomosynthesis; unilateral (new CPT code effective 1/1/2015)
77062	Digital breast tomosynthesis; bilateral (new CPT code effective 1/1/2015)
The following CPT codes have a billable limit of one screening per year for women 40 and older	
+77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure (new CPT code effective 1/1/2015)
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed.

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ICD-10 Codes* – For All CPTs EXCEPT FOR 77067, 77066, 77065, and G0279 (no diagnosis restrictions for these 4 CPTs)

Code	Description
611.79	Other sign and symptom in breast
C50.011 – C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.02	Lobular carcinoma in situ of left breast
D05.82	Other specified type of carcinoma in situ of left breast
D24.1	Benign neoplasm of right breast
D24.2	Benign neoplasm of left breast
D48.60-D48.62	Neoplasm of uncertain behavior, breast
N60.09	Solitary cyst of unspecified breast
N60.41	Mammary duct ectasia of right breast
N63	Unspecified lump in breast
N64.4	Mastodynia
N64.52	Nipple discharge
N64.59	Other signs and symptoms in breast
N64.89	Other specified disorders of breast
R06.02	Shortness of breath
R92.0	Mammographic microcalcification found on diagnostic imaging of breast
R92.1	Mammographic calcification found on diagnostic imaging of breast
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
Z08	Encounter for follow-up examination after completed treatment for malignant neoplasm
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z12.39	Encounter for other screening for malignant neoplasm of breast
Z78.0	Asymptomatic menopausal state
Z85.3	Personal history of malignant neoplasm of breast
Z98.89	Other specified post procedural states

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References

1. American Cancer Society (ACS) – American Cancer Society Recommendations for Early Breast Cancer Detection in Women without Breast Symptoms. Last revised 2021.
<http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-acs-recs>
2. American College of Radiology (ACR) Statement on Breast Tomosynthesis. November 24, 2014. <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Breast-Tomosynthesis>
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: L33950 – Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography. Revision Effective Date: 11/28/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33950&ver=32&bc=CAAAAAAAAAAAAA>
4. Friedewald SM, Rafferty EA, Rose SL et al. Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography. JAMA. 2014;311(24):2499-2507. doi:10.1001/jama.2014.6095. June 25, 2014. <https://pubmed.ncbi.nlm.nih.gov/25058084/>
5. Hayes Medical Technology Directory. Digital Breast Tomosynthesis for Breast Cancer Diagnosis or Screening. October 24, 2017. Annual Review: December 5, 2019.
6. Peppard HR, NicholSEN BE, Rochman CM et al. Digital Breast Tomosynthesis in the Diagnostic Setting: Indications and Clinical Applications. Radiographics. 2015 Jul-Aug;35(4):975-90. doi: 10.1148/rg.2015140204 <http://www.ncbi.nlm.nih.gov/pubmed/26024062>
7. U.S. Food and Drug Administration (FDA). MAMMOMAT Inspiration with Tomosynthesis – P140011. Last updated: 05/03/2021. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=391690>
8. U.S. Food and Drug Administration (FDA). Selenia Dimensions 3D System – P080003. Last updated: 05/03/2021. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003>
9. U.S. Food and Drug Administration (FDA). SenoClaire – P130020. Last updated: 05/03/2021. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130020S001>
10. US Preventive Services Task Force (USPSTF) Draft Recommendation Statement – Breast Cancer: Screening. January 21, 2021. <https://uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/breast-cancer-screening1>

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