# MedStar Health, Inc.
## POLICY AND PROCEDURE MANUAL

Policy Number: MP.201.MH
Last Review Date: 11/03/2016
Effective Date: 1/1/17

## MP.201.MH – Digital Breast Tomosynthesis

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP - CSNP

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

Screening Indications:
1. Annually for women age 40-54.
2. Bi-annually for women 55-75.

**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.

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** | |
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| Code | Description |
| G0202 | Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed. |
| G0204 | Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral. |
| G0206 | Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral. |
| G0279 | Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 OR G0206) |
| **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) |

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| +77063 | Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) (new CPT code effective 1/1/2015) |

| **ICD-9 Codes** | |
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| Code | Description |
| V76.1-V76.2 | Screening mammogram |
| 238.3 | Neoplasm of uncertain behavior, breast |
| **ICD-10 Codes** | |
| Code | Description |
| Z12.31 | Encounter for screening mammogram for malignant neoplasm of breast |
| C50.011 – C50.929 | Malignant neoplasm of breast |
| C79.81 | Secondary malignant neoplasm of breast |
| D48.60-D48.62 | Neoplasm of uncertain behavior, breast |
| 611.79 | Other sign and symptom in 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 |
| 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 |

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| Z08 | Encounter for follow-up examination after completed treatment for malignant neoplasm |
| 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 |

**References**


1. American Cancer Society (ACS) – American Cancer Society Recommendations for Early Breast Cancer Detection in Women without Breast Symptoms. Last revised 10/20/2015. 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. http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/20141124-ACR-Statement-on-Breast-Tomosynthesis
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: L33950 – Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography. Updated 10/01/2015. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33950&ContrId=240&ver=8&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&CptHcpcsCode=G0279&bc=gAAAABAAAAAAAA%3d%3d&
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. http://jama.jamanetwork.com/article.aspx?articleid=1883018
5. Hayes Medical Technology Directory. Digital Breast Tomosynthesis for Breast Cancer Diagnosis or Screening. September 24, 2015.
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 05/18/ 2015. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm447240.htm

8. U.S. Food and Drug Administration (FDA). Selenia Dimensions 3D System – P080003. Last updated 09/06/2013. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm246400.htm
9. U.S. Food and Drug Administration (FDA). SenoClaire – P130020. Last updated 04/27/2015. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm412383.htm
10. US Preventive Services Task Force (USPSTF) Draft Recommendation Statement – Breast Cancer: Screening. May 18, 2015. http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementDraft/breast-cancer-screening1