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
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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:**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
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<tbody>
<tr>
<td>Code</td>
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<tr>
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<tr>
<td>G0204</td>
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<tr>
<td>G0206</td>
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**NOTE:** Breast tomosynthesis should be reported using the applicable mammography code along with the applicable add-on tomosynthesis code

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>77061</td>
<td>Digital breast tomosynthesis; unilateral (new CPT code effective 1/1/2015)</td>
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<tr>
<td>77062</td>
<td>Digital breast tomosynthesis; bilateral (new CPT code effective 1/1/2015)</td>
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<tr>
<td>+77063</td>
<td>Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) (new CPT code effective 1/1/2015)</td>
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ICD-9 Codes

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<td>V76.1-V76.2</td>
<td>Screening mammogram</td>
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<td>238.3</td>
<td>Neoplasm of uncertain behavior, breast</td>
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ICD-10 Codes

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<tr>
<td>Z12.31</td>
<td>Encounter for screening mammogram for malignant neoplasm of breast</td>
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<tr>
<td>D48.60-D48.62</td>
<td>Neoplasm of uncertain behavior, breast</td>
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</table>

References


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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

   http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm246400.htm

   http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm412383.htm


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