hmsa

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Digital Breast Tomosynthesis (3D)

Policy Number: MM.05.012	**Current Effective Date:** April 1, 2024
Lines of Business: HMO; PPO; QUEST Integration; FED 87; EUTF	**Original Effective Date:** November 01, 2013
Place of Service: Outpatient	**Precertification:** Not required

I. Description

Digital breast tomosynthesis (DBT) reduces the masking effect of superimposed breast tissue, resulting in improved cancer detection, specificity, and lower recall rate compared to traditional 2-D DM. Benefits of DBT are evident across all age and breast density groups, with the largest gains observed in patients with heterogeneously dense breast tissue. The improved outcomes are sustainable on subsequent screening rounds.

Implementation of DBT also increases detection of invasive breast cancers, without an increase in the proportion of detected ductal carcinoma in situ (DCIS. The additional invasive cancers detected at DBT have similar or more favorable tumor characteristics than cancers detected at 2-D DM, such as higher proportions of small, spiculated, low-grade tumors. In a prospective population-based trial of over 14,000 women, the interval cancer rate was lower in women screened with DBT than in the 2-D DM screening control group.

DBT also plays an important role in diagnostic breast imaging. Multiple studies have found improved accuracy in evaluation of noncalcified lesions with DBT compared with 2-D DM spot compression views alone. The number of additional views obtained is decreased or potentially eliminated when evaluating noncalcified findings, making diagnostic work-ups more efficient. Diagnostic DBT has also shown an improved positive predictive value for biopsy while maintaining the cancer detection rate. Additionally, there is a decrease in the number of patients for whom a short-interval follow-up is recommended when diagnostic evaluation is performed with DBT".

Screening with two-dimensional (2D) digital mammography alone is still the standard of care at many sites, but it has its limitations due to its inability to detect some cancers.

II. Policy Criteria

A. DBT (3D) is covered (subject to Limitations and Administrative Guidelines) for screening mammography.
B. DBT (3D) is covered (subject to Limitations and Administrative Guidelines) for diagnostic mammography.

III. Limitations

N/A

IV. Administrative Guidelines

A. Precertification is not required. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria. Documentation supporting medical necessity should be legible, maintained in the patient's medical record and made available to HMSA upon request.

B. Applicable codes

Covered Screening Codes

CPT Code	Description
77063*	Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure)
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed

*Must be billed with the primary service mammogram CPT code 77067.

ICD-10-CM Code**	Description
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z80.3	Family history of malignant neoplasm of breast
Z85.3	Personal history of malignant neoplasm of breast

**For professional claims, the applicable ICD-10-CM code must be identified as the primary line diagnosis to ensure appropriate application of benefits.

Covered Diagnostic Codes

CPT Code	Description
77061	Diagnostic digital breast tomosynthesis; unilateral
77062	Diagnostic digital breast tomosynthesis; bilateral

HCPCS Code	Description
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral

V. Scientific Background

Conventional Mammography

Conventional mammography produces 2-dimensional (2D) digital images of the breast. Overlapping tissue on a 2D image can mask suspicious lesions or make benign tissue appear suspicious, particularly in women with dense breast tissue. As a result, women may be recalled for additional mammographic spot views. Inaccurate results may lead to unnecessary biopsies and emotional stress, or to a potential delay in diagnosis. Spot views often are used to evaluate microcalcifications, opacities, or architectural distortions; to distinguish masses from overlapping tissue, and to view possible findings close to the chest wall or in the retroareolar area behind the nipple. The National Cancer Institute has reported that approximately 20% of cancers are missed at mammography screening. Average recall rates are approximately 10%, with an average cancer detection rate of 4.7 per 1000 screening mammography examinations. The U.S. Mammography Quality Standards Act

audit guidelines anticipate 2 to 10 cancers detected per 1000 screening mammograms. Interval cancers, which are detected between screenings, tend to have poorer prognoses.

Digital Breast Tomosynthesis

DBT was developed to improve the accuracy of mammography by capturing a group of tomograms of the breast, further clarifying areas of overlapping tissue. Developers proposed that its use would result in increased sensitivity and specificity, as well as fewer recalls due to inconclusive results. DBT produces multiple low-dose images per view along an arc over the breast. During breast tomosynthesis, the compressed breast remains stationary while the x-ray tube moves approximately 1 for each image in a 15 to 50 arc, acquiring 11 to 49 images. These images are projected as cross-sectional “slices” of the breast, with each slice typically 1-mm thick. Adding breast tomosynthesis takes about ten seconds per view. In a study in a research setting, Gur et al (2009) reported a mean time (standard deviation) for interpretation of results was 1.22 (1.15) minutes for digital mammography and 2.39 (1.65) minutes for combined digital mammography and breast tomosynthesis.

With conventional 2D mammography, breast compression helps decrease tissue overlap and improve visibility. By reducing problems with overlapping tissue, compression with breast tomosynthesis may be reduced by up to 50%. This change could result in improved patient satisfaction.

A machine equipped with breast tomosynthesis can perform 2D digital mammography, DBT, or a combination of both 2D mammography and DBT during a single compression. Radiation exposure from tomosynthesis is roughly equivalent to mammography. Therefore, adding tomosynthesis to mammography doubles the radiation dose, although it still is below the maximum allowable dose established in the Mammography Quality Standards Act.

Studies typically compare 1-view (i.e., mediolateral oblique view), or more commonly, 2-view (mediolateral oblique plus craniocaudal view) breast tomosynthesis either alone or combined with standard 2D mammography, against standard 2D mammography alone.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

VI. Supplemental Information

National Comprehensive Cancer Network
All instances of screening or diagnostic mammography within the algorithm (excluding footnotes) have been modified to include with tomosynthesis.

American College of Radiology
"DBT also plays an important role in diagnostic breast imaging. Multiple studies have found improved accuracy in evaluation of noncalcified lesions with DBT compared with 2-D DM spot compression views alone. The number of additional views obtained is decreased or potentially eliminated when evaluating noncalcified findings, making diagnostic work-ups more efficient. Diagnostic DBT has also shown an improved positive predictive value for biopsy while maintaining the cancer detection rate. Additionally, there is a decrease in the number of patients for whom a short-interval follow-up is recommended when diagnostic evaluation is performed with DBT".

U.S. Preventive Services Task Force Recommendations
The USPSTF is currently reviewing the benefits and risks of tomosynthesis and has not published its final recommendation.

USPSTF Draft recommendation (June 2023) states "Screening for breast cancer is commonly done using digital mammography (also known as DM) or digital breast tomosynthesis, also known as DBT screening or 3D mammography. Both use X-rays to produce an image of the breast. DM images the breast with X-rays from 2 angles, and DBT images the breast with X-rays from multiple angles. Both are effective ways to screen for breast cancer."

Medicare National Coverage
Medicare covers 3-D digital tomosynthesis when prescribed by physician.

VII. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), or for QUEST members, under Hawaii Administrative Rules (HAR 1700.1-42), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically

necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VIII. References

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IX. Policy History

Action Date	Action
November 2012	Topic reviewed annually at TEC.
May 20, 2013	Policy reviewed by Joan Kendall, M.D.
June 18, 2013	Policy approved at OMD
June 28, 2013	Policy approved at UMC
August 1, 2013	90-day notice given

August 11, 2014	Policy reviewed by Joan Kendall, M.D.
August 19, 2014	Policy approved by Medical Directors
August 22, 2014	Policy approved by UMC
November 1, 2015	Policy reviewed by Joan Kendall, M.D.
November 3, 2015	Policy approved by Medical Directors
November 20, 2015	Policy approved by UMC
Novmeber 1, 2016	Policy reviewed by Joan Kendall, M.D.
November 14, 2016	Policy approved by Medical Directors
November 18, 2016	Policy approved by UMC
March 13, 2017	Policy reviewed by Joan Kendall, M.D.
April 4, 2017	Policy approved by Medical Directors
April 28, 2017	Policy approved by UMC
November 08, 2018	Policy reviewed by Joan Kendall, M.D.
November 20, 2018	Policy approved by Medical Directors
November 21, 2018	Policy approved by UMC
February 12, 2019	Policy reviewed by Joan Kendall, M.D.
February 19, 2019	Policy approved by Medical Directors
February 22, 2019	Policy approved by UMC
July 01, 2019	90 Day Notice
July 01, 2020	EUTF added to the header- approved benefit
November 8, 2021	Policy reviewed by Joan Kendall, M.D.
November 16, 2021	Policy approved by Medical Directors
November 19, 2021	Policy approved by UMC
November 8, 2022	Policy reviewed by Joan Kendall, M.D.
November 15, 2022	Policy approved by Medical Directors
November 18, 2022	Policy approved by UMC
September 28, 2023	Policy reviewed by Joan Kendall, M.D.
October 17, 2023	Policy approved by Medical Directors
October 27, 2023	Policy approved by UMC
April 1, 2024	Policy effective date following notification period