Breast Tomosynthesis

Policy MP-022

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Breast cancer is the most common noncutaneous cancer in women. According to the American Society of Clinical Oncology (ASCO), in 2020 the United States is estimated to have 276,480 new cases of invasive breast cancer diagnosed in women and 2,620 cases in men. An additional prediction of 48,530 new cases of non-invasive (in situ) breast cancer in women. The ASCO anticipates that in 2020, approximately 42,690 deaths (42,170 women and 520 men) from breast cancer will occur in the U.S.

Standard approaches to screening and diagnosis of breast cancer are analog or digital mammography, breast ultrasound, and breast MRI.

Mammography or full-field digital mammography (FFDM) remains the mainstay of screening for breast cancer. Mammography may detect cancer one and a half to four years before a cancer becomes clinically evident.

Tomosynthesis is a tomographic application of digital mammography. The tomosynthesis acquisition mimics conventional mammography with regard to breast positioning and compression, but unlike conventional mammography, the x-ray tube takes multiple low-dose exposures as it moves through a limited (e.g., 30°) arc of motion. The individual images are then reconstructed into a series of thin high-resolution slices that can be displayed individually or in a dynamic ciné mode, with a total radiation dose similar to conventional mammography.

Ultrasonography is commonly used for diagnostic follow-up of an abnormality seen on screening digital mammography, to clarify features of a potential lesion. Ultrasound is used to

further evaluate masses or asymmetries and can differentiate a solid mass from a cyst. Ultrasonography is also used to provide guidance for biopsies and other interventions. It is the first line of imaging in a woman who is pregnant or less than thirty years old with focal breast symptoms or findings.

The role of magnetic resonance imaging (MRI) for breast cancer screening is emerging. Currently MRI screening, in combination with mammography is targeted to high risk patients. Screening MRI is recommended for women with an approximately 20%-25% or greater lifetime risk of breast cancer, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin's disease.

The combination of MRI and mammography is recommended by the American Cancer Society in women at high risk of breast cancer (≥20% to 25% lifetime risk), as defined by risk prediction models based primarily on family history. The cancer mortality risk in this population is assumed to be high enough to justify the increased cost and numbers of follow-up procedures that would be generated because of low specificity.

Policy Statement and Criteria

1. **Commercial Plans/CHIP**

   U of U Health Plans covers breast tomosynthesis as a screening and diagnostic modality in the assessment and management of breast cancer.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Previous reviews of breast tomosynthesis (BT) in 2008 and 2011 failed to identify sufficient evidence for this technology to be considered proven. Since the previous review of this technology in 2011 two systematic reviews and thirteen primary literature articles have been published. The studies evaluated the results of more than 59,000 patients who underwent mammography and/or BT. The majority of the articles report taking into consideration inter-rater reliability, recall rates, cancer detection rate and study design.

Since the previous review most of the primary literature articles assess similar endpoints. Both the systematic reviews and 11 of 13 (85%) of the primary literature articles used BT specifically for screening. With regard to their findings, several key endpoints are assessed – inter-rater reliability, recall

rates, cancer detection and comparative outcomes to digital mammography. The following summarizes these findings on several of these areas:

- **Inter-rater Reliability**: Kappa statistics (a statistical measure of inter-rater reliability with values between 0 and 1 where 0 is no agreement at all and 1 is complete agreement) were reported by two authors. Both of these papers compared full field digital mammography (FFDM) to BT and compared the conclusions of five radiologists when viewing each type of image. The average kappa statistic was 0.90. Where kappa statistics were not reported but where there were multiple readers, decreases in recall rates and increases in area under the curve were still identified with use of BT.
- **Recall Rates**: Ten of the thirteen papers (77%) addressed the potential for a decrease in recall rates with the use of BT. With the exception of the Rafferty et al. paper which reported a recall reduction rate of 6-67%, from which reasonable conclusions cannot be drawn, the average recall reduction rate with the use of BT was 27.5% (range = 17.2-37%).
- **Cancer Detection**: There was an inherent inclusion bias against tomosynthesis with respect to cancer detection in a screening population. Many cancers were acquired in patients scheduled for biopsy and had been detected on conventional mammograms as part of standard screening evaluation. It is likely that studies underestimate the potential gains in sensitivity that might occur in clinical practice. For example, the study by Gennaro et al. both cranio-caudal (CC) and mediolateral oblique (MLO) images were acquired with FFDM but this information was compared to BT which only assessed MLO images. This in turn will decrease the sensitivity of BT as it compares to FFDM. All studies that addressed cancer detection noted an increase in detection with the use of BT. Studies varied, however, in their ability to increase cancer detection to a statistically significant degree.

Specific to comparative sensitivity and specificity to FFDM, all thirteen papers illustrated noninferiority to 2D mammography when used as either a screening tool or in follow-up imaging studies. These studies showed sensitivities for breast tomosynthesis ranging from 76.2% to 100% compared with 64.1% to 97.5% for FFDM. Similarly specificity for BT ranged from 74.2 to 92% in these studies compared with a range of 51% to 83% for FFDM. In those studies which looked at recall rates studies identified a reduction in recall rates ranging from 17.2% to 37%.

There is a degree of heterogeneity that exists between the papers that make clear and concise inferences regarding how BT will be used in routine practice difficult. Some studies used a combined technique comparing BT + FFDM to FFDM alone; some were prospective where others were retrospective; some papers assessed BT as a triage tool after FFDM had been done; some used BT as a screening tool and others used it as a diagnostic test. Overall, however, the studies demonstrated that breast tomosynthesis improved identification of clinically relevant abnormalities and reduced un-necessary biopsies or further imaging.

Hunter et al (2017) reported on a retrospective data analysis that was performed between July 15, 2013, and July 14, 2014, with data on women presenting for screening mammography that included any additional radiologic workup (n = 6319). Patients chose to undergo Digital Breast Tomosynthesis (DBT) or FFDM on the basis of personal preference, physician suggestion, and cost difference. 6319 patients who participated were divided: 3655 patients underwent DBT, and 2664 underwent FFDM during the year of screening. After standardization of the difference in cancer detection rates between the two groups, DBT was a cost-equivalent alternative to FFDM for private insurance billing but was a cost-inefficient alternative with respect to Medicare costs. In a community-based setting, DBT is a cost-

equivalent or potentially cost-effective alternative to FFDM and has the capacity for improving cancer detection and recall rates.

Li et.al. (2018) evaluated reducing some of the limitations of digital mammography (DM), such as overlapping tissue, by adding digital breast tomosynthesis (DBT). Emerging evidence has shown that DBT increases breast cancer detection and improves assessment of screen-recalled findings. In conclusion, evidence on DBT for breast cancer screening reinforces that DBT integrated with DM increases cancer detection rates compared to DM alone.

The American Academy of Radiology's (ACR) 2014 statement on breast tomosynthesis announced that breast tomosynthesis has shown to be an advance over digital mammography, with higher cancer detection rates, fewer patient recalls for additional testing and improved key screening parameters compared to digital mammography.

The NCCN (National Comprehensive Cancer Network) guidelines for breast cancer screening and diagnosis (Version 1.2017) shows that digital breast tomosynthesis in conjunction with two-dimensional (2D) mammography improves cancer detection and decreases call back rates.

The 2019 American Society of Breast Surgeon's (ASBrS) Position Statement on Screening Mammography recommends that women age >25 should undergo formal risk assessment for breast cancer. Women with an average risk of breast cancer should initiate yearly screening mammography (3D preferred modality) at age 40. Women with a higher-than-average risk of breast cancer should undergo yearly screening mammography (3D preferred modality) and be offered yearly supplemental imaging; this screening should be initiated at a risk-based age and screening mammography should cease when life expectancy is <10 years.

A recent UpToDate article (2020, updated in 2023) evaluated the effectiveness and harms of screening for breast cancer. When compared with digital mammography, multiple retrospective cohort and prospective clinical trials suggest that tomosynthesis modestly increases rates of cancer detection and decreases recall rates for false-positive mammography readings. Digital breast tomosynthesis may detect more breast cancers in younger women and women with extremely dense breasts. In one meta-analysis, the incremental cancer detection rate was higher with tomosynthesis than with digital mammography screening alone, with an increase of 1.6 cancers detected per 1000 screens (95% CI 1.1-2.0). The recall rate for tomosynthesis was lower than for digital mammography alone (pooled absolute reduction -2.2, 95% CI -3.0 to -1.4). No studies have assessed the effects of tomosynthesis on breast cancer mortality. Two important clinical trials comparing screening digital mammography with tomosynthesis are ongoing: the Tomosynthesis Mammographic Imaging Screening Trial (TMIST) in North America and the Digital Breast Tomosynthesis plus Synthesized Images versus Standard Full-Field Digital Mammography in Population-Based Screening (TOSYMA) trial in Germany.

In conclusion, based upon the updated published evidence, breast tomosynthesis appears to be a tool that is non-inferior to FFDM, decreases recall rates, identifies a statistically significant and non-significant number of breast cancers unidentifiable in FFDM and has a better area under the curve statistic than does FFDM (GRADE 1B).

Applicable Coding

CPT Codes

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 Codes

G0279 Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

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