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, and Healthy U (Medicaid) plans. Refer to the “Policy” section for more information.

Description:
Breast cancer is the most common noncutaneous cancer in women. According to the American Society of Clinical Oncology (ASCO), in 2018 the United States is estimated to have 266,120 new cases of invasive breast cancer diagnosed in women and 2,550 cases in men. An additional prediction of 63,960 new cases of non-invasive (in situ) breast cancer in women. Of those new cases an estimated 41,400 deaths (40,920 women and 480 men) will occur.

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.

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.

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.

Policy Statement and Criteria

1. Commercial Plans

   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 http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

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.

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.

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.

A recent UpToDate article (2018) evaluated the effectiveness and harms of screening for breast cancer. In one retrospective study, comparing digital mammography alone (n=281,187) with digital mammography plus tomosynthesis (n=173,663) performed in two different periods, addition of tomosynthesis was associated with an increase in the positive predictive value for recall from 4.3 to 6.4
percent and for biopsy from 24.2 to 29.2 percent. Per 1000 screens, there were 16 fewer recalls (95% CI 18-14), and 1.2 more invasive cancers detected (95% CI 0.8-1.6) in patients who had an examination with tomosynthesis. Combined biennial tomosynthesis and mammography screening, compared with biennial mammography alone, in women aged 50 to 74 years with dense breasts was found likely to be cost-effective in a simulation model study. The addition of tomosynthesis to mammography increases radiation exposure and reading time, however, newer techniques will significantly decrease the radiation required for tomosynthesis. While studies have found little difference in cancer detection rates between digital and film mammography, digital mammography may detect more breast cancers in younger women and women with dense breasts, but is also associated with an increased rate of false-positive findings.

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.

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)

**References:**

4. American Society of Clinical Oncology (ASCO), Breast Cancer: Statistics (Jan 2018); Available at: https://www.cancer.net/cancer-types/breast-cancer/statistics.


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