Medical Coverage Policy

Effective Date...09/15/2019
Next Review Date....................................09/15/2020
Coverage Policy Number 0123

Screening Mammography

Table of Contents

Related Coverage Resources

Preventive Care Services

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses screening mammography including screening digital breast tomosynthesis.

Coverage Policy

An annual screening mammography* is considered medically necessary for ANY of the following indications:

- woman with a prior history of breast cancer
- woman age 40 and over
- woman age 25-39 when ANY of the following criteria are met:
  - ➢ history of prior high-dose thoracic irradiation (e.g., prior therapeutic radiation therapy)
  - ➢ a strong family history or genetic predisposition for breast cancer including ANY of the following:
    - o the individual has a known BRCA mutation
    - o a first-degree relative of BRCA carrier, but untested
    - o a five-year risk of invasive breast cancer ≥ 1.7% as determined by a risk assessment tool based upon the modified Gail model (e.g., National Cancer Institute risk assessment tool)
    - o a lifetime risk of breast cancer > 20% as determined by a risk assessment tool such as BRCAPRO (i.e., Duke model) or other model that is largely dependent on family history (e.g.,

BOADICEA [Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm], Gail, Claus, or Tyrer-Cusick model)
   o personal history of or a first-degree relative with Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome

*Digital breast tomosynthesis is considered a medically appropriate imaging option in the screening of breast cancer.

General Background

Mammography is a specific type of imaging that uses a low-dose x-ray system for examination of the breasts. In full-field digital mammography (FFDM or two-dimensional [2D] mammogram), x-rays are exposed to an electronic x-ray detector. Currently, more than 95 percent of mammography units in the United States are full-field digital (FFDM). A large body of literature validated its clinical benefits over film screen mammography. Digital mammography offers many other advantages, including rapid and reliable electronic storage and retrieval of images, easy image transfer to other facilities, and simplification of quality control. Computer-aided detection (CAD) and diagnosis involves the use of imaging software to identify suspicious areas on a mammogram for further radiologist review. Software programs for diagnosis are more complex than for detection, with the algorithms continuing to analyze the suspicious areas after detection. Digital breast tomosynthesis (DBT) (i.e., three-dimensional [3D] mammography) is a mammography system where the x-ray tube moves in an arc over the breast during the exposure. It creates a series of thin slices through the breast.

The goal of mammography is the detection, characterization, and evaluation of findings suggestive of breast cancer and other breast diseases. Annual screening mammography of age-appropriate asymptomatic women is currently the only imaging modality that has been proven to significantly reduce breast cancer mortality. A screening mammogram is an X-ray examination of the breast of an asymptomatic woman. A diagnostic mammogram is an x-ray examination of the breast of a patient with signs or symptoms of breast disease, a possible abnormality detected on screening mammography or other imaging, or who has prior mammography findings requiring imaging follow-up. The focus of this Coverage Policy is screening mammography.

Risks
Radiation: The effective radiation dose from a mammogram is about 0.7 mSv, which is similar to that which the average person receives from background radiation in three months. Total radiation dose when DBT is added is approximately 2 times the current digital mammography dose but remains below the limits defined by the FDA (Friedewald, et al 2014). The radiation dose can be minimized by synthetic 2D reconstruction (National Comprehensive Cancer Network [NCCN], 2019).

False-Positive 2D Mammograms: On average, 10% of women will be recalled from each screening examination for further testing, and only 5 of 100 women recalled will have cancer. Approximately 50% of women screened annually for 10 years in the United States will experience a false positive, of whom 7% to 17% will have biopsies. Additional testing is less likely when prior mammograms are available for comparison (National Cancer Institute, 2019).

U.S. Food and Drug Administration (FDA)
Mammographic x-ray systems are classified as Class II devices intended to produce radiographs of the breast. The FDA regulates the marketing of mammography devices and regulates the use of such devices via the Mammography Quality Standards Act (MQSA), which requires that all mammography facilities become accredited and certified to provide mammography services. In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its MQSA certificate extended to include that portion of the unit. The FDA has approved several computer-aided detection (CAD) systems (product code MYN) for evaluating 2D screening mammograms. FDA approval for CAD states that CAD is to be applied only after the interpreting radiologist has reviewed and interpreted all mammograms for a given patient and that the purpose of CAD is to minimize observational oversights by identifying and calling attention to regions of concern that warrant close attention, or a second look.

The first DBT system to be approved was Hologic's Selenia Dimensions DBT System (P080003) in February 2011. The Approval order statement read: Intended for use in the same clinical applications as 2D mammography systems for screening mammograms. Specifically, the Selenia dimensions system can be used to acquire 2D digital mammograms and 3D mammograms. The screening examination will consist of a 2D image set or a 2D and 3D image set. The Selenia dimensions system may also be used for additional diagnostic workup of the breast. In April 2017, the name was changed from the Selenia Dimensions name to 3Dimensions. In May 2017, the FDA granted PMA for a change to the Physician Labeling, to claim superior screening accuracy of 3D plus 2D imaging, where the 2D image can be either a synthesized 2D or a FFDM image, as compared to FFDM alone, for women with dense breasts.

Additional FDA-approved DBT systems may include (this list is not all inclusive):
- Siemen's Mammomat Inspiration with tomosynthesis option (P140011). In March 2017, the FDA approved this system as the first 3D stand alone system, stating a screening exam may consist of a 2D image set, 3D DBT image set and a 2D FFDM image set, or 3D DBT image set alone.
- Fujifilm Medical Systems' ASPIRE Cristalle digital breast tomosynthesis option (P160031)
- GE Healthcare's SenoClaire System/ Senographe Pristina 3D (P130020)
- PowerLook® Tomo Detection (from iCAD Inc., P160009) received PMA approval in March 2017. The computer-assisted detection (CAD) software device is intended to be used concurrently by radiologists while reading GE Senoclaire breast tomosynthesis exams. The system detects up to five soft tissue densities (masses, architectural distortions and asymmetries) in the 3D tomosynthesis images. The detections are blended with the standard 2D synthetic image and the CAD-enhanced 2D synthetic image is viewed on a mammography review workstation. The CAD-enhanced 2D synthetic image assists radiologists in identifying densities (masses, architectural distortions and asymmetries) that may be confirmed or dismissed by the radiologist in the DBT images.

Screening Mammography
Screening mammography is a radiological examination performed to detect unsuspected breast cancer in asymptomatic women. Mammography plays a central part in early detection of breast cancers because it can show changes in the breast up to two years before a patient or physician can feel them. Although research has shown that regular screening mammography may lead to early detection of breast cancers, there is mixed opinion among professional societies and organizations regarding the most beneficial age to begin screening average-risk women, as well the frequency of screening.

Digital Breast Tomosynthesis (DBT)/ 3D mammogram
DBT also called three-dimensional (3-D) mammography, 3D mammogram, or breast tomosynthesis is an advanced form of mammography that uses a low-dose x-ray system and computer reconstructions to create three-dimensional images of the breasts. 3D image sets help minimize the tissue overlap that may occur with 2D breast tissue compression that can hide cancers or make it difficult to distinguish normal overlapping breast tissue from tumors.

Large prospective and retrospective trials demonstrate the use of screening DBT (3D mammography) in addition to 2D screening mammography (i.e., 2D) when used for annual screening provides a statistically significant increase in cancer detection rates (including invasive cancers) and a statistically significant decrease in recall rates compared to 2D mammography alone. Although long term studies on survival are lacking, it is reasonable to postulate from large prospective and retrospective trials that the addition of DBT may confer a positive impact on mortality (Conant, et al., 2019; Ciatto, et al., 2013; Skaane, et al., 2013b; Skaane, et al., 2014; Friedewald, et al., 2014; Lång, et al., 2015; Conant, et al., 2016).

In a meta-analysis that compared the diagnostic value of DBT plus FFDM and FFDM, pooled estimates from 11 studies for the overall cancer detection rate were significantly higher in the DBT plus FFDM group than for FFDM alone. Pooled risk ratios showed a greater cancer detection for DBT plus FFDM than for FFDM alone for invasive cancer, stage T1, nodal-negative, all histologic grades, and histologic types of invasive cancer (ductal, lobular). Adding DBT did not increase for detection of carcinoma in situ, stage ≥T2, or nodal-positive cancer (Yun, et al., 2017).

Professional Societies/Organizations

American Cancer Society (ACS): The ACS Breast Cancer Screening for Women at Average Risk 2015 Guideline Update published the following recommendations*:

- Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years. (Strong Recommendation)
  - Women aged 45 to 54 years should be screened annually. (Qualified Recommendation)
  - Women ≥ 55 years and older should transition to biennial (every other year) screening or have the opportunity to continue screening annually. (Qualified Recommendation)
  - Women should have the opportunity to begin annual screening between the ages of 40 and 44 years. (Qualified Recommendation)
- Women should continue screening mammography as long as their overall health is good and they have a life expectancy of ≥ 10 years. (Qualified Recommendation)
- The ACS does not recommend clinical breast examination for breast cancer screening among average-risk women at any age. (Qualified Recommendation)

*A strong recommendation conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening. Qualified recommendations indicate there is clear evidence of benefit of screening but less certainty about the balance of benefits and harms, or about patients' values and preferences, which could lead to different decisions about screening.

Average-risk women are considered to be those women without a personal history of breast cancer, a confirmed or suspected genetic mutation known to increase risk of breast cancer (e.g., BRCA1 or 2, etc.), or a history of previous radiotherapy to the chest at a young age. An update of the ACS breast cancer screening guideline for women at higher than average risk (Saslow et al., 2007) is currently underway (Oeffinger, et al., 2015; Smith, et al., 2018).

The ACS does not have a published position on DBT. The ACS Breast Cancer Screening for Women at Average Risk 2015 Guideline Update (Oeffinger, et al., 2015) mentions DBT in the background, stating Accumulating data on digital breast tomosynthesis (DBT) appear to demonstrate further improvements in accuracy (both sensitivity and specificity), [citing Friedewald, et al., 2014] and DBT is steadily increasing in prevalence in mammography facilities. Smith et al. (2019) does not address tomosynthesis.

The 2003 ACS Recommendations for Early Breast Cancer Detection are as follows:

- Women age 40 and older should have a screening mammogram every year, and should continue to do so for as long as they are in good health.
- Women in their 20s and 30s should have a clinical breast exam (CBE) as part of a periodic (regular) health exam by a health professional preferably every 3 years. After age 40, women should have a breast exam by a health professional every year.
- BSE is an option for women starting in their 20s. Women should be told about the benefits and limitations of BSE. Women should report any breast changes to their health professional right away.
- Women at high risk (greater than 20% lifetime risk) should get an MRI (magnetic resonance imaging) and a mammogram every year. Women at high risk include those who:
  - have a known BRCA1 or BRCA2 gene mutation
  - have a first-degree relative (mother, father, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves
  - have a lifetime risk of breast cancer of 20%-25% or greater, according to risk assessment tools that are based mainly on family history
  - had radiation therapy to the chest when they were between the ages of 10 and 30 years
  - have a genetic disease such as Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have one of these syndromes in first-degree relatives
- Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%. Women at moderately increased risk include those who:

- have a lifetime risk of breast cancer of 15%-20%, according to risk assessment tools that are based mainly on family history
- have a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH)
- have extremely dense breasts or unevenly dense breasts when viewed by mammograms

- If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because while an MRI is a more sensitive test, it may still miss some cancers that a mammogram would detect.
- For most women at high risk, screening with MRI and mammograms should begin at age 30 years and continue for as long as a woman is in good health. But because the evidence is limited regarding the best age at which to start screening, this decision should be based on shared decision making between patients and their health care providers, taking into account personal circumstances and preferences.
- Several risk assessment tools, with names such as BRCAPRO, the Claus model, and the Tyrer-Cuzick model, are available to help health professionals estimate a woman's breast cancer risk. These tools give approximate, rather than precise, estimates of breast cancer risk based on different combinations of risk factors and different data sets. As a result, they may give different risk estimates for the same woman. Their results should be discussed by a woman and her doctor when being used to decide on whether to start MRI screening.
- It is recommended that women who get screening MRI do so at a facility that can do an MRI-guided breast biopsy at the same time if needed. Otherwise, the woman will have to have a second MRI exam at another facility at the time of biopsy.
- There is no evidence at this time that MRI will be an effective screening tool for women at average risk. While MRI is more sensitive than mammograms, it also has a higher false-positive rate (where the test finds things that turn out to not be cancer), which would result in unneeded biopsies and other tests in a large portion of these women (Smith, et al., 2003; Saslow, et al., 2007).

American Congress/College of Obstetricians and Gynecologists (ACOG): The ACOG Practice Bulletin (Number 179, July 2017, Reaffirmed 2019) on Breast Cancer Risk Assessment and Screening in Average Risk Women, includes a Summary of Recommendations:

- Recommendations based on good and consistent scientific evidence (Level A):
  - Women at average risk of breast cancer should be offered screening mammography starting at age 40 years. Women at average risk of breast cancer should initiate screening mammography no earlier than age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years. The decision about the age to begin mammography screening should be made through a shared decision-making process. This discussion should include information about the potential benefits and harms.
  - Women at average risk of breast cancer should have screening mammography every 1 or 2 years based on an informed, shared decision-making process that includes a discussion of the benefits and harms of annual and biennial screening and incorporates patient values and preferences. Biennial screening mammography, particularly after age 55 years, is a reasonable option to reduce the frequency of harms, as long as patient counseling includes a discussion that with decreased screening comes some reduction in benefits.
  - Women at average risk of breast cancer should continue screening mammography until at least age 75 years.
- Recommendations based on limited or inconsistent scientific evidence (Level B):
  - Health care providers periodically should assess breast cancer risk by reviewing the patient's history.
  - Women with a potentially increased risk of breast cancer based on initial history should have further risk assessment.
  - Breast self-examination is not recommended in average-risk women because there is a risk of harm from false-positive test results and a lack of evidence of benefit.
- Recommendations based primarily on consensus and expert opinion (Level C):
  - Screening clinical breast examination may be offered to asymptomatic, average-risk women in the context of an informed, shared decision-making approach that recognizes the uncertainty of additional benefits and the possibility of adverse consequences of clinical breast examination

beyond screening mammography. If performed for screening, intervals of every 1–3 years for women aged 25–39 years and annually for women aged 40 years and older are reasonable. The clinical breast examination continues to be a recommended part of evaluation of high-risk women and women with symptoms.

➢ Average-risk women should be counseled about breast self-awareness and encouraged to notify their health care provider if they experience a change. Breast self-awareness is defined as a woman's awareness of the normal appearance and feel of her breasts.

➢ Age alone should not be the basis to continue or discontinue screening. Beyond age 75 years, the decision to discontinue screening mammography should be based on a shared decision making process informed by the woman's health status and longevity.

The ACOG issued a Committee Opinion on the Management of Women With Dense Breasts Diagnosed by Mammography (April 2014, Reaffirmed 2019.) stating "Women with dense breasts have a modestly increased risk of breast cancer and experience reduced sensitivity of mammography to detect breast cancer. However, evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes. Currently, screening mammography remains the most useful tool for breast cancer detection and has consistently demonstrated a reduction in breast cancer mortality. The American College of Obstetricians and Gynecologists does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors. The American College of Obstetricians and Gynecologists recommends that health care providers comply with state laws that may require disclosure to women of their breast density as recorded in a mammogram report."

ACOG Technology Assessment Digital Breast Tomosynthesis (June 2013, Reaffirmed 2018) states "Mammography has been the primary screening test for early breast cancer for more than five decades, but conventional mammography imaging continues to have limitations in sensitivity and specificity. Digital mammography detects some cases of cancer that are not identified by film mammography, but overall detection is similar for many women. Digital breast tomosynthesis offers the potential to overcome one of the primary limitations of mammography, which is the inability to image overlapping dense normal breast tissue. Clinical data suggest that digital mammography with tomosynthesis produces a better image, improved accuracy, and lower recall rates compared with digital mammography alone. Further study will be necessary to confirm whether digital mammography with tomosynthesis is a cost-effective approach, capable of replacing digital mammography alone as the first-line screening modality of choice for breast cancer screening."

American College of Radiology (ACR): The ACR Position Statement on Breast Cancer Screening in Women at Higher-Than-Average Risk (Monticciolo, et al., 2018) states these 'Take-home Points' related to mammography:

- For women with genetics-based increased risk (and their untested first-degree relatives) or with a calculated lifetime risk of 20% or more, digital mammography (DM), with or without digital breast tomosynthesis (DBT), should be performed annually beginning at age 30.
- For women with histories of chest radiation therapy before the age of 30, DM, with or without DBT, should be performed annually beginning at age 25 or 8 years after radiation therapy, whichever is later.
- All women, especially black women and those of Ashkenazi Jewish descent, should be evaluated for breast cancer risk no later than age 30, so that those at higher risk can be identified and can benefit from supplemental screening.

The ACR Position Statement on Breast Cancer Screening for Average-Risk Women (Monticciolo, et al., 2017) states these 'Take-home Points':

- Regular mammographic screening results in a substantial reduction in breast cancer mortality across multiple study designs.
- The ACR recommends annual mammographic screening beginning at age 40 for women at average risk for developing breast cancer.
- The age to stop screening should be based on each woman's health status rather than an age-based determination.

- These ACR recommendations allow women to obtain the maximum life-extending benefits and provide improved treatment options for those diagnosed with breast cancer.
- Women should be helped to understand the risks of screening; weighing benefits and risks should be done by women, not for women.
- Overdiagnosis should not be factor in deciding when to start screening or what screening interval to choose.

The ACR Practice Guideline for the performance of screening and diagnostic mammography (2018) notes that along with x-ray mammography, digital breast tomosynthesis (DBT) may also be used in screening and/or diagnostic settings. DBT decreases the masking effect of superimposed normal tissue, allowing greater sensitivity and specificity to be attained. The Practice Guideline document collectively refers to analog mammography, full-field digital mammography, and DBT as "mammography".

American Society of Breast Surgeons (ASBS): The ASBS Position Statement on Screening Mammography. (May 3, 2019) states:

1. Women age >25 should undergo formal risk assessment for breast cancer.
2. Women with an average risk of breast cancer should initiate yearly screening mammography at age 40.
3. Women with a higher-than-average risk of breast cancer should undergo yearly screening mammography and be offered yearly supplemental imaging; this screening should be initiated at a risk-based age.
4. Screening mammography should cease when life expectancy is <10 years.

National Cancer Institute (NCI): The Breast Cancer Risk Assessment Tool is an interactive tool based on the modified Gail model, designed for use by health professionals and is available online at the National Cancer Institute.

National Comprehensive Cancer Network® (NCCN®): The NCCN Breast Cancer Screening and Diagnosis Guideline (1.2019 – May 17, 2019) notes in algorithms on page 7, 8, and 9: Average risk, age ≥ 40 years – annual screening mammogram (cat 1) Consider tomosynthesis with a footnote that states tomosynthesis can decrease call back rates and improve cancer detection but has not been sufficiently studied to determine if it improves disease-specific mortality. NCCN 2019 states under Breast Screening Considerations, that multiple studies show tomosynthesis can decrease call back rates and improve cancer detection. Of note, most studies used double the dose of radiation. The NCCN goes on to note that synthetic 2D reconstruction can minimize radiation doses. The NCCN provides additional recommendations for women at various risk levels/risk populations.

The NCCN Breast Cancer guideline (2.2019) recommends an annual diagnostic mammography for surveillance after breast cancer including but not limited to lobular carcinoma in situ, ducal carcinoma in situ and invasive breast cancer (Grade 2A/2B recommendations). This may include the affected and contralateral breast in a person with a history of breast cancer. NCCN states that studies indicate annual mammograms are the appropriate frequency for surveillance of breast cancer patients who have had breast-conserving surgery and radiation therapy with no clear advantage to shorter interval imaging.

U.S. Preventive Services Task Force (USPSTF): The USPSTF 2016 Breast Cancer Screening Recommendation Summary states:
- Women ages 50 to 74 years (Grade B)
  The USPSTF recommends biennial (every other year) screening mammography for women ages 50 to 74 years.
- Women ages 40 to 49 years (Grade C)
  The decision to start screening mammography in women prior to age 50 years should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin biennial (every other year) screening between the ages of 40 and 49 years.
- For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 years. Of all of the age groups, women aged 60 to 69 years are most likely to avoid breast cancer death through mammography screening. While screening

mammography in women aged 40 to 49 years may reduce the risk for breast cancer death, the number of deaths averted is smaller than that in older women and the number of false-positive results and unnecessary biopsies is larger. The balance of benefits and harms is likely to improve as women move from their early to late 40s.

- In addition to false-positive results and unnecessary biopsies, all women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to their health, or even apparent, during their lifetime (known as "overdiagnosis"). Beginning mammography screening at a younger age and screening more frequently may increase the risk for overdiagnosis and subsequent overtreatment.
- Women with a parent, sibling, or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average-risk women from beginning screening in their 40s.
- Women age 75 years and older
  The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women age 75 years and older.
- Women with dense breasts
  The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.
- The USPSTF 2016 Breast Cancer Screening Recommendation Summary concludes that the current evidence is insufficient to assess the benefits and harms of digital breast tomosynthesis (DBT) as a primary screening method for breast cancer (Grade Insufficient).

In December 2009, the USPSTF recommendations were updated as follows:
- Women, Age 50-74 Years (Grade B)
  The USPSTF recommends biennial screening mammography for women 50-74 years.
- Women, Before the Age of 50 Years (Grade C)
  The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
- All Women (Grade D)
  The USPSTF recommends against teaching breast self-examination (BSE).
- Women, 75 Years and Older
  The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of screening mammography in women 75 years and older.
- Women, 40 Years and Older
  The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older.
- All Women
  The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer.

In 2002, the USPSTF Breast Cancer Screening recommendations were as follows:
- Women, 40 and Older (Grade B)
  The U.S. Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older.
- All Women
  The USPSTF concludes that the evidence is insufficient to recommend for or against routine CBE alone to screen for breast cancer.
  The USPSTF concludes that the evidence is insufficient to recommend for or against teaching or performing routine breast self-examination (BSE).

Technology Assessments

Hayes, Inc. evaluated Digital Breast Tomosynthesis for Breast Cancer Diagnosis and Screening (October 24, 2017) and concluded:

- C rating for use of digital breast tomosynthesis (DBT) alone or combined with conventional digital mammography (DM) for breast imaging in women with suspected or known breast cancer. This Rating reflects low-quality evidence of improved accuracy for DBT alone or DBT plus DM versus DM alone and preliminary evidence from 2 studies that DBT plus DM has similar or lower accuracy than ultrasonography (US) alone or US plus DM. This Rating also reflects a lack of evidence on the clinical utility of DBT for breast cancer diagnosis and the concerns that adjunct DBT approximately doubles radiation dosage.
- C rating for use of DBT combined with conventional DM for routine breast cancer screening in asymptomatic women. This Rating reflects low-quality evidence suggesting apparent benefits, such as increased cancer detection and reduced recall rate, associated with the addition of DBT but a lack of evidence concerning the influence of DBT plus DM on treatment decision making and health outcomes, particularly breast cancer mortality.
- D2 rating for use of DBT as a replacement for DM for breast cancer screening. This Rating reflects insufficient evidence to draw any conclusions regarding DBT alone as an alternative to DM for breast cancer screening.

Annual review dated Nov 14, 2018 did not change existing ratings.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative (2019)
The Choosing Wisely initiative includes the following recommendations:

- American Society of Breast Surgeons – Benign Breast Disease (January 8, 2018): Don't perform screening mammography in asymptomatic patients with normal exams who have less than 5-year life expectancy.

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determinations (NCDs): Mammograms (220.4) (1978) appears broader in scope.
- Local Coverage Determinations (LCDs): L36342 Screening and Diagnostic Mammography (First Coast Service Options, Inc.) (July 1, 2019) appears broader in scope.

Use Outside of the US
A position paper on Screening for Breast Cancer by the European Society of Breast Imaging (EUSOBI) and breast radiology bodies from 30 countries was published (Sardanelli, et al., 2017). Key findings included:

- EUSOBI and 30 national breast radiology bodies support screening mammography.
- A first priority is double-reading biennial mammography for women aged 50–69 years.
- Extension to 73–75 and from 40–45 to 49 years is also encouraged.
- Digital mammography (not film-screen or computer radiography) should be used.
- DBT is set to become "routine mammography" in the screening setting in the near future.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	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

*Current Procedural Terminology (CPT®) ©2018 American Medical Association: Chicago, IL.

References

1. American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative. Accessed August 2019. Available at URL address: http://www.choosingwisely.org/clinician-lists/

2. American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion 625: Management of Women With Dense Breasts Diagnosed by Mammography. March 2015. Reaffirmed 2019. Accessed August 2019. Available at URL address: https://www.acog.org/-/media/List-of-Titles/COListOfTitles.pdf

3. American College of Obstetricians and Gynecologists (ACOG). Digital Breast Tomosynthesis. Technology Assessment No. 9. American College of Obstetricians and Gynecologists. June 2013. Reaffirmed 2018. Accessed August 2019. Available at URL address: https://www.acog.org/-/media/List-of-Titles/COListOfTitles.pdf

4. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 179 Summary: Breast Cancer Risk Assessment and Screening in Average-Risk Women. Obstet Gynecol. 2017 Jul;130(1):241-243.. Reaffirmed 2019. Accessed August 2019. Available at URL address: https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Breast-Cancer-Risk-Assessment-and-Screening-in-Average-Risk-Women?IsMobileSet=false https://www.acog.org/Resources-And-Publications/Practice-Bulletins-List https://www.acog.org/Womens-Health/Breast-Cancer-Screening

5. American College of Radiology (ACR) Position Statements. Accessed August 2019. Available at URL address: https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements (Monticciolo, et al., 2018; Monticciolo, et al., 2017)

6. American College of Radiology (ACR) Practice Guideline for the performance of screening and diagnostic mammography. 2018. Accessed August 2019. Available at URL https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards/Practice-Parameters-by-Organ-or-Body-System

7. American Society of Breast Surgeons. Position Statement on Screening Mammography. May 3, 2019. Accessed August 2019. Available at URL address: https://www.breastsurgeons.org/resources/statements

8. Bargalló X, Santamaría G, Del Amo M, Arguis P, Ríos J, Grau J, et al. Single reading with computer-aided detection performed by selected radiologists in a breast cancer screening program. Eur J Radiol. 2014 Nov;83(11):2019-23.

9. Bernardi D, Macaskill P, Pellegrini M, Valentini M, Fantò C, Ostillio L et al. Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study. Lancet Oncol. 2016 Aug;17(8):1105-13.

10. Birdwell RL, Bandodkar P, Ikeda DM. Computer-aided detection with screening mammography in a university hospital setting. Radiology. 2005 Aug;236(2):451-7.

11. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Mammograms (220.4). 5/15/1978. Accessed August 2019. Available at URL address: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=186&ncdver=1&bc=AAAAQAAAAAAA&

12. Centers for Medicare & Medicaid Services. Medicare Preventive Services. ICN MLN006559 June 2019. Accessed August 2019. Available at URL address:
https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html
https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#MAMMO

13. Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, et al. Integration of DBT digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. Lancet Oncol. 2013 Jun;14(7):583-9.

14. Conant EF, Barlow WE, Population-based Research Optimizing Screening Through Personalized Regimen (PROSPR) Consortium, et al. Association of Digital Breast Tomosynthesis vs Digital Mammography With Cancer Detection and Recall Rates by Age and Breast Density. JAMA Oncol. 2019 May 1;5(5):635-642.

15. Conant EF, Beaber EF, Sprague BL, Herschorn SD, Weaver DL, Onega T, et al. Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: a cohort study within the PROSPR consortium. Breast Cancer Res Treat. 2016 Feb;156(1):109-16.

16. Cupples TE, Cunningham JE, Reynolds JC. Impact of computer-aided detection in a regional screening mammography program. AJR Am J Roentgenol. 2005 Oct;185(4):944-50.

17. Dang PA, Freer PE, Humphrey KL, Halpern EF, Rafferty EA. Addition of tomosynthesis to conventional digital mammography: effect on image interpretation time of screening examinations. Radiology. 2014 Jan;270(1):49-56.

18. Destounis S, Arieno A, Morgan R. Initial experience with combination digital breast tomosynthesis plus full field digital mammography or full field digital mammography alone in the screening environment. J Clin Imaging Sci. 2014 Feb 25;4:9.

19. Durand MA, Haas BM, Yao X, Geisel JL, Raghu M, et al. Early Clinical Experience with Digital Breast Tomosynthesis for Screening Mammography. Radiology. 2015 Jan;274(1):85-92.

20. Elizalde A, Pina L, Etxano J, Slon P, Zalazar R, Caballeros M. Additional US or DBT after digital mammography: which one is the best combination? Acta Radiol. 2016 Jan;57(1):13-8.

21. Fenton JJ, Taplin SH, Carney PA, Abraham L, Sickles EA, D'Orsi C, et al. Influence of computer-aided detection on performance of screening mammography. N Engl J Med. 2007 Apr 5;356(14):1399-409.

22. Fenton JJ, Xing G, Elmore JG, Bang H, Chen SL, Lindfors KK, et al. Short-term outcomes of screening mammography using computer-aided detection: a population-based study of medicare enrollees. Ann Intern Med. 2013 Apr 16;158(8):580-7.

23. Freer TW, Ulissey MJ. Screening mammography with computer-aided detection: prospective study of 12,860 patients in a community breast center. Radiology. 2001 Sep;220(3):781-6.

24. Friedewald SM, Rafferty EA, Rose SL, Durand MA, Plecha DM, Greenberg JS, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. JAMA. 2014;311(24):2499-2507.

25. Georgian-Smith D, Moore RH, Halpern E, Yeh ED, Rafferty EA, D'Alessandro HA, et al. Blinded comparison of computer-aided detection with human second reading in screening mammography. AJR Am J Roentgenol. 2007 Nov;189(5):1135-41.

26. Gilbert FJ, Astley SM, Gillan MG, Agbaje OF, Wallis MG, CADET II Group, et al. Single reading with computer-aided detection for screening mammography. N Engl J Med. 2008 Oct 16;359(16):1675-84

27. Greenberg JS, Javitt MC, Katzen J, Michael S, Holland AE. Clinical performance metrics of DBT digital breast tomosynthesis compared with 2D digital mammography for breast cancer screening in community practice. AJR Am J Roentgenol. 2014 Sep;203(3):687-93.

28. Gromet M. Comparison of computer-aided detection to double reading of screening mammograms: review of 231,221 mammograms. AJR Am J Roentgenol. 2008 Apr;190(4):854-9.

29. Gur D, Sumkin JH, Rockette HE, Ganott M, Hakim C, Hardesty L, et al. Changes in breast cancer detection and mammography recall rates after the introduction of a computer-aided detection system. J Natl Cancer Inst. 2004 Feb 4;96(3):185-90.

30. Haas BM, Kalra V, Geisel J, Raghu M, Durand M, Philpotts LE. Comparison of Tomosynthesis Plus Digital Mammography and Digital Mammography Alone for Breast Cancer Screening. Radiology. 2013 Dec;269(3):694-700.

31. Hayes Inc. Hayes Medical Technology Directory. Digital Breast Tomosynthesis for Breast Cancer Diagnosis or Screening. Lansdale, PA: Hayes, Inc. Published October 24, 2017. Annual Review Nov 14, 2018.

32. Houssami N, Bernardi D, Pellegrini M, Valentini M, Fantò C, Ostillio L, et al. Breast cancer detection using single-reading of breast tomosynthesis (3D-mammography) compared to double-reading of 2D-mammography: Evidence from a population-based trial. Cancer Epidemiol. 2017 Apr;47:94-99.

33. Jørgensen KJ, Gøtzsche PC, Kalager M, Zahl PH. Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Overdiagnosis. Ann Intern Med. 2017 Mar 7;166(5):313-323.

34. Khoo LA, Taylor P, Given-Wilson RM. Computer-aided detection in the United Kingdom National Breast Screening Programme: prospective study. Radiology. 2005 Nov;237(2):444-9.

35. Ko JM, Nicholas MJ, Mendel JB, Slanetz PJ. Prospective assessment of computer-aided detection in interpretation of screening mammography. AJR Am J Roentgenol. 2006 Dec;187(6):1483-91.

36. Lee CH, Dershaw DD, Kopans D, Evans P, Monsees B, Monticciolo D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. J Am Coll Radiol. 2010 Jan;7(1):18-27.

37. Lehman CD, Wellman RD, Buist DS, Kerlikowske K, Tosteson AN, Breast Cancer Surveillance Consortium, et al. Diagnostic Accuracy of Digital Screening Mammography With and Without Computer-Aided Detection. JAMA Intern Med. 2015 Nov;175(11):1828-37.

38. Lehman CD, Arao RF, Sprague BL, Lee JM, Buist DS, Kerlikowske K, et al. National Performance Benchmarks for Modern Screening Digital Mammography: Update from the Breast Cancer Surveillance Consortium. Radiology. 2017 Apr;283(1):49-58

39. Lei J, Yang P, Zhang L, Wang Y, Yang K. Diagnostic accuracy of digital breast tomosynthesis versus digital mammography for benign and malignant lesions in breasts: a meta-analysis. Eur Radiol. 2014 Mar;24(3):595-602.

40. Lourenco AP, Barry-Brooks M, Baird GL, Tuttle A, Mainiero MB. Changes in recall type and patient treatment following implementation of screening digital breast tomosynthesis. Radiology. 2015 Feb;274(2):337-42.

41. Margolies L, Cohen A, Sonnenblick E, Mandeli J, Schmidt PH, Szabo J, et al. Digital breast tomosynthesis changes management in patients seen at a tertiary care breast center. ISRN Radiol. 2014 Mar 3;2014:658929.

42. McCarthy AM, Kontos D, Synnestvedt M, Tan KS, Heitjan DF, Schnall M, et al. Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program. J Natl Cancer Inst. 2014 Oct 13;106(11).

43. Michell MJ, Iqbal A, Wasan RK, Evans DR, Peacock C, Lawinski CP, et al. A comparison of the accuracy of film-screen mammography, full-field digital mammography, and digital breast tomosynthesis. Clin Radiol. 2012 Oct;67(10):976-81.

44. Moss SM, Cuckle H, Evans A, Johns L, Waller M, Bobrow L; Trial Management Group. Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial. Lancet. 2006 Dec 9;368(9552):2053-60.

45. Miller AB, Wall C, Baines CJ, Sun P, To T, Narod SA. Twenty five year follow-up for breast cancer incidence and mortality of the Canadian National Breast Screening Study: randomised screening trial. BMJ. 2014 Feb 11;348:g366.

46. Monticciolo DL, Newell MS, Moy L, Niell B, Monsees B, Sickles EA. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. J Am Coll Radiol. 2018 Mar;15(3 Pt A):408-414.

47. Monticciolo DL, Newell MS, Hendrick RE, Helvie MA, Moy L, et al. Breast Cancer Screening for Average-Risk Women: Recommendations From the ACR Commission on Breast Imaging. J Am Coll Radiol. 2017 Sep;14(9):1137-1143

48. Myers ER, Moorman P, Gierisch JM, Havrilesky LJ, Grimm LJ, Ghate S, et al. Benefits and Harms of Breast Cancer Screening: A Systematic Review. JAMA. 2015;314(15):1615-1634.

49. National Cancer Institute. The Breast Cancer Risk Assessment Tool. Accessed August 2019. Available at URL address: https://bcrisktool.cancer.gov/

50. National Cancer Institute. Breast Cancer Screening–for health professionals (PDQ®). Updated: August 2, 2019. Accessed August 2019. Available at URL address: https://www.cancer.gov/types/breast/hp/breast-screening-pdq

51. National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology™. Breast cancer. V.2.2019 – July 2, 2019. Accessed August 2019. Available at URL address: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp?button=I+Agree#site

52. National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology™. Breast cancer screening and diagnosis guidelines v.1.2019 – May 17, 2019. Accessed August 2019. Available at URL address: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp?button=I+Agree#site

53. Noble M, Bruening W, Uhl S, Schoelles K. Computer-aided detection mammography for breast cancer screening: systematic review and meta-analysis. Arch Gynecol Obstet. 2009 Jun;279(6):881-90. Epub 2008 Nov 21.

54. Oeffinger KC, Fontham EH, Etzioni R, Herzig A, Michaelson JS, PhD; Shih YT, et al. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. JAMA. 2015;314(15):1599-1614.

55. Pisano E, Gatsonis C, Hendrick E, Yaffe M, Baum J, Acharyya S, Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group, et al. Diagnostic Performance of Digital versus Film

Mammography for Breast-Cancer Screening. N Engl J Med 2005;353. Erratum in: N Engl J Med. 2006 Oct 26;355(17):1840.

56. Pisano ED, Hendrick RE, Yaffe MJ, Baum JK, Acharyya S, DMIST Investigators Group. Diagnostic accuracy of digital versus film mammography: exploratory analysis of selected population subgroups in DMIST. Radiology. 2008 Feb;246(2):376-83.

57. Posso M, Puig T, Carles M, Rué M, Canelo-Aybar C, et al. Effectiveness and cost-effectiveness of double reading in digital mammography screening: A systematic review and meta-analysis. Eur J Radiol. 2017 Nov;96:40-49.

58. Rafferty EA, Park JM, Philpotts LE, Poplack SP, Sumkin JH, Halpern EF, et al. Assessing radiologist performance using combined digital mammography and breast tomosynthesis compared with digital mammography alone: results of a multicenter, multireader trial. Radiology. 2013 Jan;266(1):104-13

59. Rafferty EA, Park JM, Philpotts LE, Poplack SP, Sumkin JH, Halpern EF, et al. Diagnostic accuracy and recall rates for digital mammography and digital mammography combined with one-view and two-view tomosynthesis: results of an enriched reader study. AJR Am J Roentgenol. 2014 Feb;202(2):273-81.

60. Rafferty EA, Rose SL, Miller DP, Durand MA, Conant EF, Copit DS, Friedewald SM, et al. Effect of age on breast cancer screening using tomosynthesis in combination with digital mammography. Breast Cancer Res Treat. 2017 Aug;164(3):659-666.

61. Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R Jr. Implementation of breast tomosynthesis in a routine screening practice: an observational study. AJR Am J Roentgenol. 2013 Jun;200(6):1401-8.

62. Rose SL, Tidwell AL, Ice MF, Nordmann AS, Sexton R Jr, Song R. A reader study comparing prospective tomosynthesis interpretations with retrospective readings of the corresponding FFDM examinations. Acad Radiol. 2014 Sep;21(9):1204-10.

63. Sardanelli F, Aase HS, Álvarez M, Azavedo E, Baarslag HJ, Balleyguier C, et al. Position paper on screening for breast cancer by the European Society of Breast Imaging (EUSOBI) and 30 national breast radiology bodies from Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Israel, Lithuania, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland and Turkey. Eur Radiol. 2017 Jul;27(7):2737-2743.

64. Saslow D, Boetes C, Burke W, Harms S, Leach MO, American Cancer Society Breast Cancer Advisory Group et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. CA Cancer J Clin. 2007 Mar-Apr;57(2):75-89. Erratum in: CA Cancer J Clin. 2007 May-Jun;57(3):185.

65. Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, et al. Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. Radiology. 2013a Apr;267(1):47-56.

66. Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, et al. Prospective trial comparing full-field digital mammography (FFDM) versus combined FFDM and tomosynthesis in a population-based screening programme using independent double reading with arbitration. Eur Radiol. 2013b Aug;23(8):2061-71.

67. Skaane P, Bandos AI, Eben EB, Jebsen IN, Krager M, Haakenaasen U, et al. Two-view digital breast tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images. Radiology. 2014 Jun;271(3):655-63

68. Skaane P, Kshirsagar A, Stapleton S, Young K, Castellino RA. Effect of computer-aided detection on independent double reading of paired screen-film and full-field digital screening mammograms. AJR Am J Roentgenol. 2007(b) Feb;188(2):377-84.

69. Smith RA, Andrews KS, Brooks D, Fedewa SA, Manassaram-Baptiste D, Saslow D, et al. Cancer screening in the United States, 2019: A review of current American Cancer Society guidelines and current issues in cancer screening. CA Cancer J Clin. 2019 May;69(3):184-210.

70. Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP et al. American Cancer Society guidelines for breast cancer screening: update 2003. CA Cancer J Clin. 2003 May-Jun;53(3):141-69.

71. Sharpe RE Jr, Venkataraman S, Phillips J, Dialani V, Fein-Zachary VJ, et al. Increased Cancer Detection Rate and Variations in the Recall Rate Resulting from Implementation of DBT Digital Breast Tomosynthesis into a Population-based Screening Program. Radiology. 2016 Mar;278(3):698-706.

72. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health. PMA approvals. Accessed August 2019. Available at URL address:
Hologic's Selenia Dimensions DBT System (P080003). February 2011.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p080003
Siemen's Mammomat Inspiration with tomosynthesis option (P140011).
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140011
Fujifilm Medical Systems' ASPIRE Cristalle digital breast tomosynthesis option (P160031).
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p160031
GE Healthcare's SenoClaire System/ Senographe Pristina 3D (P130020).
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130020
iCAD, Inc. PowerLook® Tomo Detection (P160009). March 2017.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p160009

73. U.S. Food and Drug Administration (FDA). For Consumers. Mammography. Page Last Updated 11/16/2018 Accessed August 201. Available at URL address: https://www.fda.gov/consumers/womens-health-topics/mammography

74. U.S. Food and Drug Administration (FDA). For Consumers. Mammography: What You Need to Know. Updated 03/27/2019. Accessed August 2019. Available at URL address: https://www.fda.gov/forconsumers/consumerupdates/ucm420463.htm

75. U.S. Preventive Services Task Force (USPSTF). Screening for breast cancer recommendation statement. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); Release Date: January 2016. Accessed August 2019. Available at URL: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1

76. Yi M, Hunt KK. Optimizing Mammography Screening Intervals. JAMA. 2015;314(15):1635-1636.

77. Yun SJ, Ryu CW, Rhee SJ, Ryu JK, Oh JY. Benefit of adding digital breast tomosynthesis to digital mammography for breast cancer screening focused on cancer characteristics: a meta-analysis. Breast Cancer Res Treat. 2017 Aug;164(3):557-569.