INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. 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. Proprietary information of Cigna. Copyright ©2015 Cigna

Coverage Policy

Cigna covers an annual screening mammography as 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:
    - the individual has a known BRCA mutation
    - a first-degree relative of BRCA carrier, but untested
    - 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)
    - 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)
    - personal history of or a first-degree relative with Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome

Cigna does not cover digital breast tomosynthesis (DBT) (i.e., three-dimensional [3D]) for screening either as standalone testing or as an adjunct to screening mammography because it is considered experimental, investigational or unproven.
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. 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 3D 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], 2015). Ongoing studies are evaluating if 3D, alone, with standard 2D mammography or with synthesized 2D mammography, will replace standard 2D mammography.

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 (National Cancer Institute, 2015).

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. The FDA has granted pre-market approval to several digital mammography systems (product code MUE) for breast cancer screening and diagnosis. Also, the FDA has approved several computer-aided detection (CAD) systems (product code MYN) for evaluating 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.

In February 2011, the FDA approved Selenia Dimensions 3D System (Hologic, Inc.; Bedford, MA). This device is indicated to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as 2D mammography systems for screening mammograms. The Selenia dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of: a 2D FFDM image set; or a 2D and 3D image set, where the 2D image can be either a FFDM or a 2D image generated from the 3D image set. The Selenia dimensions system may also be used for additional diagnostic workup of the breast. Hologic’s C-View software, which is also FDA-approved, generates the FFDM image set from the 3D image set, eliminating the need for conventional 2D images. This reduces the dose to the same level as the conventional FFDM. Other approved systems include SenoClaire System (GE Healthcare) and Mammomat Inspiration with Tomosynthesis (Siemens Medical Solutions USA Inc.)
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. Research has shown that annual mammograms lead to early detection of breast cancers, when they are most curable and breast-conservation therapies are available. The American Cancer Society (ACS), American College of Radiology (ACR), American College of Obstetricians and Gynecologists (ACOG), and NCCN recommend annual screening mammography for women age 40 and older. Research has shown that annual mammograms lead to early detection of breast cancers, when they are most curable and breast-conservation therapies are available.

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

1. Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years. (Strong Recommendation)
1a. Women aged 45 to 54 years should be screened annually. (Qualified Recommendation)
1b. Women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. (Qualified Recommendation)
1c. Women should have the opportunity to begin annual screening between the ages of 40 and 44 years. (Qualified Recommendation)

2. Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer. (Qualified Recommendation)

3. 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.

These recommendations represent guidance from the ACS for women at average risk of breast cancer: women without a personal history of breast cancer, a suspected or confirmed genetic mutation known to increase risk of breast cancer (eg, BRCA), or a history of previous radiotherapy to the chest at a young age. The ACS recommends that all women should become familiar with the potential benefits, limitations, and harms associated with breast cancer screening (Oeffinger, et al., 2015).

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).

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 Guidelines (v.1.2015) recommends annual screening for average risk women age 40 years and older. The NCCN provides additional recommendations for women at various risk levels/risk populations.

U.S. Preventive Services Task Force (USPSTF): The USPSTF 2015 Draft Breast Cancer Screening Recommendation Summary is proposed:

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 screening between the ages of 40 and 49 years.
  - For women at average risk for breast cancer, most of the benefit of mammography will result from biennial screening during ages 50 to 74 years. Of all age groups, women ages 60 to 69 years are most likely to avoid a breast cancer death through mammography screening. Screening mammography in women ages 40 to 49 years may reduce the risk of dying of breast cancer, but the number of deaths averted is much smaller than in older women and the number of false-positive tests and unnecessary biopsies are larger.
  - 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 her health, or even apparent, during her lifetime (known as “overdiagnosis”). This risk is predicted to be increased when beginning regular mammography before age 50 years. 
- Women with a parent, sibling, or child with breast cancer may benefit more than average-risk women from beginning screening between the ages of 40 and 49 years.

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.

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).

Surveillance
The NCCN Breast Cancer guideline (3.2015) recommends an annual diagnostic mammography for surveillance after breast cancer including but not limited to lobular carcinoma in situ, ductal carcinoma in situ and invasive breast cancer (Grade 2A recommendation). This may include the affected and contralateral breast in a person with a history of breast cancer.

Computer-Aided Detection (CAD)
Computer-aided detection (CAD) systems use a digitized mammographic image that can be obtained from either a conventional film mammogram or a digitally acquired mammogram. The computer software then searches for abnormal areas of density, mass, or calcification that may indicate the presence of cancer. CAD is
used as an adjunct to the radiologists’ interpretation. This technology was originally FDA-approved in 1998, and has since become widely used in the United States and is consistent with standard of care (Bargalló, et al., 2014; Noble, et al., 2009; Gilbert, at al., 2008; Ko, et al., 2006; Cupples, et al., 2005; Birdwell, et al., 2005; Khoo, et al., 2005; Freer, et al., 2001).

American Cancer Society (ACS): The ACS breast cancer screening guidelines (Smith, et al., 2003) state that for digital mammography and CAD there is “some clinical evidence for effectiveness or equivalence to screen-film mammography for screening” (Rating B).

Digital Breast Tomosynthesis (DBT)
Large prospective and retrospective trials demonstrate the use of screening digital breast tomosynthesis (DBT) or 3D screening mammography (i.e., 3D) 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 decrease in recall rates compared to 2D mammography alone. However, long term, randomized controlled trials tracking the impact on survival are lacking. The impact of adding 3D to 2D mammography on long term mortality remains unknown. Other concerns remain, including the increased dose of radiation when 3D is added to standard 2D mammography.

The Oslo Tomosynthesis Screening Trial (OTST (Skaane, et al., 2013b; Skaane, et al., 2014) is a prospective trial of a population-based screening program using independent double reading with arbitration. This study was conducted at one site in Norway and included a screening population of 12,621 women age 50–69 years (women with breast implants were excluded). Study arms included: Arm A: 2D; Arm B: 2D+CAD; Arm C: standard 2D+3D; and Arm D: synthesized 2D+3D (2D images reconstructed from the 3D dataset). The design of the trial includes two very similar 2D alone-based arms and two very similar 2D+3D-based arms allowing for a comparison between independent double reading of 2D and independent double reading of 2D+3D. Paired double readings of 2D (Arm A+B) and 2D+3D (Arm C+D) were analyzed. Results per 1000 screening exams were as follows: cancer detection rates, 2D: 0.71%, 2D+3D: 0.94% (p<0.001); pre-arbitration false-positive scores, 2D: 10.3%, 2D+3D: 8.5% (p<0.001); recall rates, 2D: 2.9%, 2D+3D: 3.7% (p=0.005); and positive predictive values (detected cancer patients per 100 recalls), 2D: 24.7 %, 2D+3D: 25.5% (p=0.97) . 2D+3D detected 27 additional invasive cancers (p<0.001). The authors concluded that double reading using tomo-based imaging resulted in a significant increase in cancer detection rates, specifically in the detection of invasive, node-negative cancers, and at the same time a reduction in false-positive scores compared with a double reading of 2D imaging alone. The authors proposed that synthesized 2D can reduce radiation exposure. True 2D+3D requires more than doubling (2.2 times) of the radiation dose to the breast being imaged. With synthesized 2D, the radiation dose can be reduced to comparable levels to those used in 2D imaging (in this study 1.2 times the dose for 2D alone). Skaane et al. (2014) compared the performance of standard 2D+3D with two different methods of synthesizing 2D images +3D and did not find significant differences in the synthesizing methods, concluding that the use of a high-quality 2D synthesized view plus 3D should be viewed as acceptable for replacing radiation dose–requiring standard 2D images. Study limitations include lack of randomization, a lack of reported long term health outcomes (i.e., survival), lack of histology verification of cancer detection, and the use of 2D images from three different methodologies.

Friedewald et al. (2014) retrospectively evaluated 454,850 women across a spectrum of 13 radiology practices in the United States. This study compared performance of breast cancer screening before and after introduction of 3D over 2 periods. Period 1 included one full year of screening with digital mammography alone, ending on the date of 3D introduction at each institution. Period 2 included screening with digital mammography (2D) + 3D until December 31, 2012. Of the 454,850 examinations, 281,187 (61.8%) were performed in the first period (2D alone) and 173,663 (38.2%) were performed in the second period (2D+3D). The asymptomatic screening population had a mean age of 56.2 years. Friedewald et al. compared 2D mammograms to combined 2D and 3D mammograms. Model-adjusted rates per 1000 screens were as follows: cancer detection, 2D: 4.2, 2D+3D: 5.4 (p<.001); invasive cancer detection, 2D: 2.9, 2D+3D: 4.1 (p<.001); and recall rates, 2D: 107, 2D+3D: 91 (p<.001). Greenberg et al. (2014) evaluated 3D in a community-based radiology practice. A total of 77,833 women were included and underwent either 2D or 3D mammography. For patients screened with 3D, the relative change in recall rate was 16.1% lower than for patients screened with 2D (p=0.0001). Overall cancer detection rate (CDR), was 28.6% greater (p = 0.035) for 3D (6.3/1000) compared with 2D (4.9/1000). The CDR for invasive cancers with 3D (4.6/1000) was 43.8% higher (p=0.0056) than with 2D (3.2/1000). The positive predictive value for recalls from screening was 53.3% greater (p=0.0003) for 3D (4.6%) compared with 2D (3.0%). No significant difference in the positive predictive value for biopsy was found for 3D versus 2D (22.8%
and 23.8%, respectively) (p=0.696). These studies demonstrated a significant increase in cancer detection rate, including invasive cancers, and a significant decrease in recall rate. Study limitations include lack of prospective randomization and a lack of follow-up over several years.

The Malmö Breast Tomosynthesis Screening Trial (MBTST) (Lång, et al., 2015) is a study comparing 3D alone to 2D alone. A random sample of women eligible for the ordinary screening program in the city of Malmö were invited to participate in the study, with a total of 7500 women participating. There were 21 cancer cases detected by 3D alone and one cancer by 2D alone. The detection rate for 3D and 2D was 8.9 per 1000 screens and 6.3 per 1000 screens, respectively. The recall rate for 3D and 2D was 3.8 % and 2.6%, respectively. The increase in recall rate when using 3D relative to 2D was 43% (p<0.0001). The study authors note that this is half the eventual study population and it does not have an 80 % power in the statistical analyses.

The Screening with Tomosynthesis OR standard Mammography (STORM) trial (Ciatto, et al., 2013) is a prospective observational trial that was conducted at two sites in Italy and compared mammography screen-reading in two sequential phases, 2D only versus integrated 2D and 3D, yielding paired results for each screening examination. A total of 7,294 women aged 48 years or older were included. Screening mammograms were interpreted sequentially. Results demonstrated a significant increase in cancer detection rates (20 cancers with 2D+3D only versus none with 2D only, p<0.0001) and a significant decrease in false-positive scores (141 occurred at 2D only versus 73 at integrated 2D+3D, p<0.0001). Study limitations include no reported long term health outcomes.

In a prospective trial, Sumkin et al. (2015) evaluated 3D added to 2D during baseline screening mammography. A total of 1080 women between ages 34 and 56 years scheduled for their initial and/or baseline screening mammogram for any reason, were included. The average age was 42.03. The results demonstrated a recall rate of 412 of 1074 (38.4%) for 2D and 274 of 1074 (25.5%) for 2D+3D (p<.001). The authors noted large inter-reader variability in terms of recall reduction was observed among the 14 readers. The authors stated because of a small sample size combined with low expected prevalence in this age range, they could not assess quantitatively cancer detection rates of the two modalities being compared. This was a single institution trial.

Two retrospective screening studies, McCarthy et al. (2014) with 26,299 participants and Rose et al. (2013) with 23,355 participants, found no significant difference in cancer detection but did see a significant decrease in recall rates. McCarthy et al. (2014) evaluated patient-level outcomes of implementing 3D screening for the entire screening population at one site in the United States beginning October 2011. Outcomes for the cohort screened with 3D over a period of 17 months were compared to the cohort screened with 2D alone during the 12 months prior to 3D implementation. With a screening population mean age of mean age 56.7, results were reported as follows: cancer detection rate was 4.6 per 1000 for 2D compared with 5.5 per 1000 for 3D, this difference was not statistically significant (p=.32); recall rate was 10.4% for 2D compared with 8.8% for 3D (p< .001); and biopsy rates were similar for 2D and 3D (p=.14). Rose et al. (2013) used procedure outcome-related databases to evaluate the recall, biopsy, and cancer detection rates and computed positive predictive values (PPVs) in a clinical breast imaging practice before and after the introduction of 3D for routine screening mammography. With a screening population (n=23,355) mean age of mean age 54.5, results were reported as follows: cancer detection rates (per 1000 screenings) was 4.04 for 2D and 5.37 for 2D+3D, this difference was not statistically significant (p=0.18); recall rates were 2D: 8.7% and 2D+3D: 5.5% (p<0.001). Study limitations include a retrospective design.

In a retrospective study, Lourenco et al. (2015) evaluated cancer detection rates and recall rates before and after implementation of 3D screening. A total of 25,498 screening examinations were performed, 12,577 2D and 12,921 3D. Recalls were defined as BI-RADS category 0 (needs additional imaging). There was a significant difference in recall rates for 2D (1175, 9.3%) compared to 3D (827, 6.4%) (p=00001). There was no significant difference between 2D and 3D with regard to biopsy PPV (30.2% vs 23.8%, p=.21) or cancer detection rate per 1000 patients (5.4 vs 4.6, p=.44). This study was retrospective in design and authors note another limitation is that accurate assessment of false-negative findings was not performed because many patients had not yet returned for subsequent imaging.

Durand et al. (2014) held a retrospective trial at 4 sites, including 17,955 women, to evaluate the performance of 3D in a clinical practice by identifying the mammographic abnormalities that had the greatest reduction in screening mammography recall rates. Recall rates for 2D were 12.3% (1154 of 9364), and for 2D+3D were 7.8% (671 of 8592) (p<.0001). Recall rates for patients with asymmetries for 2D were 7.4% (689 of 9364), and for
2D+3D were 3.1% (267 of 8591) (p< .0001). Recall rates for calcifications for 2D were 3.2% (297 of 9364), and for 2D+3D were2.4% (205 of 8591) (p= .0014). Study limitations include a lack of prospective design.

**American Cancer Society:** 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.

**American College of Radiology (ACR):** The ACR released a Statement on Breast Tomosynthesis on November 24, 2014. The ACR stated “A new digital technology, breast tomosynthesis has shown to be an advance over digital mammography, with higher cancer detection rates and fewer patient recalls for additional testing. This is extremely important. The medical community has long sought ways to improve breast cancer screening accuracy. Better sensitivity will likely translate into more lives saved. Lower recall rates result in fewer patients who may experience short-term anxiety awaiting test results. This is important evidence that tomosynthesis will have a positive impact on patient care. ACR presented this evidence during the evaluation process for the new Current Procedural Terminology (CPT) codes 77061, 77062 and 77063 which were developed for CPT 2015.

As this technology is used in clinical practice, we anticipate that further studies will clarify its impact on long-term clinical outcomes, including reduced mortality. It will also be important to further elucidate which subgroups of women might benefit most from these exams (by age, breast density, frequency of examination, etc.).

To facilitate such large scale outcome data collection, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The College applauds the decision by the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these exams by covering beneficiaries for tomosynthesis and urges private payers to do the same.

To be clear: tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography. While the College encourages more studies to clarify the clinical role(s) of tomosynthesis and its long-term outcomes, it is clear that tomosynthesis represents an advance in breast imaging. The ACR will continue to update members and external stakeholders on this important matter.”

**American College of Obstetricians and Gynecologists (ACOG):** The ACOG issued a Committee Opinion on the Management of Women With Dense Breasts Diagnosed by Mammography (April 2014) 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) 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 Society of Breast Disease (ASBD): The ASBD Statement on Digital Breast Tomosynthesis (December 2013) concludes:

- The addition of 3D to conventional 2D improves the accuracy of diagnostic mammographic interpretation. This improvement in diagnostic accuracy can be achieved by enhanced detection of lesion, improvement in the analysis of the margins of a lesion and precise localization of a lesion. 3D with 2D has a higher sensitivity than 2D alone. Published studies showed an increase cancer detection rate of 27 - 30% at screening.
- Single center studies have shown that 3D and 2D has increased specificity compared to 2D alone. Multiple studies noted reduction in the recall rates of screening mammography with the addition of 3D. Recent studies suggest that young women with dense mammographic breast tissue may benefit the most from 3D and may have the greatest reduction in the recall rates.
- The three largest published DBT screening studies demonstrate a 40-50% increase in cancer detection rates.

Blues Cross/Blue Shield: The Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) published a Technology Assessment on Use of Digital Breast Tomosynthesis with Mammography for Breast Cancer Screening or Diagnosis (January 2014) noting that The evidence currently available on the use of breast tomosynthesis plus mammography versus mammography alone for screening is insufficient to permit conclusions regarding the effect on health outcomes of adding breast tomosynthesis.

Hayes, Inc.: Hayes evaluated digital breast tomosynthesis for breast cancer diagnosis or screening (September 2015) and concluded:

- C rating for breast tomosynthesis combined with (2D) digital mammography (DM) as a replacement for DM alone for breast cancer screening or for breast imaging in women who have suspected or known breast lesions. This Rating reflects consistent findings that DM combined with tomosynthesis provides better lesion detection than DM alone but lack of evidence that tomosynthesis reduces breast cancer mortality and concerns that adjunct tomosynthesis approximately doubles radiation dosage, increases time required for breast imaging and image reading, and has not been adequately compared with DM that includes supplemental views.
- D2 rating for breast tomosynthesis alone as a replacement for conventional DM for breast cancer screening or for breast imaging in women who have suspected or known breast lesions. This Rating reflects the divergent results of studies comparing breast tomosynthesis alone with conventional DM, as well as the lack of evidence that tomosynthesis reduces breast cancer mortality.

NCCN: The NCCN Breast Cancer Screening and Diagnosis Guideline (1.2015) states Early studies show promise for tomosynthesis mammography. Several studies show a combined use of digital mammography and tomosynthesis resulted in improved cancer detection and decreased call back rates. Of note, most studies used double the dose of radiation. The radiation dose can be minimized by synthetic 2D reconstruction. Definitive studies are pending.

U.S. Preventive Services Task Force (USPSTF): The USPSTF 2015 Draft Breast Cancer Screening Recommendation Summary concludes that the current evidence is insufficient to assess the benefits and harms of tomosynthesis (3-D mammography) as a screening modality for breast cancer (Grade I - Insufficient).

Use Outside of the US
The Hologic Selenia Dimensions, GE SenoClaire, and Siemens Mammomat tomosynthesis systems have all received CE Marking (Hayes, 2015).

Summary
Women of any age who think they may be at an increased risk for breast cancer should consult with their physicians about a personalized screening mammography schedule. Numerous professional societies and government organizations recommend annual or biennial screening mammography for average-risk and higher-risk women. Computer-aided detection has become standard of care in the United States. Large prospective and retrospective trials demonstrate the use of screening digital breast tomosynthesis (DBT) (i.e., three-dimensional [3D] mammography) in addition to two-dimensional [2D] mammography significantly increases in
cancer detection rates including invasive cancers, and decreases in recall rates compared to 2D mammography
alone. However, the impact on mortality and the increased dose of radiation when 3D is added to standard 2D
mammography remain unclear. Synthesized 2D images may alleviate the increased radiation dose.

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

Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77057</td>
<td>Screening mammography, bilateral (2 view film study of each breast)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0202</td>
<td>Screening mammography, producing direct digital image, bilateral, all views</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77063</td>
<td>Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>


References

   recommendations for early breast cancer detection in women without breast symptoms. Last Revised: 08/19/2015. Available at URL address:


The registered marks “Cigna” and the “Tree of Life” logo are owned by Cigna Intellectual Property, Inc., licensed for use by Cigna Corporation and its operating subsidiaries. All products and services are provided by or through such operating subsidiaries and not by Cigna Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, Cigna Health and Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation.