Subject: Mammography

Background: Breast cancer is the most common cancer in women in the United States, being estimated to have been diagnosed in 232,000 women in 2015. Most frequently diagnosed in women fifty-five through sixty-four years in age, the standard screening methodology is mammography, in which low-energy x-rays, which are more easily blocked by the dense tissue ("masses") associated with cancers, are sent through the breast on to a film or, in contemporary devices, digital receiver. In general practice, two scans at right angles to one another are taken per breast.

3D mammography, or Digital Breast Tomosynthesis (DBT), is an imaging technology used to for breast cancer screening and diagnosis. 3D mammography provides a 3-dimensional (3D) digital x-ray of the breast, and is proposed as an adjunct to 2D full-field digital mammography (FFDM) in screening for breast cancer or in helping to clarify unclear mammographic findings, particularly in young women, in whom mammography has lower sensitivity.

3D mammography was developed in an effort to improve the accuracy of mammography by providing 3D images of the breast and allowing for clarity in areas where two-dimensional (2D) system limitations (due to overlapping tissue in the breast) may hide malignant lesions or cause benign masses to appear suspicious. It is believed that the use of 3D mammography/DBT could result in increased sensitivity and specificity, thus eliminating much of the need for patient recalls due to results that are inconclusive.

Policy and Coverage Criteria:

Screening Mammography
Harvard Pilgrim Health Care (HPHC) considers annual screening mammography as medically necessary for members when medical record documentation confirms ANY of the following:

- Per the United States Preventive Service Taskforce Guidelines, member is at least forty years in age but no more than seventy-four years in age or high-risk individuals
- Member has a prior history of breast cancer; or
- Member is older than twenty-four years in age and has ANY of the following:
  - A known BRCA mutation,
  - A first-degree relative with a BRCA mutation unless member has received BRCA mutation testing and received a negative finding,
  - Prior radiation therapy to the chest between the ages of ten and thirty years,
  - A personal history of primary breast cancer or primary breast cancer treatment,
  - A personal or immediate family history of Bannayan-Riley-Ruvalcaba, Cowden, and/or Li-Fraumeni syndrome,
  - An estimated lifetime breast cancer risk of at least 20% per a valid model, such as the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm, Gail model, BRCAPRO (the "Duke model"), Claus model, or Tyrer-Cusick model.
  - An estimated five-year breast cancer risk of at least 1.7% per a valid model, such as the National Cancer Institute risk assessment tool (modified Gail model).

Diagnostic Mammography
Harvard Pilgrim Health Care (HPHC) considers diagnostic mammography as medically necessary for members when medical record documentation confirms ANY of the following conditions:
• Member has signs or symptoms suggestive of breast cancer; or
• Member has a history of breast cancer

Digital Breast Tomosynthesis
Harvard Pilgrim Health Care (HPHC) considers digital breast tomosynthesis (“3D mammography”) to be an appropriate substitution for mammography in all settings.

NOTE: In accordance with the 2016 Connecticut state mandate, screening 3D mammography/DBT is covered for members enrolled in plans subject to Connecticut insurance law. In addition, per Connecticut State Mandate, members age 35 to 39 are also covered for screening mammography.

Supporting Information:

Mammography
Mammograms are low-energy x-rays of the breast used to visually differentiate tissue by density. As a regular screening, mammography is the primary tool for detecting asymptomatic breast cancer, doing so early enough that breast is among the most survivable of cancers. In recent years, the age and frequency at which mammography is routinely applied has been the source of some controversy, as several medical guideline groups have designated annual mammography and mammography before certain ages as lacking supporting evidence and unnecessary. Beyond time and money wasted, potential harms of unnecessary mammography include benign biopsies, over diagnosis, false positives, and radiation exposure.

A large 2016 meta-study using multiple validated models that were kept updated to contemporary screening and treatment compared different frequencies and initiation ages, including “hybrid” strategies that transition from annual to biennial at age fifty. This analysis found that biennial screening achieves roughly 80% of the screening benefits of annual screening with half the false-positive risk for normal-risk women, and that annual screening starting at age forty for double- and quadruple-risk women has a similar risk-benefit ration as biennial screening starting at fifty for normal-risk women. Risk-benefit ratios were similar for biennial screening starting at forty, forty-five, and fifty. Biennial schedules starting at forty, forty-five, and fifty were all on the efficiency frontier, with hybrid strategies close behind.

A small number of studies have looked at mammography frequency. A 2015 prospective analysis of women who had been diagnosed with breast cancer from 1996 through 2012 found that premenopausal women diagnosed with breast cancer after a biennial screening had worse prognostic characteristics than those diagnosed after an annual screening, while there was no difference for postmenopausal women. A 2013 analysis using Breast Cancer Surveillance Consortium data to compare annual, biennial, and triennial screening found that cumulative false-positive risk decreased as screening interval increased and no frequent or consistent patterns of worse tumor characteristics upon detection. A 2005 retrospective analysis of British Columbian women before and after the local health system switched from providing mammography annually to providing mammography biennially for women over age fifty. It found that annual mammography was associated with 1.2% increase in estimated ten-year breast-cancer-specific survival for women diagnosed with invasive breast cancer after screening. A 2008 analysis using matched samples of the same population found that annual and biennial screening had no significant difference in cancer detection or mortality for women over fifty, while the same shift in period was associated with an increase in screen-detected cancers and cancer survival and decrease in postscreen-detected cancers in women under age fifty.

The most recent United States Preventative Services Task Force Recommendation Statement recommends biennial screening mammography for women age 50 to age 74. Breast cancer screening prior to age 50 is designated an individual choice and given an evidence grade of “C,” indicating at least moderate certainty that the benefit of the screening is small. The 2017 American College of Obstetricians and Gynecologists practice bulletin has largely the same recommendations, with the primary difference being that mammography may be continued after age 75 if there is a life expectancy of at least ten more years.
The most recent American Cancer Society recommendations for the early detection of breast cancer for women at average risk for breast cancer, released in 2015, advise annual mammograms from the ages of forty-five to fifty-four and biennial screenings from the age of fifty-five until age and health status contraindicate an expectation of living another decade. Women of normal cancer risk between the ages of forty and forty-four are said to “have the opportunity to begin annual screening.” Women at increased risk are advised to get annual mammograms, with “increased risk” being defined as having a BRCA1 and/or BRCA2 gene mutation or such a mutation in an immediate family member and no negative genetic test ruling it out, a personal or immediate family history of Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, radiation therapy to the chest between the ages of ten and thirty years, or a lifetime risk of breast cancer of at least 20%.

The Canadian Task force on Preventative Health Care recommends biennial or triennial routine screening for women between fifty and seventy-four, and against routine screening for women younger than fifty.

The 2014 American College of Radiology/Society of Breast Imaging guidelines support annual mammography from age forty until life expectancy is less than five to seven years.

Digital Breast Tomosynthesis (“3D mammography”)
Digital breast tomosynthesis (DBT) systems are used as an adjunct and alternative to x-ray mammography for the screening and diagnosis of breast cancer. Digital tomosynthesis techniques are also in development for orthopedic, lung, and radiotherapy imaging applications. Unlike conventional mammography units, a tomosynthesis system’s x-ray tube sweeps along an arc around the breast to acquire between sixty and seventy-two-dimensional (2-D) projections from slightly different angles in about 10 to 20 seconds. The resulting 2-D images are digitally manipulated to create tomograms (i.e., slices) in any plane, thus allowing for three-dimensional (3-D) reconstruction that reveals depth. The number of tomograms that can be created depends on the number of 2-D projections captured during the x-ray sweep. The slices can be displayed individually (resembling conventional mammograms with sharper details) or in a dynamic “movie” mode. Providing a 3-D reconstruction of the breast eliminates the problem of overlying tissue that might be mistaken for lesions or that might obscure small cancers.

A 2016 update to the 2009 U.S Preventative Services Task Force Recommendation focusing on harms associated with breast cancer screening found that four of five studies analyzed found lower rates of recall in DMT with 2D mammography than in 2D mammography alone, although one study also found a modest increase in biopsies. It also found consistent evidence supporting earlier conclusions that false positive results are most common in women with dense breasts, women in their forties, and women using combination hormone therapy. A similar update focusing on the benefits of screening found insufficient evidence to conclude that DMT increases true positives.

A 2016 review and cost-effectiveness analysis of DBT found that, when early-detected cancers, false positives caused and prevented, and performance costs were taken together, adding DMT to routine mammography had a net monetary benefit of $1,598 per decade in women in their forties, compared to $546 for women in their fifties. The incremental cost per quality-adjusted life-year gained for adding DMT was $20,976 for women in their forties and $49,725 for women in their fifties. These results suggest that DMT is particularly beneficial in women under the age of fifty, as cost savings largely come from reduced cancer burden. As the analysis population for the review was women who had started annual screening at age forty, the cancer risk and thus treatment savings for women over fifty was higher than would be likely in the general population, which starts screening at age fifty unless at particular risk. A similar analysis for women age fifty to seventy-four with dense breasts predicted that the addition of DMT to all biennial mammography for the twenty-four year period would avert 5 deaths and 405 false-positives for every thousand women, so that adding DMT for women with dense breasts was cost effective as long as additional cost was at or below $87 per exam. One limitation of this study did not include the increased radiation exposure of the extra procedure per exam, although it notes that the combined dose is still lower than that set by the Mammography Quality Standards Act and obviated by the ability to reliably simulate 2D mammography output with DMT data.
A 2013 review of studies evaluating breast tomosynthesis (Alakhras et al.) found the message currently being presented by the available evidence is sometimes unclear, with studies demonstrating inconsistent and often conflicting findings, particularly relating to sensitivity. The authors concluded the full potential of DBT is currently unknown and more work is required using robust, comprehensive, and clinically relevant methodologies using the most rigorous analytical methods.

A 2017 review of studies evaluating DBT in women with dense breasts found that the addition of DBT to 2D mammography lowered recall rates and raised detection rates somewhat with the same percentage of cancers detected being invasive as 2D alone, but that there were only four studies of reasonable quality, and three of those were single-site retrospective. As such, data reliability is limited.

A 2016 rapid review of studies evaluating DBT in women with heterogeneously or extremely dense breasts found that adding DBT to biennial mammography yields an increase in cancer detection of 3.9 per thousand screens and decrease in recall of 23.3 per thousand screens, much larger effect sizes than seen in women not selected for breast density.

A 2016 prospective study compared DBT combined with either standard 2D mammography or equivalent images reconstructed from DBT output to 2D alone. While the addition of 3D mammography raised detection rates from 6.3 per thousand screens to 8.5 per thousand screens with true 2D mammography and 8.8 with synthetic 2D, but also increased the false positive rate from 3.42% to 3.97% with true 2D and 4.45% with synthetic. This suggests that adding 3D mammography increases sensitivity, but not necessarily specificity. At the same time, a 2017 secondary analysis using the same data set found that single-read combined 2D(true or simulated)/3D mammography produced significantly higher cancer detection rates than the clinically common double-read 2D (8.2 or 8.4 per thousand screens versus 6.3) and a lower false positive recall rate (2.60 or 2.76% versus 3.42).

Durand et al. (2015) examined recall rates from screening mammography and the mammographic findings that caused recall in women who underwent digital breast tomosynthesis with conventional mammography and in women who underwent conventional mammography alone. A retrospective review of 2D + 3D and 2D screening mammograms was performed for 17,955 screening mammograms (8591 were 2D + 3D and 9364 were 2D alone). The rate of recall was 36.6% lower in the 2D + 3D group than in the 2D group. The authors concluded that use of tomosynthesis compared with conventional mammography is associated with a lower recall rate of screening mammography, most often for asymmetries.

A relatively small 2016 prospective blinded study in women with breasts of various densities found that the addition of DMT led to more appropriate lesion BI RADS (cancer risk) categorization and diagnostic confidence in 35 and 54% of lesions, respectively, in women with heterogeneously dense breasts and 42 and 63.6% of lesions, respectively, in women with extremely dense breasts, compared to 19 and 27.3% for women with fatty breasts and 17 and 33.4% for women with scattered areas of fibroglandular density.

A 2014 analysis of an older prospective study sought to assess the overall impact of true and false positives associated with DBT. It found that combined 2D/DBT yielded a favorable false to true positive ratio, particularly when recall requires confirmation using the DBT output rather than 2D alone, suggesting that DBT is a worthwhile addition to breast cancer screening.

Friedewald et al. (2014) conducted a retrospective analysis to determine if mammography combined with tomosynthesis is associated with better performance of breast cancer screening programs in the US. A total of 454,850 examinations were evaluated. With digital mammography, 29,726 patients were recalled and 5056 biopsies resulted in cancer diagnosis in 1207 patients. With digital mammography + tomosynthesis, 15,541 patients were recalled and 3285 biopsies resulted in cancer diagnosis in 950 patients. Adding tomosynthesis was associated with an increase in the positive predictive value for recall from 4.3% to 6.4% and for biopsy from 24.2% to 29.2%. The authors concluded that addition of tomosynthesis to digital mammography was associated with a decrease in recall rate and an increase in cancer detection rate, however study limitations were short term
follow-up and the lack of prospective randomization and further studies are needed to assess the relationship to clinical outcomes.

A retrospective comparative cohort study by Greenberg et al (2014) evaluated clinical performance of combined 2D-3D digital breast tomosynthesis (3D DBT) to 2D digital mammography (DM) alone for the detection of breast cancer in 59,617 women. Outcomes from the screening mammography (study period August 9, 2011 to November 30, 2012 using 3D DBT (n=23,149) versus 2D DM (n=54,684) were compared. Recall rate in individuals screening with 3D DBT was 16.1% lower than individuals screening with 2D DM (p>0.0001). The overall cancer detection rate, expressed as number cancers per 1000 individuals screened was 28.6% greater (p=0.035) for 3D DBT (6.3/1000) compared with 2D DM (4.9/1000); the cancer detection rate for invasive cancers with 3D DBT was 43.8% higher than with 2D. The positive predictive value for recalls from screening (PPV1) was 53.3% greater (p = 0.0003) for 3D DBT (4.6%) compared with 2D DM (3.0%). No significant difference in the positive predictive value for biopsy (PPV3) was found for 3D DBT versus 2D DM (22.8% and 23.8%, respectively) (p = 0.696). The authors concluded that the mammography screening with 3D DBT yielded lower recall rates, and increased cancer detection ratio for cancer overall. Limitations of this study include retrospective and nonrandomized design. The higher positive predictive value and cancer detection rate could be attributable to the individuals with known risk factors for developing breast cancer self-selecting 3D DBT versus 2D DM.

Houssami and Skaane (2013) presented an overview of DBT evidence for breast cancer detection. In reviewing the literature, the researchers found there is insufficient evidence to justify a change from standard digital mammography to breast tomosynthesis. They note further randomized, large-scale trials are needed. Skaane et al. (2013) presented results of a clinical trial comparing DM alone and DM plus DBT in a population-based screening program. Results found detection rates, including those for invasive and in situ cancers, were 6.1 per 1000 examinations for mammography alone and 8.0 per 1000 examinations for mammography plus tomosynthesis (27% increase, adjusted for reader; P = .001). False-negative rates before arbitration were 61.1 per 1000 examinations with mammography alone and 53.1 per 1000 examinations with mammography plus tomosynthesis (15% decrease, adjusted for reader; P < .001). After arbitration, positive predictive values for recalled patients with cancers verified later were comparable (29.1% and 28.5%, respectively, with mammography alone and mammography plus tomosynthesis; P = .72). Twenty-five additional invasive cancers were detected with mammography plus tomosynthesis (40% increase, adjusted for reader; P < .001). The mean interpretation time was 45 seconds for mammography alone and 91 seconds for mammography plus tomosynthesis (P < .001). The researchers found the use of mammography plus tomosynthesis in a screening environment resulted in a significantly higher cancer detection rate and enabled the detection of more invasive cancers.

A 2011 article by Spangler et al. compared the ability of digital breast tomosynthesis to full field digital mammography (FFDM) to detect and characterize calcifications. One hundred paired examinations were performed utilizing FFDM and digital breast tomosynthesis. Twenty biopsy-proven cancers, 40 biopsy-proven benign calcifications, and 40 randomly selected negative screening studies were retrospectively reviewed by five radiologists in a crossed multireader multimodal observer performance study. Data collected included the presence of calcifications and forced BI-RADS scores. Receiver operator curve analysis using BI-RADS was performed. Calcification detection sensitivity was higher for FFDM. In the cancer cohort, 76% of interpretations identified calcification in both modes. In the benign cohort, 62% of interpretation identified calcifications in both modes. The researchers found FFDMA to be slightly more sensitive than digital breast tomosynthesis for the detection of calcification. They note with improvements in processing algorithms and display, digital breast tomosynthesis could potentially be improved.

The Hologic digital tomosynthesis system has been evaluated in four published studies. Teertstra et al. (2010) compared the Hologic system with digital mammography in 513 women with an abnormal screening mammogram, with clinical symptoms, or referred for a second opinion. Images were interpreted by 1 of 7 breast radiologists. Both techniques detected 112 new cancers, and were false-negative in 8 cases. Sensitivity of digital
mammography and tomosynthesis was 92.9%; specificity was 86.1% and 84.4%, respectively. Of the 8 false-negative cases, cancer was detected by follow-up ultrasound in 4 of the false-negative cases, by MRI in 2 cases, by recall after tomosynthesis in 1 case, and by mastectomy in 1 case.

Poplack et al. (2007) compared digital tomosynthesis with x-ray mammography in 98 women aged 34 to 85 years who had an abnormal screening mammogram and were referred for diagnostic mammography. The image quality of tomosynthesis was found to be equivalent or superior to diagnostic x-ray mammography in 89% of the patients. Using tomosynthesis resulted in a 40% reduction in recalls. However, tomosynthesis image quality was found to be inferior to mammography for visualization of calcifications.

A 2008 study by Goode et al. evaluated issues associated with digital tomosynthesis image interpretation. Breast images from 30 women who underwent digital mammography and digital tomosynthesis were used. Nine experienced radiologists independently reviewed the 30 cases 3 times: as displayed as digital mammography, as 11 low-dose projections prior to reconstruction of tomosynthesis images, and the reconstructed digital tomosynthesis examination. They were then asked to rate each image set for the presence or absence of previously defined abnormalities. In comparison to digital mammography, the reconstructed digital tomosynthesis examination took much longer to review and interpret (1.581.07 versus 2.721.44 minutes). Three of the 9 radiologists perceived the tomosynthesis frame mode to be better than digital mammography, and 6 of the 9 radiologists perceived the reconstructed tomosynthesis examination to be better than digital mammography. The detection rate of malignancies was slightly better for the reconstructed digital tomosynthesis examination than for digital mammography (93.9% versus 90%), and the recall rate for nonmalignancies was slightly lower (62.6% versus 64.3%). The researchers noted that better visualization and training tools will need to be developed before digital tomosynthesis can be used efficiently in a screening environment.

Gur et al. (2009) discussed results of a retrospective observer study that compared digital tomosynthesis with digital mammography from 125 selected breast examinations from 8 experienced radiologists. In 35 examinations, cancer had been verified, and in 90, no cancer had been detected. Combining digital mammography with digital tomosynthesis was associated with a 30% reduction in recalls for the cancer-free examinations compared with the use of digital mammography alone. Digital tomosynthesis alone reduced recall rates by approximately 10%. Digital tomosynthesis did not substantially improve sensitivity.

The 2016 American College of Radiology Appropriateness Criteria for breast cancer screening finds that DBT with 2D mammography is superior to 2D mammography alone, particularly in women with features that necessitate greater specificity or challenge 2D mammography such as an age lower than 50, dense breasts, or “lesion types including speculated masses and asymmetries.” The main drawback cited was that performing two scans increases radiation exposure and expense, but also found that 2D composites constructed from DBT output. The 2016 United States Preventive Service Task Force (USPSTF) guidelines, which based its recommendation on a systematic review of the evidence which addressed the test performance characteristics of DBT as a primary screening modality for breast cancer, performed either alone or simultaneously with 2D digital mammography, concluded “that the current evidence is insufficient to assess the benefits and harms of [DBT] as a primary screening method for breast cancer.” Similarly, a systematic review attached to this report states that long-term evidence is insufficient to recommend supplemental screening, including DBT, to women classified as having dense breasts.

The 2014 edition of the American College of Radiology/Society of Breast Imaging guidelines for the screening of women of normal cancer risk states that it considers DBT to no longer be investigational and to improve screening compared to 2D mammography. The 2015 American Cancer Society guidelines state that DBT shows improvements in accuracy compared to 2D mammography, but that data is insufficient to endorse its use. National Comprehensive Cancer Network guidelines recommends clinicians “Consider tomosynthesis” for annual screening mammograms and states “Multiple studies show a combined use of digital mammography and tomosynthesis appears to improve cancer detection and decrease call back rates. Of note, most studies used double the dose of radiation. The radiation dose can be minimized by synthetic 2D reconstruction.”
The American College of Obstetricians and Gynecologists 2011 Guidelines on breast Cancer Screening states: “color Doppler ultrasonography, computer-aided detection, position emission tomography, scintimammography, and [DBT] have shown promise in selected clinical situations or as adjuncts to mammography for breast cancer diagnosis. However, these technologies are not considered alternatives to routine mammography.” The American College of Obstetricians and Gynecologists 2013 technology assessment, Digital Breast Tomosynthesis, states: “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.”

The Food and Drug Administration (FDA) gave final regulatory approval for the Selenia Dimensions System (manufactured by Hologic) on February 11, 2011. This system is a software and hardware upgrade of the Selenia® Dimensions 2D Full-Field Digital Mammography (FFDM) system, which the FDA approved in 2008. In May 2013, the FDA approved Hologic's C-View 2D imaging software. This software is used to create 2D images from the tomosynthesis results rather than performing a separate mammogram.

In August 2014, the FDA approved SenoClai™ breast tomosynthesis system, from GE Healthcare, through the PMA approval process. SenoClai is an imaging option for the Senographe™ Essential FFDM system.

In April 2015, the FDA approved Siemens Medical Solutions' Mammomat™ Inspiration® mammography platform with tomosynthesis option through the PMA approval process. The tomosynthesis option is a software upgrade to the Mammomat™ Inspiration® FFDM system that received FDA approval for conventional mammography in 2011.

**Coding:**

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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<td>Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed</td>
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HPHC policies are based on medical science, and written for the majority of people with a given condition. Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:


Summary of Changes:

<table>
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<th>Date</th>
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<tr>
<td>10/20</td>
<td>Annual review; criteria clarified</td>
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<tr>
<td>10/19</td>
<td>Annual review; no changes</td>
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<tr>
<td>10/18</td>
<td>Changes to age for screening coverage</td>
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<tr>
<td>9/17</td>
<td>Policy criteria for screening mammography revised; added criteria for diagnostic mammography. Added note 3D mammography to be an appropriate substitution for mammography in all settings.</td>
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Approved by Medical Policy Committee: 10/6/2020
Approved by Clinical Policy Operational Committee: 5/11; 5/13; 2/15; 10/16; 9/17; 9/18; 10/19; 10/20
Policy Effective Date: 10/23/20
Initiated: 5/11