Breast Imaging for Screening and Diagnosing Cancer

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➲ Instructions for Use

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Related Commercial/Individual Exchange Policies

- Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service
- Omnibus Codes
- Preventive Care Services

Community Plan Policy

- Breast Imaging for Screening and Diagnosing Cancer

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

The following are proven and medically necessary:

- Magnetic resonance imaging (MRI) of the breast for individuals who are at high risk for breast cancer, as defined as having any of the following:
  - Heterogeneously dense breasts (category C) or extremely dense breasts (category D) (screening beginning at age 40 years)
  - Prior thoracic radiation therapy between the ages of 10 and 30 years (screening starting at age 25 years or 8 years after treatment, whichever is later)
  - Lifetime risk estimated at greater than or equal to 20%, as defined by models that are largely dependent on family history (e.g., Gail, Claus, Tyrer-Cuzick, or BRCAPRO) (screening beginning at age 40 years*)
  - Personal history of breast cancer (not treated with bilateral mastectomy)
  - Personal history with any of the following:
    - *ATM* (screening beginning at age 30 years*)
    - *BARD1* (screening beginning at age 40 years*)
    - *BRCA1* or *BRCA2* (screening beginning at age 25 years)
    - *CDH1* (screening beginning at age 30 years*)
    - *CHEK2* (screening beginning at age 30 years*)
    - *NF1* (screening beginning at age 30 years*)
    - *PALB2* (screening beginning at age 30 years*)
    - *PTEN* gene mutation (Cowden syndrome) (screening beginning at age 30 years*)

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        - *RAD51C* (screening beginning at age 40 years*)
        - *RAD51D* (screening beginning at age 40 years*)
        - *STK11* gene mutation (Peutz-Jehgers syndrome) (screening beginning at age 30 years*)
        - *TP53* gene mutation (Li-Fraumeni syndrome) (screening beginning at age 20 years)
    - Family history with any of the following:
        - At least one first-degree relative who has a *BRCA1* or *BRCA2* mutation (screening beginning at age 40 years*)
        - First-degree relative who carries a genetic mutation in the *TP53* or *PTEN* genes (Li-Fraumeni syndrome, Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome, or Peutz-Jehgers syndrome)
        - At least two first-degree relatives with breast or ovarian cancer (screening beginning at age 40 years*)
        - One first-degree relative with bilateral breast cancer or both breast and ovarian cancer (screening beginning at age 40 years*)
        - First- or second-degree male relative (father, brother/half-brother, uncle, or grandfather) diagnosed with breast cancer (screening beginning at age 40 years*)

*Screening can begin at the listed age or starting 10 years prior to the age at diagnosis of the youngest relative who has been diagnosed with breast cancer (up to third-degree relatives), whichever comes first, but not before age 25 years.

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Computer-Aided Tactile Breast Imaging
- Computed tomography of the breast
- Magnetic Resonance Elastography of the Breast
- MRI of the breast for individuals who do not meet the criteria above
- Molecular Breast Imaging (e.g., breast-specific gamma imaging, scintimammography) for routine screening in normal or high-risk individuals
- Positron Emission Mammography

Note: For three-dimensional rendering of breast ultrasound, three-dimensional rendering of breast MRI, computed tomography of the breast, or additional indications for MRI of the breast, refer to the Breast Imaging Guidelines section of the *Cardiovascular and Radiology Imaging Guidelines*.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Breast Composition Categories: Levels of breast tissue density described by the American College of Radiology's Breast Imaging Reporting and Data System.

- Category A: Almost entirely fatty
- Category B: Scattered areas of fibroglandular density
- Category C: Heterogeneously dense
- Category D: Extremely dense

(Sickles et al., 2013)

Computer-Aided Tactile Breast Imaging: Tactile breast imaging includes placing a tactile array sensor in contact with the breast. As the clinician gently moves the handheld sensor across the breast and underarm area, data signals are then processed into multidimensional color images that instantly appear on a computer screen in real time, allowing the clinician to view the size, shape, hardness, and location of suspicious masses immediately. [American Cancer Society (ACS), 2022]

Magnetic Resonance Elastography of the Breast: Magnetic Resonance Elastography of the Breast is a phase contrast–based magnetic resonance imaging technique that is based on quantitative differences in the mechanical properties of normal and malignant tissues. Specifically, the elastic modulus of breast cancer tissue is approximately five- to 20-fold higher than that of the surrounding fibroglandular tissue, i.e., breast cancers are usually harder than normal tissues. This difference can be measured by applying a known stressor and measuring the resulting deformation.

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Magnetic resonance elastography is performed by a radiologist in a magnetic resonance imaging suite that is equipped with the electromechanical driver and integrated radiofrequency coil unit. (ACS, 2022)

Molecular Breast Imaging: Molecular Breast Imaging is a nuclear medicine technique for functional imaging of the breast in which an intravenously administered radiotracer (typically technetium-99m–labeled agents) is detected with a gamma camera to identify regions of increased uptake associated with malignancy; it represents the modern evolution of breast scintigraphy (scintimammography) and includes dedicated breast-optimized approaches such as breast-specific gamma imaging. (ACS, 2022)

Positron Emission Mammography: Positron Emission Mammography performs high-resolution metabolic imaging for breast cancer using a fluorodeoxyglucose tracer. The Positron Emission Mammography detectors are integrated into a conventional mammography system, allowing acquisition of the emission images immediately after the mammogram. (ACS, 2022)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

Coding Clarification: Computer-aided detection is included with the MRI breast CPT code 77048 and 77049 procedures. If computer-aided detection is performed with these codes, there is no additional reimbursement.

CPT Code	Description
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral
0633T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material
0634T	Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)
0635T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)
0636T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)
0637T	Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)
0638T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
76391	Magnetic resonance (e.g., vibration) elastography
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral

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CPT Code	Description
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral

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HCPCS Code	Description
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

Description of Services

Regular screening is the most reliable method for detecting breast cancer early when treatment is the most effective. Screening recommendations vary according to breast cancer risk, and several tools are available to approximate breast cancer risk based on various combinations of risk factors. Current methods of breast screening and diagnosis include breast self-examination, clinical breast examination, ultrasonography, mammography, and magnetic resonance imaging.

Mammography remains the generally accepted standard for breast cancer screening and diagnosis. However, efforts to provide new insights regarding the origins of breast disease and to find different approaches for addressing several key challenges in breast cancer, including detecting disease in mammographically dense tissue, distinguishing between malignant and benign lesions, and understanding the impact of neoadjuvant chemotherapies, have led to the investigation of several novel methods of breast imaging for breast cancer management.

Benefit Considerations

Certain breast cancer screenings are included in the Preventive Care Services benefit. Refer to the Medical Policy titled Preventive Care Services.

Clinical Evidence

Computer-Aided Tactile Breast Imaging

The current evidence consists of very low-quality, uncontrolled studies of the diagnostic efficacy of either tactile breast imaging device. The impact of these devices on individuals' outcomes has not been determined. There is significant potential for bias in these studies that could result in hyperinflated estimates of diagnostic accuracy of tactile breast imaging relative to other screening modalities. Limitations to the research include insufficient reporting of the referral process and workup prior to tactile breast imaging; lack of randomization; unclear blinding; and inconsistent application of the gold standard. Future research should include better-designed studies, including comparative, prospective, and randomized controlled trials that evaluate this technology.

Tasoulis et al. (2014) conducted a prospective, blinded comparative study that enrolled 276 consecutive women who were aged 19 to 92 years and referred to a breast clinic for palpable breast lumps that were confirmed by both the participant and primary care physician. Inclusion required female participants who were aged 18 years or older and had a palpable lump, while those who were referred for other reasons or under age 18 years were excluded. Each participant underwent a clinical breast examination (CBE) by a consultant breast surgeon and a tactile imaging (TI) scan by a trained research fellow using the SureTouch system, with both examiners blinded to each other's findings. Radiological findings from mammography and ultrasound served as the primary reference standard, and histology or cytology provided the secondary reference standard. Sensitivity, specificity, predictive values, and accuracy were calculated with exact binomial 95% CIs, and receiver operator characteristic (ROC) curve analysis was performed using IBM SPSS version 20. For radiological diagnosis, TI showed a sensitivity of 85.5% (95% CI, 79.9%-91.1%) and specificity of 35% (25.6%-44.3%), while CBE showed a sensitivity of 80.3% (73.9%-86.6%) and specificity of 76% (67.6%-84.4%), with statistically significant differences ($p < 0.0001$). For the final diagnosis, TI had a sensitivity of 88.2% (83%-93.3%) and specificity of 38.5% (28.5%-48.5%) compared with the CBE sensitivity of 81.6% (75.4%-87.7%) and specificity of 85.7% (78.5%-92.9%), which was also statistically significant ($p < 0.0001$). The prespecified secondary end points included diagnostic performance based on fine-needle aspiration cytology. These results suggest a trend toward higher sensitivity of TI compared with CBE but significantly lower specificity. A subgroup analysis revealed superior sensitivity of TI in detecting a histological entity in premenopausal women. However, CBE's overall performance was superior compared with TI's according to the ROC curve analysis. The authors concluded that (1) TI served as a selection tool to help primary care physicians identify participants who needed a referral to a breast specialist, especially in premenopausal women, which

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potentially reduced unnecessary referrals for triple assessment, and that (2) the device complemented CBE rather than substituted imaging.

Computed Tomography of the Breast

There is a very low-quality body of evidence that is aimed at computed tomography (CT) of the breast for the screening and diagnosis of breast cancer. This consists of uncontrolled studies that are insufficient to draw conclusions regarding evidence and individuals' outcomes in lieu of conventional breast imaging modalities. These studies have failed to yield diagnostic accuracy and are at a high risk of bias due to no controls, a retrospective design, and a single-center focus.

Yang et al. (2024) conducted a systematic review and meta-analysis study to compare the diagnostic performance of cone-beam breast CT (CBBCT) and mammography in primary breast cancer. Eight studies met the inclusion criteria (n = 847). Diagnostic performance between CBBCT and mammography was analyzed using Z-test statistics. The meta-analysis revealed that CBBCT was superior to mammography in terms of sensitivity and area under the curve (AUC) values. The diagnostic performance of CBBCT in primary breast cancer was better than that of mammography. CBBCT sensitivity and specificity in diagnosing primary breast cancer were 0.92 and 0.79, respectively, and the AUC of the summary ROC was 0.93. The summary sensitivity and specificity for mammography were 0.77 and 0.75, respectively, with an AUC of 0.83. The Z-test revealed that the summary sensitivity of CBBCT was significantly higher than that of mammography. Additionally, the summary AUC of CBBCT was significantly higher than that of mammography. The authors concluded that the diagnostic performance of CBBCT was better than that of mammography in cases of primary breast cancer. Sample sizes were limited, and more extensive, large-scale, prospective studies are warranted. Limitations in the study are the small sample size and high heterogeneity, which impact data reliability.

Gong et al. (2023) conducted a systematic review and meta-analysis that evaluated the diagnostic accuracy of CBBCT for breast cancer detection compared with that of digital mammography (DM) and magnetic resonance imaging (MRI). Studies were included if they were diagnostic clinical trials that used CBBCT to assess breast tumor malignancy and provided sufficient data to calculate sensitivity and specificity, while duplicates, abstracts, and simulation studies were excluded. Overall, 18 studies, with a total of 1,792 individuals, were analyzed; all individuals underwent CBBCT before invasive testing. Random-effects and univariate meta-analysis models were used to pool sensitivity and specificity, and study quality was assessed using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies 2) tool. The pooled sensitivity and specificity of CBBCT were 0.95 (95% CI, 0.91-0.97) and 0.72 (95% CI, 0.62-0.80), respectively, with an AUC of 0.92 (95% CI, 0.90-0.94). In head-to-head comparisons, CBBCT showed higher diagnostic accuracy than DM (AUC, 0.94, 95% CI, 0.92-0.96 vs 0.83, 95% CI, 0.80-0.86) but slightly lower than MRI (AUC, 0.88, 95% CI, 0.85-0.91 vs 0.96, 95% CI, 0.94-0.97). The authors concluded that CBBCT demonstrated significant diagnostic potential for breast cancer detection and showed greater sensitivity and diagnostic accuracy than DM but slightly inferior performance compared with MRI. Key limitations identified by the authors include the small sample sizes of the studies contributing to the meta-analysis and the limited number of head-to-head comparisons between CBBCT and MRI. There are limitations related to study design, as no large, multicenter, prospective trials with standardized acquisition protocols were available, and only studies using both CBBCT and MRI in the same cohorts of individuals were included to minimize selection bias. Measurement limitations include incomplete reporting of individuals' characteristics such as age, ethnicity, and study type, which restricted subgroup analyses and reduced diagnostic agreement among physicians due to limited experience with CBBCT.

Komolafe et al. (2022) performed a systematic review and meta-analysis to evaluate the comparison of the diagnostic accuracy of CBBCT and digital breast tomosynthesis (DBT) to characterize breast cancers. Two independent reviewers identified screening on diagnostic studies from January 1, 2015, to December 30, 2021, with at least reported sensitivity and specificity for both CBBCT (n = 5) and DBT (n = 17). A univariate pooled meta-analysis was performed using the random-effects model to estimate the sensitivity and specificity, while other diagnostic parameters like the area under the ROC curve, positive likelihood ratio (LR+), and negative likelihood ratio (LR-) were estimated using the bivariate model. The pooled sensitivity, specificity, LR+, LR-, and AUC at 95% CI were 86.7% (80.3%-91.2%), 87.0% (79.9%-91.8%), 6.28 (4.40-8.96), 0.17 (0.12-0.25), and 0.925 for the 17 included studies in DBT arm, respectively, while 83.7% (54.6%-95.7%), 71.3% (47.5%-87.2%), 2.71 (1.39-5.29), 0.20 (0.04-1.05), and 0.831 were the pooled sensitivity, specificity, LR+, LR-, and AUC in the five studies in the CBBCT arm, respectively. The authors concluded that their study demonstrates that DBT shows improved diagnostic performance over CBBCT regarding all estimated diagnostic parameters, with the statistical improvement in the AUC of DBT over CBBCT. The CBBCT might be a useful modality for breast cancer detection, thus more prospective studies on CBBCT application were recommended. There are limitations to the studies reviewed. The result of both arms was not extracted from the same studies and compared with a different cohort, which introduces potential bias. The sample size in the CBBCT arm is one-third of that in the DBT arm, thus the CBBCT result is underrepresented. In addition, there are no large, multicenter, prospective or clinical trial studies available. The findings of this study need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of this procedure is proven.

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The 2020 ECRI Clinical Evidence Assessment Report titled *Breast Computed Tomography for Breast Cancer Screening* found limited information to support the use of this technology for breast cancer screening. The authors concluded that the evidence is inconclusive and has no clinical validity or utility data.

Uhlig et al. (2019) published a systematic review of the diagnostic accuracy of CBBCT. Overall, 362 studies were screened, of which six, with 559 individuals, were included. All studies were conducted between 2015 and 2018 and evaluated female individuals. Five studies included noncontrast CBBCT (NC-CBBCT), and three included contrast-enhanced CBBCT (CE-CBBCT). Overall, the study quality was high, except for one study of NC-CBBCT that was presented as a conference abstract and given a lower rating due to the lack of a complete study design and conduct details. There was high between-study heterogeneity among the NC-CBBCT studies (I^2 = 98.4%; 95% CI, 80.6%-94.2%). With NC-CBBCT, the pooled sensitivity was 0.789 (95% CI, 0.66-0.89), and the pooled specificity was 0.697 (95% CI, 0.471-0.851). The NC-CBBCT partial AUC, which was calculated from only regions with reported study specificities and standardized to the whole space, was 0.817. There was no statistically significant heterogeneity among the three studies that evaluated CE-CBBCT (I^2 = 57.3%; 95% CI, 0%-84.1%). Protocols for administration of iodinated intravenous contrast media were different in each study. The pooled sensitivity was 0.899 (95% CI, 0.785-0.956), and the pooled specificity was 0.788 (95% CI, 0.709-0.85). The CE-CBBCT partial AUC was 0.869. The evidence available for CBBCT tends to show superior diagnostic performance for CE-CBBCT over NC-CBBCT regarding sensitivity, specificity, and partial AUC. The diagnostic accuracy of CE-CBBCT was numerically comparable to that of breast MRI, with meta-analyses reporting a sensitivity of 0.9 and specificity of 0.72. The authors concluded that the results are encouraging but that additional further large-scale, prospective studies and long-term follow-up studies are required.

Magnetic Resonance Elastography of the Breast

Researchers have tested the feasibility of breast elastography, and the results confirm the hypothesis that breast elastography can quantitatively depict the elastic properties of breast tissues and reveal high shear elasticity in known breast tumors. However, the clinical benefits of elastography imaging are still under evaluation, and no clinical diagnosis can be made, other than being able to tell whether or not a structure inside the individual is stiffer than another one. Further research is needed to evaluate the potential clinical applications of breast elastography, such as detecting breast carcinoma and characterizing suspicious breast lesions.

Patel et al. (2022) conducted a prospective study to (1) quantify biomechanical tissue properties in various breast densities in average-risk and high-risk women using MRI/magnetic resonance elastography (MRE) and (2) examine the association between breast biomechanical properties and cancer risk based on participant demographics and clinical data. The study included 57 average-risk participants and 86 high-risk participants. In the average-risk group, 50 met the inclusion criteria. All 50 average-risk participants had breast stiffness, elasticity, and viscosity data available for both breasts. Overall, 86 participants met the inclusion criteria in the high-risk portion of the study. In this group, 82 had breast stiffness, elasticity, and viscosity data available for both breasts, and four had these data available for one breast. Among participants with dense breasts, mean stiffness, elasticity, and viscosity were significantly higher in high-risk participants (n = 55) compared with average-risk participants (n = 34; all $p < 0.001$). Stiffness remained a significant predictor of risk status [odds ratio (OR), 4.26; 95% CI, 1.96-9.25], even after controlling for breast density, breast parenchymal enhancement, age, and menopausal status. Similar results were seen for elasticity and viscosity. The authors concluded that structurally based quantitative biomarker of tissue stiffness obtained from MRE is associated with differences in breast cancer risk in dense breasts. Stiffness values could help stratify individuals with dense breasts into those who are at elevated risk and would benefit from increased surveillance with supplemental imaging techniques and/or risk reduction measures.

Siegmann et al. (2010) conducted a prospective study to evaluate the value of adding MRE to contrast-enhanced MRI for evaluating breast lesions in 57 participants. The sensitivity of MRI was 97.3%, whereas the specificity was 55%. If contrast-enhanced MRI was combined with α0 (indicator of tissue stiffness), the diagnostic accuracy could be significantly increased. The authors concluded that combining MRE with MRI increases the diagnostic performance of breast MRI; however, larger studies are needed to validate the results and to identify the individuals who are best suited for a combined procedure.

Magnetic Resonance Imaging of the Breast

A 2026 Hayes Evidence Analysis Research Brief titled *Magnetic Resonance Imaging With Computer-Aided Detection for Identification of Breast Lesions* found sufficient published, peer-reviewed literature to evaluate MRI with computer-aided diagnosis for breast lesion identification. However, the authors stated that conclusions regarding clinical validity and clinical utility could not be determined in the brief, as a full-text evidence review would be required. The analysis included five studies: three cross-sectional studies, one case-control study, and one systematic review with meta-analysis.

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Akwo et al. (2024) conducted a systematic review and meta-analysis to identify the best imaging modality that can be used for the testing of women who are recalled following mammography screening. The imaging modalities that were reviewed included DM, DBT, handheld ultrasound (HHUS), contrast-enhanced mammography (CEM), and MRI in screen-recalled lesions. A total of 54 studies met the inclusion criteria and examined between one and three imaging modalities. The authors' pooled results of each imaging modality demonstrated that CEM has the highest sensitivity (95; 95% CI, 90-97), followed by MRI (93; 95% CI, 88-96), DBT (91; 95% CI, 87-94), HHUS (90; 95% CI, 86-93), and DM (85; 95% CI, 78-90). The DBT demonstrated the highest specificity (85; 95% CI, 75-91), followed by DM (77; 95% CI, 66-85), CEM (73; 95% CI, 63-81), MRI (69; 95% CI, 55-81), and HHUS (65; 95% CI, 46-80). The authors concluded that CEM, MRI, DBT, and HHUS demonstrate excellent performance in correctly identifying and classifying cancer lesions referred for diagnostic workup but that DBT and DM discriminate benign lesions better than CEM, MRI, and ultrasound. The pooled malignant prevalence was much higher than that in typical screening populations. This likely inflates the sensitivity and specificity, as it is being used for diagnostic callbacks rather than initial screening. Additional studies, including head-to-head trials embedded in screening pathways, are warranted to confirm these findings.

Zeng et al. (2021) conducted a systematic review of published literature to explore the effect of supplemental screening (MRI or breast ultrasound) compared with mammography alone on cancer detection and interval cancer rates (ICRs). A further aim was to identify specific groups in which supplemental screening is most effective at reducing the ICR. This study reviewed the evidence that evaluated the effect of supplemental imaging on ICR in women who were undergoing screening mammography. This systematic review included studies that reported both cancer detection rate (CDR) and ICR in women who were undergoing screening mammography alone compared with those who were undergoing screening mammography with supplemental imaging. Five studies (three randomized trials) were eligible. These reported on 142,153 women who were undergoing mammography screening alone or mammography with supplemental imaging (three ultrasound and two MRI studies). Two studies included a general screening population, and three included special populations (young, high genetic risk, and/or dense breasts). The incremental CDR for supplemental MRI was 14.2 to 16.5 per 1,000 screens and for ultrasound was 0 to 4.4 per 1,000 screens. The effect on ICR was variable, but evidence of a reduced ICR was more consistent for studies using supplemental MRI (ICR, 0.3-0.8 per 1,000 screens) than those using ultrasound (ICR, 0.49-1.9 per 1,000 screens). The higher CDR and lower ICR with supplemental screening were associated with higher recall and biopsy rates, particularly with supplemental MRI (9.5%-15.9%; up to 69 per 1,000 screens). The authors concluded that cancers that were detected with supplemental imaging modalities were generally smaller and earlier stage. Mammography with supplemental MRI or ultrasound increases detection of cancers (vs mammography only) in some subgroups, increases recall and biopsy rates, and may have a relatively modest effect in reducing ICRs. Limitations include a small number of studies and the heterogeneity of the studies.

Molecular Breast Imaging

The published literature on molecular breast imaging (MBI) is limited by a number of factors. The studies include populations that usually do not represent those encountered in clinical practice and that have mixed indications. There are methodological limitations in the available studies, which have been judged to have a medium to high risk of bias, and they lack information on the impact on therapeutic efficacy. Limited evidence on the diagnostic accuracy of molecular imaging reports that these tests have a relatively high sensitivity and specificity for detecting malignancy. However, the evidence does not establish that this imaging improves outcomes when used as an adjunct to mammography for breast cancer screening. Larger, higher-quality studies are required to determine whether molecular imaging has a useful role as an adjunct to mammography.

Kalakattawi et al. (2025) conducted a systematic review and meta-analysis that evaluated the diagnostic accuracy of breast-specific gamma imaging (BSGI), MRI, mammography, and ultrasound for detecting breast lesions and their associations with molecular subtypes of breast cancer. The population included women with suspected breast lesions, and studies that were published between January 2014 and October 2024 were retrieved from the PubMed, Embase, and Cochrane databases; the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed. Nine studies met the inclusion criteria, encompassing both retrospective and prospective designs, with sample sizes ranging from 162 to 2,482 individuals. Diagnostic outcomes were defined as true or false positive or negative, forming the basis for calculating sensitivity, specificity, and predictive values, and pooled analyses were conducted using STATA V.14.0 with the QUADAS-2 quality assessment. BSGI demonstrated a pooled sensitivity of 0.91 and specificity of 0.81, with a diagnostic OR of 4.90 (95% CI, 3.12-7.68), outperforming mammography (77.3% sensitivity; 74.5% specificity) and ultrasound (82.1% sensitivity; 70.8% specificity); MRI showed the highest sensitivity at 92.5% but lower specificity at 69.7%. The prespecified secondary end points included correlation of imaging findings with molecular subtypes such as *HER2* (human epidermal growth factor receptor)–positive and triple-negative cancers. The authors concluded that integrating advanced imaging modalities such as BSGI and MRI into clinical workflows can improve diagnostic accuracy and early detection of breast lesions, particularly in dense breast tissues, supporting personalized treatment strategies. Limitations that were identified by the authors include potential selection bias and incomplete indexing of studies, which may have affected the methodological rigor and reliability of the systematic review. There are

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limitations related to imaging performance, including MRI's lower specificity that can lead to false positives and overestimation of disease extent, as well as ultrasound's operator-dependent variability in diagnostic accuracy. Additional limitations involve variability in tumor metabolism or imaging parameters that could influence comparative results and restrict the generalizability of findings across different clinical settings. (De Feo et al., 2022, Kim 2012, and Cho et al., 2016, previously cited in this policy, are included in this systematic review.)

Li et al. (2023) conducted a systematic review and meta-analysis to evaluate the diagnostic test accuracy of different imaging modalities for axillary lymph node metastases in individuals with breast cancer. The modalities in the analysis included ultrasonography (US), MRI, mammography, ultrasound elastography (UE), positron emission tomography (PET), CT, PET/CT, scintimammography, and PET/MRI. Overall, 61 studies met the inclusion criteria. On the individual-based level, the authors' findings identified that UE had the highest superiority index (5.95), with the highest relative sensitivity of 1.13 (95% CI, 0.93-1.29) among all imaging methods, compared with US. At the lymph node level, MRI had the highest superiority index (6.91), with the highest relative sensitivity of 1.13 (95% CI, 1.01-1.23) and highest relative specificity of 1.11 (95% CI, 0.95-1.23) among all imaging methods compared with US. The authors concluded that UE and MRI had better diagnostic value than the other imaging modalities for the diagnosis of axillary lymph node metastases in individuals with breast cancer at the individual level and the lymph node level, respectively. Limitations in the study include a small sample size, limited data on some of the imaging modalities, lack of standardization of imaging protocols, and patient subgroup analysis of factors such as tumor type or body mass index. Further studies are needed to provide high-quality evidence to validate the findings.

Zhang and Xiao (2018) conducted a network meta-analysis that compared the diagnostic value of 19 imaging methods for breast cancer. Included studies were diagnostic test studies that enrolled Chinese individuals who were aged 12 to 92 years and had a possible breast lesion that was detected by self-examination, physical examination, or screening mammography; individuals underwent imaging before final diagnosis, which was confirmed by histopathologic examination. Overall, 39 diagnostic tests met the inclusion criteria, comprising 2,890 individuals who were diagnosed with breast cancer using the gold standard and covering 19 imaging methods (including mammography, BSGI, contrast-enhanced MRI, MRI, magnetic resonance mammography, scintimammography, UE, US, and combinations such as mammography plus US, mammography plus scintimammography, and UE plus US). The network meta-analysis combined direct and indirect comparisons using bayesian methods to estimate ORs and draw the surface under the cumulative ranking curves rankings, with node-splitting indicating consistency between direct and indirect evidence (all $p > 0.05$) and a consistency model adopted. For the primary outcomes of diagnostic performance (sensitivity, specificity, positive predictive value, negative predictive value, and accuracy), compared with mammography, MRI had higher sensitivity (OR, 4.00; 95% CI, 2.72-5.89; $p = 0.000$), and US had higher sensitivity (OR, 1.84; 95% CI, 1.52-2.23; $p = 0.000$). The authors concluded that BSGI, mammography plus scintimammography, MRI, and contrast-enhanced MRI had relatively higher diagnostic value for breast cancer in terms of sensitivity, specificity, and accuracy. Limitations identified by the authors include limited references; data that prevented sufficient direct comparisons between individual imaging methods; and the predominance of low-quality included studies. Chinese literature was not retrieved due to failure to conform to the QUADAS-2 quality standard, which may have affected the network meta-analysis results. Variations in test technology, execution, or interpretation may have influenced estimates of diagnostic accuracy.

Guo et al. (2016) conducted a systematic review and meta-analysis study to establish if technetium-99m sestamibi scintimammography is useful in the prediction of neoadjuvant chemotherapy responses in breast cancer. Electronic databases were searched for relevant publications in English, and 14 studies, for a total of 503 individuals, fulfilled the inclusion criteria. The results indicated that technetium-99m sestamibi scintimammography had acceptable sensitivity in the prediction of neoadjuvant chemotherapy response in breast cancer; however, its relatively low specificity showed that a combination of other imaging modalities would still be needed. A subgroup analysis indicated that performing early midtreatment technetium-99m sestamibi scintimammography (using the reduction rate of one or two cycles or within the first half-courses of chemotherapy compared with the baseline) was better than carrying out later (after three or more courses) or posttreatment scintimammography in the prediction of neoadjuvant chemotherapy response.

Clinical Practice Guidelines

American Cancer Society (ACS)

The ACS recommendation for breast cancer early detection and diagnosis states that breast ultrasound is useful for looking at some breast changes, such as lumps (especially those that can be felt but not seen on a mammogram). Ultrasound can be especially helpful in women with dense breast tissue, which can make it hard to see abnormal areas on mammograms. It also can be used to get a better look at a suspicious area that was seen on a mammogram. Ultrasound is useful because it can often tell the difference between fluid-filled masses like cysts and solid masses. (ACS, 2022)

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The ACS guidelines for breast cancer screening state that scintimammography, PET, and electrical impedance imaging have received U.S. Food and Drug Administration approval as diagnostic adjuncts to mammography. None of these new technologies have successfully undergone clinical testing that would justify their use in screening for breast cancer. (Oeffinger et al., 2015)

The ACS guideline on breast cancer screening for women at average risk specifically recommends against annual MRI screening in women at less than a 15% lifetime risk of breast cancer. (Oeffinger et al., 2015)

American College of Obstetricians and Gynecologists (ACOG)

In 2020, ACOG reaffirmed their recommendation for routine screening with the use of DM for women who are diagnosed with dense breasts. They do 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 College strongly supports additional research to identify more effective screening methods that will enhance meaningful improvements in cancer outcomes in women with dense breasts and minimize false-positive screening results. ACOG also 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.

American College of Radiology (ACR)

A 2024 update to the ACR Appropriateness Criteria on supplemental breast cancer screening based on breast density states that supplemental screening may be considered based on the patient's risk level and breast density. The ACR's recommendations include average-risk women with heterogeneously dense tissue, intermediate-risk women with nondense tissue, and intermediate-risk women with heterogeneously dense and extremely dense tissue. Breast MRI or abbreviated breast MRI is usually appropriate in all high-risk women regardless of density. (Paulis et al., 2025)

The 2023 updated ACR recommendations on breast cancer screening for women at higher-than-average risk state the following:

- All women should undergo risk assessment by age 25 years, especially Black women and women of Ashkenazi Jewish heritage.
- For most women at a higher-than-average risk, the supplemental screening method of choice is breast MRI. For those who qualify for but cannot undergo breast MRI, CEM or ultrasound could be considered.
- Women with genetic mutations (and their untested first-degree relatives) or those with a calculated lifetime risk of 20% or more should undergo annual DM, with or without DBT, starting at age 30 years and annual MRI starting at ages 25 to 30 years. Mutation carriers can delay mammographic screening until age 40 years if annual breast MRI is performed as recommended. Women who are exposed to a cumulative chest radiation therapy dose of ≥ 10 Gy by age 30 years should undergo annual mammography starting at age 25 years or 8 years after radiation therapy, whichever is later, and annual breast MRI beginning at ages 25 to 30 years.
- Women who are diagnosed with breast cancer before age 50 years or with a personal history of breast cancer and dense breasts should undergo annual supplemental screening with breast MRI. Others with a personal history should strongly consider supplemental screening with MRI, especially if other risk factors are present. For women with dense breasts who desire supplemental screening, breast MRI is recommended. Women with atypia or lobular carcinoma in situ should consider supplemental surveillance with MRI, especially if other risk factors are present.

(Monticciolo et al., 2023)

The ACR Appropriateness Criteria for breast cancer screening consider MRI for screening high-risk women, including women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, and women with 20% or greater lifetime risk of breast cancer, to usually be appropriate. (Mainiero et al., 2017)

According to the practice parameter for the performance of MBI using a dedicated gamma camera, there is insufficient evidence to support the use of BSGI. Also, the relatively high radiation dose that is currently associated with BSGI/MBI has prompted the ACR to recommend against the use for screening. (ACR, 2017; revised 2022)

American Society of Breast Surgeons (ASBrS)

A consensus guideline by the ASBrS on diagnostic and screening MRI of the breast (2017) also supports the use of MRI as a screening technique in women. The guideline particularly supports women who are aged 25 years or older with a BRCA gene mutation, women with other germline mutations known to predispose to a high risk of breast cancer, women with a history of chest irradiation, and women with a 20% to 25% or greater estimated lifetime risk of breast cancer based on models that are primarily based on family history.

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European Society of Breast Imaging (EUSOBI)

Breast density is an independent risk factor for the development of breast cancer and also decreases the sensitivity of mammography for screening. Consequently, women with extremely dense breasts face an increased risk of late diagnosis of breast cancer. Therefore, these women are underserved with current mammographic screening programs. The results of recent studies that report on contrast-enhanced breast MRI as a screening method in women with extremely dense breasts provide compelling evidence that this approach can enable an important reduction in breast cancer mortality in these women and is cost-effective. Because there is now a valid option to improve breast cancer screening, EUSOBI recommends that women should be informed about their breast density. EUSOBI thus calls on all providers of mammography screening to share density information with the women who are being screened. Considering the available evidence, in women aged 50 to 70 years with extremely dense breasts, EUSOBI now recommends offering screening breast MRI every 2 to 4 years. EUSOBI acknowledges that it may currently not be possible to offer breast MRI immediately and everywhere and underscores that quality assurance procedures need to be established; EUSOBI urges radiological societies and policymakers to act on this now. Since the wishes and values of individual women differ, in screening, the principles of shared decision-making should be embraced. Women should be counseled on the benefits and risks of mammography and MRI-based screening so that they can make an informed choice about their preferred screening method. (Mann et al., 2022)

National Comprehensive Cancer Network® (NCCN®)

The 2024 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer Screening and Diagnosis state the following:

- Supplemental screening with breast MRI with and without contrast, abbreviated breast MRI with and without contrast, ultrasound, MBI, or CEM can increase CDRs but may increase recalls and benign breast biopsies.
- For patients who are at a high risk for breast cancer and cannot undergo breast MRI, supplemental screening with CEM or MBI should be considered. Whole-breast ultrasound may be done if contrast-enhanced imaging or functional imaging is not available/accessible.
- Limited data exist regarding the use of CEM for breast cancer screening. In patients who are at an increased risk for breast cancer, CEM increases CDR compared with mammography alone. CEM carries the risk of iodinated contrast reactions (reaffirmed 2025).

The 2021 NCCN Guidelines® for Breast Cancer Screening and Diagnosis state, “Current evidence does not support the routine use of molecular imaging (e.g., breast-specific gamma imaging, sestamibi scan, or positron emission mammography) as screening procedures, but there is emerging evidence that these tests may improve detection of early breast cancers among women with mammographically dense breasts. However, the whole-body effective radiation dose with these tests is substantially higher than that of mammography.”

Society of Breast Imaging (SBI)/American College of Radiology (ACR)

The 2010 SBI and ACR recommendation for breast cancer screening with breast ultrasound states the following:

- Can be considered in high-risk women for whom MRI screening may be appropriate but who cannot have MRI for any reason
- Can be considered in women with dense breast tissue as an adjunct to mammography

(Lee et al., 2010)

Society of Nuclear Medicine and Molecular Imaging (SNMMI)

The SNMMI published a procedure standard (2010) for breast scintigraphy with breast-specific gamma cameras that indicates that further study is needed to determine the population that is most likely to benefit from this procedure and the usefulness. This guideline lists potential indications and cites references for each indication but does not provide a systematic review of the literature, including assessment of study quality. The guideline is based on consensus, and most of it is devoted to procedures and specifications of the examination, documentation and recording, quality control, and radiation safety.

Society of Nuclear Medicine and Molecular Imaging (SNMMI)/European Association of Nuclear Medicine (EANM)

In the 2022 *Practice Guideline for Molecular Breast Imaging With Dedicated Gamma-Cameras*, the SNMMI and EANM state that for breast cancer screening, MBI has been useful in detecting mammographically occult breast cancer in women with dense breast tissue (heterogeneously or extremely dense on mammography) and in women who are at an elevated risk for breast cancer and are unable to undergo breast MRI screening.

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U.S. Preventive Services Task Force (USPSTF)

The 2024 USPSTF recommendation statement on screening for breast cancer states that the evidence is insufficient to determine the balance of benefits and harms of supplemental screening for breast cancer with breast US or MRI in women who have a negative screening mammogram result regardless of breast density.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Mammographic x-ray systems are classified as Class II devices. The FDA regulates the marketing of mammography devices and regulates the use of such devices via the Mammography Quality Standards Act. The FDA has granted premarket approval to several digital mammography systems (product code MUE) for breast cancer screening and diagnosis.

Breast-Specific Gamma Imaging

Breast-specific gamma imaging (BSGI) for diagnosing breast cancer is a procedure and therefore is not subject to FDA regulation. However, the equipment used to conduct BSGI is subject to FDA regulation. The cameras used during BSGI are considered Class I radiological devices. A scintillation (gamma) camera is a device that is intended to image the distribution of radionuclides in the body by means of a photon radiation detector. Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2026)

Computer-Aided Detection for Magnetic Resonance Imaging of the Breast

Refer to the following website for more information on devices used for computer-aided detection for MRI of the breast (search by product name in the device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2026)

Computer-Aided Detection for Ultrasound

Refer to the following website for more information on devices used for computer-aided detection for ultrasound (search by product names MYN and LLZ in the device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2026)

Computed Tomography of the Breast

Refer to the following website for more information on devices used for computed tomography of the breast (search by product name JAK in the device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2026)

Magnetic Resonance Elastography of the Breast

Refer to the following website for more information on devices used for elastography of the breast (search by product name LNH in the device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2026)

References

Akwo J, Hadadi I, Ekpo E. Diagnostic efficacy of five different imaging modalities in the assessment of women recalled at breast screening- a systematic review and meta-analysis. Cancers (Basel). 2024 Oct;16(20):3505.

American College of Obstetricians and Gynecologists (ACOG). Management of women with dense breasts diagnosed by mammography. Reaffirmed 2020.

American College of Radiology (ACR). Appropriateness Criteria: supplemental breast cancer screening based on breast density. September 2024.

American College of Radiology (ACR). Practice parameter for the performance of molecular breast imaging (MBI) using a dedicated gamma camera. 2017; revised 2022.

American Society of Breast Surgeons (ASBrS). Consensus guideline on diagnostic and screening magnetic resonance imaging of the breast. 2017.

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Cho KR, Seo BK, Woo OH, et al. Breast cancer detection in a screening population: comparison of digital mammography, computer-aided detection applied to digital mammography and breast ultrasound. J Breast Cancer. 2016 Sep;19(3):316-323.

De Feo MS, Sidrak MMA, Conte M, et al. Breast-specific gamma imaging: an added value in the diagnosis of breast cancer, a systematic review. Cancers (Basel). 2022 Sep;14(19):4619.

ECRI. Breast Computed Tomography for Breast Cancer Screening. Plymouth Meeting (PA): ECRI; 2020 Dec. (Evidence Analysis).

Gong W, Zhu J, Hong C, et al. Diagnostic accuracy of cone-beam breast computed tomography and head-to-head comparison of digital mammography, magnetic resonance imaging and cone-beam breast computed tomography for breast cancer: a systematic review and meta-analysis. Gland Surg. 2023 Oct;12(10):1360-1374.

Guo C, Zhang C, Liu J, et al. Is Tc-99m sestamibi scintimammography useful in the prediction of neoadjuvant chemotherapy responses in breast cancer? A systematic review and meta-analysis. Nucl Med Commun. 2016 Jul;37(7):675-688.

Hayes, Inc. Evidence Analysis Research Brief. Magnetic resonance imaging with computer-aided detection for identification of breast lesions. Lansdale, PA: Hayes, Inc.; April 2026.

Kalakattawi R, Gowharji L, Marzogi A, et al. Evaluating diagnostic technologies for breast lesions: a focused review of breast-specific gamma imaging, magnetic resonance imaging, mammography, and ultrasound with molecular subtype insights. Biomed Pharmacol J. 2025;18(1).

Kim BS. Usefulness of breast-specific gamma imaging as an adjunct modality in breast cancer patients with dense breast: a comparative study with MRI. Ann Nucl Med. 2012 Feb;26(2):131-137.

Komolafe TE, Zhang C, Olagbaju OA, et al. Comparison of diagnostic test accuracy of cone-beam breast computed tomography and digital breast tomosynthesis for breast cancer: a systematic review and meta-analysis approach. Sensors (Basel). 2022 May;22(9):3594.

Lee CH, Dershaw DD, Kopans 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.

Li Z, Gao Y, Gong H, et al. Different imaging modalities for the diagnosis of axillary lymph node metastases in breast cancer: a systematic review and network meta-analysis of diagnostic test accuracy. J Magn Reson Imaging. 2023 May;57(5):1392-1403.

Mainiero MB, Moy L, Baron P, et al. ACR Appropriateness Criteria® breast cancer screening. J Am Coll Radiol. 2017 Nov;14(11S):S383-S390.

Mann RM, Athanasiou A, Baltzer PAT, et al. Breast cancer screening in women with extremely dense breasts recommendations of the European Society of Breast Imaging (EUSOBI). Eur Radiol. 2022 Jun;32(6):4036-4045.

Monticciolo DL, Newell MS, Moy L, et al. Breast cancer screening for women at higher-than-average risk: updated recommendations from the ACR. J Am Coll Radiol. 2023 Sep;20(9):902-914.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: breast cancer screening and diagnosis. April 2024; reaffirmed 2025.

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: breast cancer screening and diagnosis. May 2021.

Oeffinger KC, Fontham ET, Etzioni R, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society. JAMA. 2015 Oct;314(15):1599-1614.

Patel BK, Pepin K, Brandt KR, et al. Association of breast cancer risk, density, and stiffness: global tissue stiffness on breast MR elastography (MRE). Breast Cancer Res Treat. 2022 Jul;194(1):79-89.

Paulis LV, Lewin AA, Weinstein SP, et al. ACR Appropriateness Criteria® supplemental breast cancer screening based on breast density: 2024 update. J Am Coll Radiol. 2025 May;22(5S):S405-S423.

Sickles EA, D'Orsi CJ, Bassett LW, et al. ACR BI-RADS Mammography. In: ACR BI-RADS Atlas, Breast imaging reporting and data system. Reston, Virginia, American College of Radiology; 2013.

Siegmann KC, Xydeas T, Sinkus R, et al. Diagnostic value of MR elastography in addition to contrast-enhanced MR imaging of the breast-initial clinical results. Eur Radiol. 2010 Feb;20(2):318-325.

Society of Nuclear Medicine and Molecular Imaging (SNMMI) and European Association of Nuclear Medicine (EANM). Practice guideline for molecular breast imaging with dedicated gamma-cameras. January 2022.

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Society of Nuclear Medicine and Molecular Imaging (SNMMI). Procedure guideline for breast scintigraphy with breast-specific gamma cameras. V1. June 2010.

Tasoulis MK, Zacharioudakis KE, Dimopoulos NG, et al. Diagnostic accuracy of tactile imaging in selecting patients with palpable breast abnormalities: a prospective comparative study. Breast Cancer Res Treat. 2014 Oct;147(3):589-598.

Uhlig J, Uhlig A, Biggemann L, et al. Diagnostic accuracy of cone-beam breast computed tomography: a systematic review and diagnostic meta-analysis. Eur Radiol. 2019 Mar;29(3):1194-1202.

US Preventive Services Task Force. Screening for breast cancer: US Preventive Services Task Force recommendation statement. JAMA. 2024;331(22):1918-1930.

Yang L, Zhou Z, Wang J, et al. Head-to-head comparison of cone-beam breast computed tomography and mammography in the diagnosis of primary breast cancer: a systematic review and meta-analysis. Eur J Radiol. 2024 Feb;171:111292.

Zeng A, Brennan ME, Young S, et al. The effect of supplemental imaging on interval cancer rates in mammography screening: systematic review. Clin Breast Cancer. 2022 Apr;22(3):212-222.

Zhang XH and Xiao C. Diagnostic value of nineteen different imaging methods for patients with breast cancer: a network meta-analysis. Cell Physiol Biochem. 2018;46(5):2041-2055.

Policy History/Revision Information

Date	Summary of Changes

11/01/2026	**Coverage Rationale**
	• Revised list of unproven and not medically necessary indications; replaced:
	  ○ "Magnetic Resonance Elastography" with "Magnetic Resonance Elastography *of the Breast*"
	  ○ "Molecular Breast Imaging (e.g., breast specific gamma imaging, scintimammography, Positron Emission Mammography)" with "Molecular Breast Imaging (e.g., breast specific gamma imaging, scintimammography) *for routine screening in normal or high-risk individuals or* Positron Emission Mammography"
	Definitions
	• Removed definition of "Breast Specific Gamma Imaging (BSGI)"
	• Updated definition of "Molecular Breast Imaging"
	Supporting Information
	• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version 2026D0375LL

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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