Breast Imaging for Screening and Diagnosing Cancer (for Louisiana Only)

Policy Number: CS010LA.T
Effective Date: July 18, 2024

Instructions for Use

Certain content mandated by Louisiana Department of Health

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Application

This Medical Policy only applies to the state of Louisiana. Portions of the coverage rationale contained in this policy represents Louisiana Medicaid coverage policy and is set forth below in accordance with state requirements.

Coverage Rationale

State-Specific Criteria

Screening Mammography

Louisiana Medicaid allows payment for one screening mammogram (either film or digital) per calendar year for beneficiaries meeting one of more of the following criteria:

- Any woman age 30 or older with hereditary susceptibility from pathogenic mutation carrier status or prior chest wall radiation; or
- Provider recommendation for any woman 35 years of age or older with a predicted lifetime risk greater than 20 percent; or
- Any woman who is 35 through 39 years of age (**Note**: Only one baseline mammogram is allowable between this age range for beneficiaries not meeting other criteria.); or
- Any woman who is 40 years of age or older

Providers should perform the most clinically appropriate method (film or digital) specific to the beneficiary.

Magnetic Resonance Imaging (MRI)

Under the following instances, Louisiana Medicaid may also reimburse for an annual magnetic resonance imaging (MRI):

- Women at least 25 years of age with hereditary susceptibility from pathogenic mutation carrier status or prior chest wall radiation; or
- Provider recommendation for any woman 35 years of age or older with a predicted lifetime risk greater than 20 percent; or
- Any woman 40 or older, with increased breast density (C and D density), if recommended by their physician; or
- Women with a prior history of breast cancer below 50 years of age; or
- Women with a prior history of breast cancer at any age and dense breast (C and D density)

Note: A breast ultrasound is the initial preferred modality, followed by MRI if found to be inconclusive, in this instance.

(Louisiana Department of Heath Medicaid Services Manual, 2024)

Non State-Specific Criteria

The following are proven and medically necessary:

- Diagnostic breast ultrasound
- Digital mammography for individuals with dense breast tissue

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

- Automated Breast Ultrasound system
- Computer-aided detection (CAD)
- Computer-Aided Tactile Breast Imaging
- Computed tomography (CT) of the breast
- Electrical Impedance Scanning (EIS)
- Magnetic Resonance Elastography (MRE)
- Molecular Breast Imaging (e.g., Breast Specific Gamma Imaging, scintimammography, Positron Emission Mammography)

Note: For breast computed tomography (CT) and 3D rendering of the breast, refer to the Breast Imaging Guidelines section of the Cardiovascular and Radiology Imaging Guidelines.

Definitions

Automated Breast Ultrasound (ABUS): ABUS systems are ultrasound imaging platforms that use high-frequency broadband transducers to automate the acquisition of volume data to provide two-dimensional (2D) and three-dimensional (3D) B-mode images of breast tissue. ABUS is used as an adjunct to mammography. The high center-frequency significantly sharpens detail resolution while the ultra-broadband performance simultaneously delivers distinct contrast differentiation (ECRI, 2021).

Breast Specific Gamma Imaging (BSGI): BSGI, also known as scintimammography (SMM) or molecular breast imaging (MBI) is a noninvasive diagnostic technology that detects tissues within the breast that accumulate higher levels of a radioactive tracer that emit gamma radiation. The test is performed with a gamma camera after intravenous administration of radioactive tracers. Scintimammography has been proposed primarily as an adjunct to mammography and physical examination to improve selection for biopsy in patients who have palpable masses or suspicious mammograms (ACS, 2022).

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 hand-held sensor across the breast and underarm area, data signals are then processed into multi-dimensional 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 (ACS, 2022).

Electrical Impedance Scanning (EIS): EIS was developed as a confirmatory test to be used in conjunction with mammography. The device detects abnormal breast tissue using small electrical currents. Since malignant tissue tends to conduct more electricity than normal tissue, the electrical current produced creates a conductivity map of the breast which automatically identifies sites that appear suspicious. The transmission of electricity into the body is via an electrical patch on the arm or a handheld device which travels to the breast. This is measured by a probe on the surface of the skin (ACS, 2022).

Magnetic Resonance Elastography (MRE) of the Breast: MRE of the breast is a phase-contrast-based MRI technique that is based upon quantitative differences in the mechanical properties of normal and malignant tissues. Specifically, the elastic modulus of breast cancer tissue is approximately 5- to 20-fold higher than that of the surrounding fibro glandular 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. MRE is performed by a radiologist in an MRI suite equipped with the electromechanical driver and integrated radiofrequency coil unit (ACS, 2022).

Molecular Breast Imaging (MBI): Procedure that uses a radioactive tracer and special camera to find breast cancer. Rather than simply taking a picture of a breast, molecular breast imaging is a type of functional imaging. This means that the pictures it creates show differences in the activity of the tissue (ACS, 2022).

Positron Emission Mammography (PEM): PEM is a new imaging modality that has higher resolution than PET-CT and can be performed on patients unable to have an MRI scan. PEM performs high- resolution metabolic imaging for breast cancer using an FDG tracer. The PEM 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 federal, state, or contractual requirements 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 (CAD) is included with the MRI breast CPT code 77048 and 77049 procedures. If CAD 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)
76499	Unlisted diagnostic radiographic procedure
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited
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
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
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral

CPT Code	Description
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed

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

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program.

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 exam, 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, has led to the investigation of several novel methods of breast imaging for breast cancer management.

Clinical Evidence

Automated Breast Ultrasound System (ABUS)

Clinical evidence is inconclusive to show whether automated breast ultrasound improves the detection rate of breast cancer in comparison to screening mammography and handheld ultrasound. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology.

In a Clinical Evidence Assessment, ECRI (2022) concluded that the evidence for breast ultrasound using an automated system for cancer screening in women with dense breast tissue was inconclusive due to lack of data addressing clinical utility. The evidence suggests that screening mammography plus ABUS increases breast cancer detection rate among women with dense breasts and increases recall and biopsy rates, which could increase anxiety and cost. Studies suggest similar detection rates between ABUS and HHUS; whether ABUS offers benefits over HHUS is unclear because too few data are available.

In the 2021 ECRI Clinical Evidence Assessment Report, Automated Breast Ultrasound Systems for Diagnosing Breast Cancer found that evidence shows that ABUS is as accurate as handheld ultrasound (HHUS) for detecting breast cancer in women with palpable masses, breast cancer symptoms, or abnormalities seen on a screening mammogram. However, too few data are available to determine whether ABUS provides any benefit over HHUS in terms of accuracy or care delivery. Clinical utility studies with randomly assigned patient groups are needed to assess ABUS's potential benefits and drawbacks and should report longer-term clinical outcomes (e.g., quality of life) as well as shorter-term measures of procedure time, pain, patient satisfaction, and cost-effectiveness.

In a meta-analysis of studies comparing the diagnostic performance of mammography (MG) alone versus MG combined with adjunctive imaging studies, Hadadi et al. (2021) determined that adding adjunctive modalities to MG for women with dense breasts significantly increased cancer detection rates (CDRs). The authors reviewed 41 published studies with an overall sample size of 228,508 participants that compared MG alone with MG combined with handheld ultrasound (HHUS), automated breast ultrasound (ABUS), digital breast tomosynthesis (DBT), contrast-enhanced mammography (CEM) and/or magnetic resonance imaging (MRI). Four studies (n = 23,596) compared the performance between MG and MG plus ABUS although the authors noted that none of the studies reported diagnostic accuracy for non-dense breasts. When evaluating the CDRs, the authors reported that the CDR was found to be significantly higher when using MG plus ABUS compared to MG alone and that the recall rate was approximately doubled for MG plus ABUS than for MG alone. In women with dense breasts, the authors determined that the four studies showed in increase in CDRs ranging from 27% to 105% when ABUS was used as an adjunct to MG. Limitations noted in these studies included the fact that 2 of the 4

studies included higher proportions of women at high-risk which may have contributed to the recall rate, and that 3 of the studies had lower thresholds for recall. The authors concluded that adjunctive breast imaging modalities, including ABUS, increased cancer detection in women with dense and non-dense breasts.

A comparison study by Chen et al. (2021) was performed to evaluate the dependability of automated breast ultrasound (ABUS) compared with handheld ultrasound (HHUS) and mammography (MG) on the Breast Imaging Reporting and Data System (BI-RADS) category and size assessment of malignant breast lesions. A total of 344 confirmed malignant lesions were recruited. All participants underwent MG, HHUS, and ABUS examinations. Agreements on the BI-RADS category were evaluated. Lesion size assessed using the three methods was compared with the size of the pathological result as the control. Regarding the four major molecular subtypes, correlation coefficients between size on imaging and pathology were also evaluated. The agreement between ABUS and HHUS on the BI-RADS category was 86.63% (kappa = 0.77), whereas it was 32.22% (kappa = 0.10) between ABUS and MG. Imaging lesion size compared to pathologic lesion size was assessed correctly in 36.92%/52.91% (ABUS), 33.14%/48.84% (HHUS) and 33.44%/43.87% (MG), with the threshold of 3 mm/5 mm, respectively. The correlation coefficient of size of ABUS-Pathology (0.75, Spearman) was higher than that of the MG-Pathology (0.58, Spearman) with $p < 0.01$, but not different from that of the HHUS-Pathology (0.74, Spearman) with $p > 0.05$. The correlation coefficient of ABUS-Pathology was higher than that of MG-Pathology in the triple-negative subtype, luminal B subtype, and luminal A subtype ($p < 0.01$). The authors concluded that the agreement between ABUS and HHUS in the BI-RADS category was good, whereas that between ABUS and MG was poor. ABUS and HHUS allowed a more accurate assessment of malignant tumor size compared to MG. Limitations include single-factor analysis, retrospective observations, and a small sample size making it difficult to decide whether these conclusions can be generalized to a larger population.

A prospective observation study was completed by Gatta et al. (2021) to evaluate the performance and cancer detection rate of mammography alone or with the addition of 3D prone automated breast ultrasonography (ABUS) in women with dense breasts. The study was based on the screening of 1,165 asymptomatic women with dense breasts who selected independent of risk factors. The results evaluated include the cancers detected between June 2017 and February 2019, and all surveys were subjected to a double reading. Mammography detected four cancers, while mammography combined with a prone Sofia system (3D ABUS) doubled the detection rate, with eight instances of cancer being found. The diagnostic yield difference was 3.4 per 1,000. Mammography alone was subjected to a recall rate of 14.5 for 1,000 women, while mammography combined with 3D prone ABUS resulted in a recall rate of 26.6 per 1,000 women. An additional 12.1 recalls per 1,000 women screened was observed. The authors concluded that integrating full-field digital mammography (FFDM) with 3D prone ABUS in women with high breast density increases and improves breast cancer detection rates in a significant manner, including small and invasive cancers, and it has a tolerable impact on recall rate. Moreover, 3D prone ABUS performance results are comparable with the performance results of the supine 3D ABUS system. Limitations include being a descriptive prospective mono-center study with a small sample size making it difficult to decide whether these conclusions can be generalized to a larger population. Further investigation is needed before clinical usefulness of this procedure is proven.

A prospective comparison study by Güldogan et al. (2021) was performed to compare the diagnostic performance of an automated breast ultrasound system (ABUS) with hand-held ultrasound (HHUS) in the detection and characterization of lesions regarding BI-RADS classification in women with dense breasts. After ethical approval, from July 2017 to August 2019, 592 consecutive patients were enrolled in this prospective study. On the same day, patients underwent ABUS followed by HHUS. Three breast radiologists participated in this study. The number and type of lesions and BI-RADS categorization of both ABUS and HHUS examinations of each patient were recorded in an excel file. The level of agreement between the two ultrasound systems in terms of lesion number and BI-RADS category were analyzed statistically. ABUS and HHUS detected 1,005 and 1,491 cystic and 270 and 336 mass lesions in 592 patients respectively. ABUS and HHUS detected 171 and 167 positive/suspicious cases (BIRADS 0/3/4/5). Forty suspicious lesions underwent core needle biopsy whereas 11 malignant lesions were detected by both methods. The remaining lesions were followed with a mean of 31 months. The mean size of solid lesions detected by HHUS and ABUS was 7.67 mm (range 2.1-41 mm) and 7.74 mm (range 2-42 mm) respectively. The agreement for detection of cystic lesions between two methods for each breast was good (kappa: 0.61-0.62 $p < 0.001$). The agreement of two methods for solid mass lesions for each breast was moderate ($k = 0.57$-0.60 $p < 0.001$). There was good agreement between the two methods for detecting suspicious lesions (kappa = 0.66 $p < 0.001$). The authors concluded that the level of agreement of ABUS and HHUS for dichotomic assignment of BI-RADS categories was good. Although ABUS detected fewer lesions compared to HHUS, both methods detected all malignant lesions. The authors stated that ABUS is a reliable method for the detection of malignancy in dense breasts. All researchers were well experienced in HHUS, and new in interpreting ABUS images. This may have caused bias in determining the BI-RADS category of lesions for HHUS. Limitations include being a single-center study, low volume of cancer cases, and the included patients were imaged by a single radiologist.

Hellgren et al. (2017) conducted a study to compare the sensitivity and specificity of Automated Breast Volume Scanners (ABVS) to handheld breast US for detection of breast cancer in the situation of recall after mammography screening. A total of 113 women, five with bilateral suspicious findings, undergoing handheld breast US due to a suspicious mammographic finding in screening, underwent additional ABVS. The methods were assessed for each breast and each detected lesion separately and classified into two categories: breasts with mammographic suspicion of malignancy and breasts with a negative mammogram. Twenty-six cancers were found in 25 women. In the category of breasts with a suspicious mammographic finding, the sensitivity of both handheld US and ABVS was 88% (22/25). The specificity of handheld US was 93.5% (87/93) and ABVS was 89.2% (83/93). In the category of breasts with a negative mammography, the sensitivity of handheld US and ABVS was 100% (1/1). The specificity of handheld US was 100% (102/102) and ABVS was 94.1% (96/102). The authors concluded that ABVS can potentially replace handheld US in the investigation of women recalled from mammography screening due to a suspicious finding. Due to the small size of this study population, further investigation with larger study populations is necessary before the implementation of such practice.

Kim et al. (2016) conducted a prospective study to compare the diagnostic performance of handheld ultrasound (US) and an automated breast volume scanner (ABVS) as second-look US techniques subsequent to preoperative breast magnetic resonance imaging (MRI). From March to September 2014, both types of second-look US examinations were performed on 40 patients with breast cancer who had 76 additional suspicious lesions detected via preoperative breast MRI. Each second-look US modality was reviewed independently and the detection rate of each, the correlation between the detection rate, and the MRI factors (size, distance, and enhancement type) were evaluated. The detection rate of the ABVS was higher than that of handheld US for the second-look examination (94.7% versus 86.8%). Among the 76 total lesions, 7 were only identified by the ABVS, 1 was only found by handheld US, and 3 were not detected by either the ABVS or handheld US. When we analyzed the correlation between the detection rate and MRI factors, the only meaningful factor was the enhancement type. The ability to detect a non-mass lesion was lower than the ability to detect a mass-type lesion for both the ABVS and handheld US. It was concluded that for a second-look US examination subsequent to preoperative breast MRI in patients with breast cancer, the ABVS is a more efficient modality than handheld US for preoperative evaluations. However, both techniques have limitations in detecting non mass lesions. This study is limited to a small sample size.

Computer-Aided Detection (CAD)

Clinical evidence has not yet shown that CAD improves patient outcomes or lowers breast cancer mortality when added to mammography screening, MRI of the breast, or ultrasonography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating CAD with these technologies.

Park (2022) conducted a retrospective study to evaluate cancer size measurement by CAD and radiologist on breast MRI relative to histopathology and to determine clinicopathologic and MRI factors that may affect measurements. A total of 208 preoperative MRI of breast cancers taken between January 2017 and March 2021 met inclusion criteria. Correlation between CAD-generated size and pathologic size as well as that between radiologist-measured size and pathologic size were evaluated. A classification of size discrepancies was placed into accurate and inaccurate groups. For both CAD and radiologist, clinicopathologic and imaging factors were compared between accurate and inaccurate groups. The results of the study showed the mean sizes as predicted by CAD, radiologist and pathology were 2.66 ±1.68 cm, 2.54 ±1.68 cm, and 2.30 ±1.61 cm, with significant difference ($p < 0.001$). Correlation coefficients of cancer size measurement by radiologist and CAD in reference to pathology were 0.898 and 0.823. Radiologist's measurement was more accurate than CAD, with statistical significance ($p < 0.001$). CAD-generated measurement was significantly more inaccurate for cancers of larger pathologic size (> 2 cm), in the presence of an extensive intraductal component (EIC), with positive progesterone receptor (PR), and of non-mass enhancement. Radiologist-measured size was significantly more inaccurate for cancers in presence of an in situ component, EIC, positive human epidermal growth factor receptor 2 (HER2), and non-mass enhancement. The author concluded comparison of breast cancer size measurement between CAD and pathology, and between a radiologist and pathology, showed very strong correlations. Radiologist-measured tumor size was more accurate than CAD-generated size. Cancer size measured by radiologist and CAD on MRI can be inaccurate for cancers with EIC and of the non-mass enhancement type. Limitations in the study include a lack of multicentric cancers, interobserver variability and a retrospective study design.

A retrospective mammography review was performed by Park et al. (2022) to investigate whether artificial-intelligence-based, computer-aided diagnosis (AI-CAD) could facilitate the detection of missed cancer on digital mammography. A total of 204 women diagnosed with breast cancer with diagnostic (present) and prior mammograms between 2018 and 2020 were included in this study. Two breast radiologists reviewed the mammographic features and classified them into true negative, minimal sign or missed cancer. They analyzed the AI-CAD results with an abnormality score and assessed whether the AI-CAD correctly localized the known cancer sites. Of the 204 cases, 137 were classified as true negative, 33 as minimal signs, and 34 as missed cancer. The sensitivity, specificity and diagnostic accuracy of AI-CAD were 84.7%, 91.5% and 86.3% on diagnostic mammogram and 67.2%, 91.2% and 83.38% on prior mammogram, respectively. The

authors concluded that AI-CAD correctly localized 27 cases from 34 missed cancers on prior mammograms. The findings in the preceding mammography of AI-CAD-detected missed cancer were common in the order of calcifications, focal asymmetry, and asymmetry. Asymmetry was the most common finding among the seven cases, which could not be detected by AI-CAD in the missed cases (5/7). The assistance of AI-CAD can be helpful in the early detection of breast cancer in mammography screenings. Limitations to this study include a small number of patients with biopsy-proven malignancy with selection bias. Only one AI-CAD software was used for analysis. In addition, it is still difficult to determine the extent to which the suspicious findings detected by the AI-CAD in prior mammograms will lead to early cancer detection in actual practice. Additionally, false positive findings can affect the radiologist's judgment and lead to an increase in recall rate. Further research with randomized controlled trials is needed to validate these findings.

In a secondary analysis of data from a prospective study, Dahlblom et al. (2021) examine how an artificial intelligence (AI) system performs at digital mammography (DM) from a screening population with ground truth defined by digital breast tomosynthesis (DBT), and whether AI could detect breast cancers at DM that had originally only been detected at DBT. In this secondary analysis of data from a prospective study, DM examinations from 14,768 women (mean age, 57 years), examined with both DM and DBT with independent double reading in the Malmö Breast Tomosynthesis Screening Trial (MBTST) (ClinicalTrials.gov: NCT01091545; data collection, 2010-2015), were analyzed with an AI system. Of 136 screening-detected cancers, 95 cancers were detected at DM and 41 cancers were detected only at DBT. The system identifies suspicious areas in the image, scored 1-100, and provides a risk score of 1 to 10 for the whole examination. A cancer was defined as AI detected if the cancer lesion was correctly localized and scored at least 62 (threshold determined by the AI system developers), therefore resulting in the highest examination risk score of 10. Data were analyzed with descriptive statistics, and detection performance was analyzed with receiver operating characteristics. The highest examination risk score was assigned to 10% (1,493 of 14,786) of the examinations. With 90.8% specificity, the AI system detected 75% (71 of 95) of the DM-detected cancers and 44% (18 of 41) of cancers at DM that had originally been detected only at DBT. The majority were invasive cancers (17 of 18). The authors concluded that almost half of the additional DBT-only screening-detected cancers in the MBTST were detected at DM with AI. AI did not reach double reading performance; however, if combined with double reading, AI has the potential to achieve a substantial portion of the benefit of DBT screening. As this retrospective study is based on radiologist readings without AI, the authors state it was not possible to study how the sensitivity and number of false-positive recalls would be affected by integrated AI and radiologists' readings in a real-world screening situation. The results here thus establish a current maximum additional cancer detection potential; however, further studies are needed to explore the clinical potential of AI.

Cho et al. (2016) conducted a retrospective study to compare the detection of breast cancer using full-field digital mammography (FFDM), FFDM with computer-aided detection (FFDM+CAD), ultrasound (US), and FFDM+CAD plus US (FFDM+CAD+US), and to investigate the factors affecting cancer detection. This study was conducted from 2008 to 2012, and 48,251 women underwent FFDM and US for cancer screening. The clinical and pathological data was reviewed to investigate factors affecting cancer detection and used generalized estimation equations to compare the cancer detectability of different imaging modalities. The results of this study showed the detectability of breast cancer by US or FFDM+CAD+US to be superior to that of FFDM or FFDM+ CAD. However, cancer detectability was not significantly different between FFDM versus FFDM+CAD and US alone versus FFDM+CAD+US. The tumor size influenced cancer detectability by all imaging modalities. In FFDM and FFDM+CAD, the non-detecting group consisted of younger patients and patients with a denser breast composition. In breast US, carcinoma in situ was more frequent in the non-detecting group. The authors concluded that for breast cancer screening, breast US alone is satisfactory for all age groups, although FFDM+CAD+US is the perfect screening method. Patient age, breast composition, and pathological tumor size and type may influence cancer detection during screening. The study is also limited by small sample size, retrospective and non-blinded study design.

Computer-Aided Tactile Breast Imaging

The current evidence consists of very low-quality, uncontrolled studies of the diagnostic efficacy for either tactile breast imaging device. The impact of these devices on patient outcomes has not been determined. There is significant potential for bias in these studies that could result in hyper-inflated 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 work-up 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 evaluating this technology.

Tasoulis et al. (2014) unnecessary referrals of patients with breast lumps represent a significant issue, since only a few patients actually have lumps when examined by a breast specialist. Tactile imaging (TI) is a novel modality in breast diagnostics armamentarium. The aim of this study was to assess TI's diagnostic performance and compare it to clinical breast examination (CBE). This is a prospective, blinded, comparative study of 276 consecutive patients. All patients underwent conventional imaging and tissue sampling if either a radiological or a palpable abnormality was present.

Sensitivity, specificity and positive and negative predictive values for CBE and TI were calculated. Radiological findings and final diagnosis based on histology and/or cytology were used as reference standards. Receiver operator characteristic (ROC) curve analysis was also performed for each method. Sensitivity and specificity of TI in detecting radiologically proven abnormalities were 85.5% and 35%, respectively. CBE's sensitivity was 80.3% and specificity 76%. In detecting a histopathological entity according to histology/cytology, sensitivity was 88.2% for TI and 81.6% for CBE. Specificity was 38.5% and 85.7% for TI and CBE, respectively. These results suggest a trend towards higher sensitivity of TI compared to CBE but significantly lower specificity. Subgroup analysis revealed superior sensitivity of TI in detecting a histological entity in pre-menopausal women. However, CBE's overall performance was superior compared to TI's according to ROC curve analysis. Although further research is necessary, the use of TI by the primary care physician as a selection tool for referring patients to a breast specialist should be considered especially in pre-menopausal women.

Computed Tomography of the Breast

There is a very low-quality body of evidence consisting of uncontrolled studies for computed tomography of the breast, which is insufficient to draw conclusions regarding evidence and patient outcomes.

Komolafe et al. (2022) performed a systematic review and meta-analysis to evaluate the comparison of diagnostic accuracy of cone-beam breast computed tomography (CBBCT) and digital breast tomosynthesis (DBT) to characterize breast cancers. Two independent reviewers identified screening on diagnostic studies from 1 January 2015 to 30 December 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 (AUC), positive likelihood ratio (LR+), and negative likelihood ratio (LR-) were estimated using the bivariate model. The pooled sensitivity specificity, LR+ and LR- and AUC at 95% confidence interval are 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 are the pooled sensitivity specificity, LR+ and LR- and AUC for 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 they recommend more prospective studies on CBBCT application. 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, introducing potential bias. The sample size of the CBBCT arm is one-third of that of 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 clinical usefulness of this procedure is proven.

In the 2020 ECRI Clinical Evidence Assessment Report, 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 (2019) published a systematic review of the diagnostic accuracy of cone beam breast CT. A total of 362 studies were screened, of which 6 with 559 patients were included. All studies were conducted between 2015 and 2018 and evaluated female participants. Five studies included non-contract cone beam breast computed tomography (NC-CBBCT) and three included contrast-enhanced cone beam breast computed tomography (CE-CBBCT). Overall, the study quality was high, except for one study of NC-CBBCT which was presented as a conferenced abstract and was given a lower rating due to lack of complete study design and conduct details. There was high between-study heterogeneity among the NC-CBBCT studies (I2 = 98.4%, 95% CI 80.6 to 94.2%. Using NC-CBBCT, pooled sensitivity was 0.789 (95% CI 0.66 to 0.89) and pooled specificity was 0.697 (95% CI 0.471 to 0.851). The NC-CBBCT partial area under the curve (AUC), 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 (I2 = 57.3, 95% CI 0 to 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 to 0.956) and the pooled specificity was 0.788 (95% CI 0.709 to 0.85). The CE-CBBCT partial AUC for 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 area under the curve (AUC). Diagnostic accuracy of CE-CBBCT was numerically comparable to that of breast MRI with meta-analyses reporting sensitivity of 0.9 and specificity of 0.72. The authors conclude that the results are encouraging but that additional “further large-scale, prospective studies and long-term follow-up studies are required.

Electrical Impedance Scanning (EIS)

There is a lack of evidence in the published literature to show that electrical impedance scanning for the detection and classification of breast lesions can predict clinical events, alter treatment or is effective as or more effective than currently

used methods. Additional well-designed studies are needed to determine whether or not EIS is effective as an adjunct to mammography or provides a positive clinical benefit and outcome.

In a 2022 systematic review and meta-analysis, Rezanejad Gatabi et al. sought to evaluate the accuracy of the electrical impedance tomography (EIT) technique for breast cancer diagnosis. A total of 12 selected studies met inclusion criteria and included data for 5487 patients with breast cancer. The findings revealed EIT had a higher diagnostic accuracy (sensitivity and specificity of 75.88% and 82.04%, respectively). The pooled diagnostic odds ratio was 14.37 and the pooled effect of accuracy was 0.79 with 95% CI. The authors concluded that EIT can be used as a useful method alongside mammography. EIT sensitivity could not be compared with the sensitivity of MRI, but in terms of specificity, it can be considered as a new method that probably can get more attention. Furthermore, large-scale studies will be needed to support the evidence. Limitations include heterogeneity in the study, insufficient information, and unclear mean age in different groups and unable to analyze patients histopathology. (Author Stojadinovic 2006 which was previously cited in this policy, is included in this systematic review.)

Impedance measuring acquisition systems focused on breast tumor detection, as well as image processing techniques for 3D imaging, are examined in this systematic review by Gómez-Cortés (2022) to define potential opportunity areas for future research. The description of reported works using electrical impedance tomography (EIT)-based techniques and methodologies for 3D bioimpedance imaging of breast tissues with tumors is presented. The review is based on searching and analyzing related works reported in the most important research databases and is structured according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) parameters and statements. Nineteen papers reporting breast tumor detection and location using EIT were systematically selected and analyzed in this review. Clinical trials in the experimental stage did not produce results in most of analyzed proposals (about 80%), wherein statistical criteria comparison was not possible, such as specificity, sensitivity, and predictive values. The authors concluded that a 3D representation of bioimpedance is a potential tool for medical applications in malignant breast tumors detection being capable to estimate an ap-proximate the tumor volume and geometric location, in contrast with a tumor area computing capacity, but not the tumor extension depth, in a 2D representation. Clinical trials are required to consider statistical parameters in the comparison of the proposed systems. Only 20% of the reviewed articles concluded in clinical trials, this limitation does not allow comparative studies with other breast tumor detection methods. Further investigation is needed before clinical usefulness of this procedure is proven.

In a prospective, multicenter study, Wang et al. (2010) reported the sensitivity and specificity for the combination of EIS and ultrasound in identifying breast cancer and calculated the relative risk of breast cancer in young women. The young women (583 cases) scheduled for mammary biopsy underwent EIS and ultrasound, respectively. EIS and ultrasound results were compared with final histopathology results. Of the 583 cases, 143 were diagnosed with breast cancer. The relative probability of breast cancer for the young women was detected by EIS, ultrasound, and the combination method. The authors concluded that the combination of EIS and ultrasound is likely to become an applicable method for early detection of breast cancer in young women.

A prospective, multicenter clinical trial by Stojadinovic et al. (2005) evaluated EIS in 1,103 women. Twenty-nine cancers with a mean tumor size 1.7 cm were confirmed thru biopsy. Electrical impedance scanning had 17% sensitivity, 90% specificity, and a negative predictive value (NPV) of 98%. Statistically significant increases in specificity were observed for women who were premenopausal and women who were not using hormone replacement therapy. False-positive rates were increased in postmenopausal women and those taking exogenous hormones. While the authors concluded that EIS appears promising for early detection of breast cancer, the increased false positive rates in postmenopausal women and those taking exogenous hormones is concerning.

Magnetic Resonance Elastography of the Breast (MRE)

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 patient 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.

A prospective study by Siegmann et al. (2010) evaluated the value of adding magnetic resonance elastography (MRE) to contrast-enhanced MR imaging (MRI) for evaluating breast lesions in 57 patients. The sensitivity of MRI was 97.3% whereas specificity was 55%. If contrast-enhanced MRI was combined with $\alpha 0$ (indicator of tissue stiffness), the diagnostic accuracy could be significantly increased. The authors concluded that combining MRE with MRI increase the diagnostic performance of breast MRI; however, larger studies are needed to validate the results and to identify the patients best suited for a combined procedure.

Molecular Imaging

The published literature on molecular breast imaging 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 methodologic limitations in the available studies, which have been judged to have 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.

De Feo et al. (2022) conducted a systematic review to assess if breast-specific gamma imaging (BSGI) is a more valuable choice in detecting breast malignant lesions compared to morphological counterparts such mammography (MMG), ultrasound (US), and magnetic resonance imaging in terms of specificity, sensibility, and positive and negative predictive value. A total of 15 studies compared BSGI with MMG, US, and MRI. BSGI sensitivity was similar to MRI, but specificity was higher. Specificity was always higher than MMG and US. BSGI had higher positive predictive value and negative predicative value. When used for the evaluation of a suspected breast lesion, the overall sensitivity was better than the examined overall sensitivity when BSGI was excluded. Risk of bias and applicability concerns domain showed mainly low risk of bias. The authors concluded BSGI is a valuable imaging modality with similar sensitivity to MRI but higher specificity, although at the cost of higher radiation burden. (Authors Kim 2012 and Cho 2016 which were previously cited in this policy, are included in this systematic review.)

In a 2016 systematic review and meta-analysis, Guo et al. sought to establish if Tc-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 fourteen studies, for a total of 503 individuals, fulfilled the inclusion criteria. The results indicated that Tc-99m MIBI 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. Subgroup analysis indicated that performing early mid-treatment Tc-99m MIBI 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 post-treatment scintimammography in the prediction of neoadjuvant chemotherapy response.

In the 2013 ECRI Evidence Report, Noninvasive Diagnostic Tests for Breast Abnormalities found that only women with a pre-scintimammography suspicion of malignancy of 5 percent or less will have their post-scintimammography suspicion of malignancy change sufficiently to suggest that a change in patient management may be appropriate.

A meta-analysis of scintimammography included 5,473 patients from studies performed since 1997. The overall sensitivity was 85% and the specificity was 84% for single-site trial studies, and for multicenter trial studies the overall sensitivity was 85% and the specificity was 83% (Hussain and Buscombe, 2006). Another meta-analysis evaluating scintimammography included 5,340 patients from studies published between January 1967 and December 1999. The aggregated summary estimates of sensitivity and specificity for scintimammography were 85.2% and 86.6% respectively. The authors concluded that scintimammography may be used effectively as an adjunct to mammography when additional information is required to reach a definitive diagnosis. The authors also indicated that the role of scintimammography should be assessed on the basis of large, multicenter studies. (Liberman et al., 2003)

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).

The ACS guidelines for breast cancer screening states scintimammography, positron emission tomography, and electrical impedance imaging, have received FDA approval as diagnostic adjuncts to mammography. None of these new technologies has successfully undergone clinical testing that would justify its use in screening for breast cancer (ACS, 2003; updated 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 (ACS, 2007; updated 2015).

American College of Obstetricians and Gynecologists (ACOG)

In 2020 ACOG reaffirmed their recommendation for routine screening with use of digital mammography for women 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 for 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)

The ACR practice parameter for the performance of screening and diagnostic mammography states the following:

- Double reading and CAD may be used but may slightly increase the sensitivity of mammographic interpretation.
- This sensitivity is usually at the expense of decreased specificity with increased recall and biopsy rates (ACR, 2018).

The ACR appropriateness criteria for breast cancer screening considers 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 usually appropriate (Mainiero, 2017).

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

American Society of Breast Surgeons (ASBrS)

A consensus guideline by the American Society of Breast Surgeons on diagnostic and screening magnetic resonance imaging of the breast (2017) also supports the use of MRI as a screening technique in women. The guideline particularly supports women age 25 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%-25% or greater estimated lifetime risk of breast cancer based on models primarily based on family history.

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. These women are, therefore, underserved with current mammographic screening programs. The results of recent studies reporting 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 for these women and is cost-effective. Because there is now a valid option to improve breast cancer screening, the 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 being screened. Considering the available evidence, in women aged 50 to 70 years with extremely dense breasts, the EUSOBI now recommends offering screening breast MRI every 2 to 4 years. The 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 but 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 counselled on the benefits and risks of mammography and MRI-based screening, so that they can make an informed choice about their preferred screening method (2022).

National Comprehensive Cancer Network (NCCN)

The 2021 NCCN Clinical Practice Guideline for Breast Cancer Screening and Diagnosis states, “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 SBI and ACR recommendation (2010) for breast cancer screening with breast ultrasound state the following:

- Can be considered in high-risk women for whom magnetic resonance imaging (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, 2010)

Society of Nuclear Medicine and Molecular Imaging (SNMMI) (formerly Society of Nuclear Medicine)

SNM published a Procedure Standard (2010) for breast scintigraphy with breast-specific gamma cameras that indicate that further study is needed to determine the population and usefulness most likely to benefit from this procedure. This guideline lists potential indications and cites references for each indication but does not provide a systemic 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.

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 (MQSA). The FDA has granted pre-market approval to several digital mammography systems (product code MUE) for breast cancer screening and diagnosis.

Automated Breast Ultrasound System (ABUS)

Automated breast (or whole breast) ultrasound devices are regulated by the FDA as Class III devices. Refer to the following website for more information on devices used for automated breast ultrasound systems (search by product name in device name section or Product Code ITX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

Breast Specific Gamma Imaging (BSGI)

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 radiologic devices. A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

Computer-Aided Detection for MRI 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 device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

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 device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

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 device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

Electrical Impedance Scanning

These devices are approved as an adjunct to mammography in patients whose lesions are American College of Radiology (ACR) Breast Imaging-Reporting and Data System (BI-RADS) category III (probably benign) or IV (suspicious abnormality), based on mammography. Refer to the following website for more information on devices used for electrical impedance scanning (search by product name in device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

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 device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 25, 2023)

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Policy History/Revision Information

Date	Summary of Changes
07/18/2024	**Application** • Added language to indicate portions of the *Coverage Rationale* contained in this policy represents Louisiana Medicaid coverage policy and is set forth [in the policy] in accordance with state requirements **Coverage Rationale** • Removed notation indicating this policy does not address routine preventive breast cancer screening (using conventional mammography) ***State-Specific Criteria*** • Added language to indicate: Screening Mammography ○ Louisiana Medicaid allows payment for one-screening mammogram (either film or digital) per calendar year for beneficiaries meeting **one of more** of the following criteria: ▪ Any woman age 30 or older with hereditary susceptibility from pathogenic mutation carrier status or prior chest wall radiation ▪ Provider recommendation for any woman 35 years of age or older with a predicted lifetime risk greater than 20 percent ▪ Any woman who is 35 through 39 years of age (note: only one baseline mammogram is allowable between this age range for beneficiaries not meeting other criteria) ▪ Any woman who is 40 years of age or older ○ Providers should perform the most clinically appropriate method (film or digital) specific to the beneficiary Magnetic Resonance Imaging (MRI) ○ Under the following instances, Louisiana Medicaid may also reimburse for an annual magnetic resonance imaging (MRI): ▪ Women at least 25 years of age with hereditary susceptibility from pathogenic mutation carrier status or prior chest wall radiation ▪ Provider recommendation for any woman 35 years of age or older with a predicted lifetime risk greater than 20 percent ▪ Any woman 40 or older, with increased breast density (C and D density), if recommended by their physician ▪ Women with a prior history of breast cancer below 50 years of age ▪ Women with a prior history of breast cancer at any age and dense breast (C and D density) ○ **Note**: A breast ultrasound is the initial preferred modality, followed by MRI if found to be inconclusive, in this instance ***Non State-Specific Criteria*** • Removed language indicating: ○ Magnetic resonance imaging (MRI) of the breast is proven and medically necessary for individuals who are high risk for breast cancer as defined as having any of the following: ▪ Prior thoracic radiation therapy between the ages 10 and 30 ▪ 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) ▪ Personal history of breast cancer (not treated with bilateral mastectomy) ▪ Personal history with any of the following: – Li-Fraumeni syndrome (TP53 mutation) – Confirmed BRCA1 or BRCA2 gene mutations – Peutz-Jehgers syndrome (STK11, LKB1 gene variations)

Date	Summary of Changes
	– PTEN gene mutation ▪ Family history with any of the following: – At least one first-degree relative who has a BRCA1 or BRCA2 mutation – First-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes, or Peutz-Jehgers syndrome) – At least two first-degree relatives with breast or ovarian cancer – One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer – First or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer ○ Magnetic resonance imaging (MRI) of the breast is unproven and not medically necessary for individuals with dense breast tissue not accompanied by defined risk factors as described [in the policy as proven and medically necessary] due to insufficient evidence of efficacy • Removed reference link to the *Cardiovascular and Radiology Imaging Guidelines* for additional indications for breast MRI **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS010LA.S

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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