MEDICAL POLICY STATEMENT
INDIANA MARKETPLACE

Original Issue Date	Next Annual Review	Effective Date
10/04/2017	04/15/2019	04/15/2018
Policy Name		**Policy Number**
Breast Imaging		MM-0141
Policy Type		
MEDICAL	Administrative / Pharmacy	Reimbursement

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Contents of Policy

A. SUBJECT

Breast Imaging

B. BACKGROUND

Mammography is a type of imaging that uses a low-dose x-ray system for examination of the breasts. Screening mammography aims to reduce morbidity and mortality from breast cancer by early detection and treatment of occult malignancies. The National Cancer Institute estimates that each year there are approximately 2,500 new cases of breast cancer in males and 250,000 cases of breast cancer among females. Many professional societies and government organizations recommend annual or biennial screening mammography for average-risk and higher-risk women. A screening mammography is one of several tools that are used for early detection of breast cancer in asymptomatic women. Full-field digital accounts for more than 95 percent of mammography units in the United States. A large body of literature has validated its clinical benefits over film screen mammography. Computer-Aided Detection and diagnosis (CAD) systems consist of computer programs designed to recognize patterns in images. CAD may be applied to digital mammograms or digitized plain film mammograms. Breast tomosynthesis is a 3-dimensional imaging technique that involves acquiring images of a stationary compressed breast at multiple angles during a short scan. Annual screening mammography of age-appropriate asymptomatic women is currently the only imaging modality that has been proven to significantly reduce breast cancer mortality. Women with an abnormal mammogram may avoid biopsy by utilizing non-invasive diagnostic tests that can accurately exclude cancer. Therefore, efforts to develop adjuvant imaging procedures continue. This policy will focus on mammography screening and the emerging imaging modalities for breast cancer detection and diagnosis.

The American College of Radiology (ACR) and the Society of Breast Imaging (SBI) recommend that women of average risk should start annual screening mammography at the age of 40. It is recommended that women who fit into any of the following categories start annual screening mammography prior to the age of 40 years, as indicated:

- *BRCA1* or *BRCA2* mutation carriers: by age 30, but not before age 25;
- Women with a mother or sister with pre-menopausal breast cancer: by age 30 but not before age 25, or 10 years earlier than the age of diagnosis of relative, whichever is later;
- Women with ≥20% lifetime risk for breast cancer on the basis of family history (both maternal and paternal): yearly starting by age 30 but not before age 25, or 10 years earlier than the age of diagnosis of the youngest affected relative, whichever is later;
- Women with histories of mantle radiation received between the ages of 10 and 30: beginning 8 years after the radiation therapy but not before age 25;
- Women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), invasive breast cancer, or ovarian cancer regardless of age.
- ACR and SBI recommend that annual screening with mammography should stop when life expectancy is <5 to 7 years on the basis of age or comorbid conditions, or when abnormal results of screening would not be acted on because of age or comorbid conditions.

C. DEFINITIONS

- **Automated Breast Ultrasound:** Automated Breast Ultrasound is the first and only ultrasound system developed and US Food and Drug Administration (FDA) approved specifically for breast cancer screening in women with dense breast tissue who have not had previous breast biopsies or surgeries. It 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.
- **Breast MRI:** MRI is a non-invasive imaging modality that uses magnetic and radiofrequency fields to image body tissue producing very detailed, cross-sectional pictures of the body. Inconsistent with CT, MRI uses no ionizing radiation and is generally a safe procedure.

However, the strong magnetic fields and radio pulses can affect metal implants within the body. MRI is sometimes used in combination with mammography.

- **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.
- **Breast Ultrasound:** Ultrasound, also known as sonography, is an imaging method using sound waves rather than ionizing radiation to a part of the body. For this test, a small, microphone-like instrument called a transducer is placed on the skin (which is often first lubricated with ultrasound gel). It emits sound waves and picks up the echoes as they bounce off body tissues. The echoes are converted by a computer into a black and white image on a computer screen. Ultrasound is useful for evaluating some breast masses and is the only way to tell if a suspicious area is a cyst (fluid-filled sac) without placing a needle into it to aspirate. Physical exam alone is not a sufficient diagnosis method for Cysts. Breast ultrasound may also be used to help doctors guide a biopsy needle into some breast lesions.
- **Computer-Aided Detection (CAD) for Ultrasound:** CAD systems for ultrasound use pattern recognition methods to help radiologists analyze images and automate the reporting process. These systems have been developed to promote standardized breast ultrasound reporting.
- **Computer Aided Tactile Breast Imaging:** Tactile breast imaging includes placing a tactile array sensor in contact with a portion of the patient's body, to generate data signals corresponding to pressure gradients encountered by portions of the tactile array sensor. 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.
- **Diagnostic/Radiologic Mammography:** A radiologic procedure furnished to a man or woman with signs and symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy proven benign breast disease, and includes a physician's interpretation of the results of the procedure.
- **Digital Mammography:** Full-Field Digital Mammography (FFDM) is gradually replacing conventional screen-film mammography (SFM), which had been the predominant technique for breast cancer screening of asymptomatic women. Images of the breast are acquired, displayed, transferred, and stored as digital data for viewing on a computer monitor or for printing and viewing with a light box. In contrast to SFM, FFDM simplifies image interpretation because image acquisition, image processing, image review, and data storage are independently executed.
- **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.
- **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 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.
- **Screening Mammography:** A radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure. A screening mammography has

limitations as it must be, at a minimum a two-view exposure (cranio-caudal and a medial lateral oblique view) of each breast.

D. POLICY

I. CareSource covers Diagnostic Breast Cancer Screening Mammography, which includes:
   A. One baseline breast cancer screening mammography for a Covered Person between 35 and 40 years of age
   B. One screening mammography performed each year for a Covered Person who is at least 40 years of age
   C. One baseline screening mammography performed each year for a Covered Person who is less than 40 years of age and determined to be high risk, if a woman meets at least one of the following criteria:
      1. Has a personal history of breast cancer
      2. Has a personal history of breast disease proven benign by biopsy
      3. Has a mother, sister, or daughter who has had breast cancer
      4. Is at least 30 years of age and has not given birth
      5. Any additional mammography views that are required for proper evaluation
      6. Ultrasound services, if determined to be Medically Necessary
   D. An individual, regardless of age, who shows clinical symptoms of breast cancer, as indicated by **1 or more** of the following:
      1. Abnormal findings identified on screening mammogram
      2. Abnormal nipple or areolar signs or symptoms (eg, bleeding, dimpling, discharge, edema, persistent focal pain, ulceration)
      3. Anatomic guidance during biopsy of breast lesion
      4. Breast abnormality on clinical examination (eg, palpable breast mass, induration), as indicated by 1 or more of the following:
         1. Female patient
         2. Male patient 25 years of age or older
      5. Breast abnormality on ultrasound
      6. Breast implant rupture, known or suspected
      7. Recommended short-interval follow-up of probable benign abnormality seen on screening mammogram

NOTE: CareSource considers screening mammography for men experimental and investigational, as the clinical benefits of such screening in men are unproven. Current guidelines from the U.S. Preventive Services Task Force and the American College of Radiology recommend such screening only for women. CareSource considers mammography medically necessary for surveillance of men with a prior history of breast cancer.

*II. CareSource may cover breast magnetic resonance imaging (MRI) as it is proven and medically necessary for patients at high risk for breast cancer and may be indicated by **one or more** of the following:*
   A. Breast abnormality evaluation needed
   B. Breast cancer known
   C. Breast cancer screening (no prior diagnosis of breast or ovarian cancer in patient) and 1 or more of the following:
      1. BRACA1 or BRCA2 mutation carrier
      2. Other high-risk family history of breast cancer
      3. Patient has diagnosis of, or has first-degree relative with, 1 or more of the following:
         1.1 Bannayan-Riley-Ruvalcaba syndrome
         1.2 Cowden syndrome
         1.3 Hereditary diffuse gastric cancer with CDH1 mutation
         1.4 Li-Fraumeni syndrome
         1.5 Peutz-Jeghers syndrome
      4. Personal history of radiation to chest between age 10 and 30 years

D. Occult breast cancer, suspected (e.g., unknown primary)
E. Repeat evaluation of specific area or structure with same imaging modality, as indicated by:
1. Change in clinical status (e.g., worsening symptoms or new associated symptoms)
2. Need for interval reassessment that may impact treatment plan
3. Need for re-imaging either prior to or after performance of invasive procedure

National Imaging Associates, Inc. (NIA) recommend Magnetic Resonance Imaging (MRI) as a useful tool in detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization.

Breast magnetic resonance imaging (MRI) is unproven and not medically necessary for patients with dense breast tissue not associated with defined risk factors as described above.

III. **Magnetic Resonance Elastography of the Breast**
Magnetic Resonance Elastography (MRE) is unproven and not medically necessary for breast cancer screening or diagnosis.
There is insufficient clinical evidence to conclude that MRE is effective for the screening or diagnosis of breast cancer. The diagnostic accuracy of MRE for detection of breast cancer remains to be determined. While data from small feasibility studies suggest that MRE may have some ability to discriminate between cancerous tissue and normal breast tissue or benign lesions based on tissue stiffness, the values were overlapping. There are no definitive patient selection criteria for MRE for breast cancer detection.

IV. **Breast Specific Gamma Imaging (Scintimammography)**
Scintimammography is unproven and not medically necessary for breast cancer screening or diagnosis.
There is inconclusive evidence that this diagnostic method can differentiate benign from malignant breast lesions. Based on current evidence, the role of scintimammography technology remains uncertain since this technology has not been shown to be accurate enough to screen for breast cancer or allow a confident decision to defer biopsy.

V. **Electrical Impedance Scanning (EIS)**
Electrical impedance scanning (EIS) is unproven and not medically necessary for the detection of breast cancer.
There is inconclusive evidence that EIS is effective in detecting malignant breast tissue. Evaluation of sensitivity and negative predictive value for EIS is inconsistent. Well-designed studies are needed to determine whether or not EIS is effective as an adjunct to mammography or provides a positive clinical benefit.

VI. **Breast Ultrasound**
Breast ultrasound is unproven and not medically necessary for routine breast cancer screening including patients with dense breast tissue.
Clinical evidence has not yet shown that routine use of ultrasonography as an adjunct to screening mammography lowers the mortality rate from breast cancer.

Breast ultrasound is proven and medically necessary to assist radiologists in localizing breast lesions and in guiding placement of instruments for cyst aspiration and percutaneous breast biopsies.

VII. **Computer Aided Detection for Ultrasound**
Computer-aided detection (CAD) is unproven and not medically necessary as an aid for radiologists to detect breast cancer during ultrasound.

Clinical evidence has not yet shown that CAD improves patient outcomes or lowers breast cancer mortality when added to ultrasonography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology in large numbers of screening ultrasounds.

VIII. **Computer Aided Tactile Breast Imaging**
Computer-aided tactile breast imaging is unproven and not medically necessary. Clinical evidence is inconclusive in determining whether tactile breast imaging improves outcomes for the screening or diagnosis of breast cancer. Future research should include better-designed studies, including comparative, prospective and randomized controlled trials evaluating this technology.

IX. **Automated Breast Ultrasound**
Automated breast ultrasound is unproven and not medically necessary. Clinical evidence is inconclusive to show whether automated breast ultrasound improves the detection rate of breast cancer in comparison to screening mammography. Future research should include better-designed studies, including prospective studies and randomized controlled trials evaluating this technology.

E. CONDITIONS OF COVERAGE

HCPCS
CPT
AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date Issued	10/04/2017	New policy
Date Revised		
Date Effective	04/15/2018	

H. REFERENCES

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This guideline contains information obtained from National Imaging Associates, Inc. (NRI).

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.