

## Breast Imaging

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

The Plan considers breast mammography, breast ultrasound, and breast MRI medically necessary as screening modalities in patients meeting certain risk criteria (described below). These modalities and breast PET are also used as a diagnostic tool, typically for the purpose of breast cancer evaluation and staging.

### Definitions

“Mammography” is an imaging modality that uses X-rays to study breast tissue for screening or diagnostic purposes. The diagnostic mammogram often requires additional views and is interpreted in real-time by a radiologist.

“Breast Tomosynthesis (3D mammography, digital mammography)” is an imaging modality that uses a moving X-ray source to create a three dimensional view of the breast tissue, as opposed to a two dimensional view provided by a standard mammogram.

“Breast Ultrasound” is an imaging modality that uses sound waves to evaluate the breast tissue, usually in the setting of diagnostic follow up to concerning areas found on previous imaging, focal breast symptoms in women under 30, or guidance for biopsy or aspiration procedures.

“Automated breast ultrasound (ABUS)” is a technique similar to a standard handheld breast ultrasound, except an automated transducer is used to standardize the image acquisition process.

“Breast MRI” is an imaging modality that utilizes magnets to provide a detailed picture of breast tissue, usually in the setting of existing breast cancer or assessment of silicone implants.

“Breast PET” is an imaging modality that uses an injected radiotracer to highlight abnormal areas in the breast that might harbor cancer cells. It is often combined with a CT scan for better anatomic delineation.

“Computer-Aided Detection” is the use of specialized software to help analyze ultrasound, mammography, or MRI breast images with the goal of decreasing the time to read and interpret images.

### Clinical Indications

#### Mammography (Digital or Film Screen)

The Plan considers mammography medically necessary for higher risk or average risk (no prior history or risk factors) members when the criteria outlined in MCG Mammography (A-0039) are met. Please refer to your plan benefits for eligibility by age for members younger than 40 years old (average risk) for breast cancer screening.

#### Breast Tomosynthesis (3D Mammography)

The Plan considers breast tomosynthesis (3D mammography) medically necessary for higher risk or average risk (no prior history or risk factors) members when the criteria outlined in MCG Mammography (A-0039) are met. Please refer to your plan benefits for eligibility by age for members younger than 40 years old (average risk) for breast cancer screening.

#### Breast MRI

The Plan considers breast MRI medically necessary when the criteria outlined in MCG Breast MRI (A-0048) are met.

#### Breast Ultrasound

The Plan considers breast ultrasound medically necessary when the criteria outlined in MCG Breast Ultrasound (A-0101) are met.

#### Breast Positron Emission Tomography (PET) scan

The Plan considers breast PET scans medically necessary when the criteria outlined in MCG Tumor Imaging Positron Emission Tomography (PET) and PET-CT (A-0098) are met for diagnostic purposes. PET scans for breast cancer screening are considered not medically necessary. Furthermore, certain PET diagnostic procedures are considered experimental or investigational, please see applicable billing codes below.

## Experimental or Investigational / Not Medically Necessary

### Breast MRI

- The Plan does NOT consider medically necessary breast MRI for the screening or initial evaluation of saline implant rupture related to a solely cosmetic breast implant not associated with a medically necessary breast reconstruction procedure. This policy is in accordance with numerous professional societies.
- The Plan does NOT consider medically necessary routine MRI surveillance of asymptomatic, average-risk patients with a history of breast cancer who have successfully completed primary therapy. The National Comprehensive Cancer Network (NCCN) guidelines for breast cancer do NOT include MRI in the recommendations for surveillance or follow-up after treatment. NCCN recommends mammogram every 12 months. The American Society of Breast Surgeons similarly, do not have recommendations regarding routine MRI in the surveillance/follow up of breast cancer.

### Transillumination

- The Plan does NOT consider medically necessary transillumination for breast imaging as it has not been established as an effective technique and is therefore considered experimental and investigational.

### Electrical Impedance Scanning (EIS)

- The Plan does NOT consider medically necessary electrical impedance scanning for breast imaging as this technique has not demonstrated improved effectiveness compared to mammography alone and is considered experimental and investigational.

### Elastography

- The Plan does NOT consider medically necessary magnetic resonance elastography or ultrasound elastography as it has not been demonstrated to be superior to MRI or ultrasound alone in breast surveillance. The accuracy of elastography remains unproven for breast cancer.

### Breast Specific Gamma Imaging (Molecular Breast Imaging) / Scintimammography

- The Plan does NOT consider medically necessary breast specific gamma imaging (BSGI) used for Scintimammography examination as current studies do not provide conclusive evidence that breast-specific gamma imaging can be relied on rather than biopsy, US, or MRI in women who have suspicious breast lesions on mammograms. Most recently the American College of Radiology reiterated that the current evidence is insufficient to recommend BSGI in the imaging algorithm of breast cancer. In the latest 2021 American College of Radiology Appropriateness Criteria, Sestamibi molecular breast imaging was usually not appropriate for breast cancer screening. BSGI remains as a limited adjunctive tool to standard mammograms, ultrasound, and MRI.

#### Computer-Aided Detection for MRI and Ultrasound

- The Plan does NOT consider medically necessary computer-aided detection for MRI and ultrasound. Although this technology remains promising for the future, there currently is insufficient evidence to recommend its use.

#### Computer-Aided Tactile Breast Imaging

- The Plan does NOT consider medically necessary computer-aided tactile breast imaging for breast applications. Studies have failed to show an improvement compared to conventional modalities.

#### Automated Breast Ultrasound

- The Plan does NOT consider medically necessary Automated Breast Ultrasound for breast imaging. This system did receive FDA approval based mainly on the safety of the technique, but its effectiveness remains questionable. The studies to date have suffered from a high prevalence of cancer in the study populations which limits the generalizability of the findings to the general population for screening purposes. Current guidelines by the American College of Radiology and the American Society of Breast Surgeons make no mention of automated breast ultrasound in their recommendations. An UpToDate review on breast imaging notes a lack of clear evidence but that the two techniques may be comparable. Furthermore, the largest study to date on 15,318 women concluded that "Addition of AB US to screening mammography in a generalizable cohort of women with dense breasts increased the cancer detection yield of clinically important cancers, but it also increased the number of false-positive results."

#### Positron Emission Tomography (PET) scan, including with 18F and 18F-fluoroestradiol tracers for Breast Cancer Screening

- The Plan does NOT consider medically necessary PET-based imaging (e.g., PET, PET-CT, PET-MRI, etc.) for breast imaging as part of breast cancer screening. NCCN guidelines for breast cancer screening do not list PET as an option. USPSTF and ACS does not list PET under breast cancer screening recommendations. PET imaging may be medically necessary for members who have already been diagnosed with breast cancer and require further workup or staging.

#### Applicable Billing Codes (HCPCS & CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
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
77061	Digital breast tomosynthesis; unilateral
77062	Digital breast tomosynthesis; bilateral
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck) [when billed for diagnostic purposes]
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh [when billed for diagnostic purposes]
78813	Positron emission tomography (PET) imaging; whole body [when billed for diagnostic purposes]
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck) [when billed for diagnostic purposes]

78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh [when billed for diagnostic purposes]
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body [when billed for diagnostic purposes]
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 mCi [when billed for diagnostic purposes for breast]
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral
G0219	PET imaging whole body; melanoma for noncovered indications [when billed for diagnostic purposes]
G0235	PET imaging, any site, not otherwise specified [when billed for diagnostic purposes]
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to G0204 or G0206)
ICD-10 codes considered medically necessary if criteria are met:	
C50.011 - C50.922	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Carcinoma in situ of breast
D24.1 - D24.2	Benign neoplasm of breast
D48.60 - D48.62	Neoplasm of uncertain behavior of breast
N60.01 - N65.1	Disorders of breast
Q85.8	Other phakomatoses, not elsewhere classified [Cowden syndrome]
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast

Z15.01	Genetic susceptibility to malignant neoplasm of breast [Li-Fraumeni syndrome]
Z40.01	Prophylactic breast removal
Z80.3	Family history of malignant neoplasm of breast
Z84.81	Family history of carrier of genetic disease
Z85.3	Personal history of malignant neoplasm of breast
Z86.000	Personal history of in-situ neoplasm of breast
Z92.3	Personal history of irradiation

CPT/HCPCS codes considered experimental, investigational	
<i>Code</i>	<i>Description</i>
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral
A9591	Fluoroestradiol F-18, diagnostic, 1 mCi
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
CPT/HCPCS codes considered Not Medically Necessary	
76499	Unlisted diagnostic radiographic procedure [when billed for Transillumination, Electrical Impedance Scanning, Scintimammography]
G0219	PET imaging whole body; melanoma for noncovered indications [when billed for breast cancer screening]
G0235	PET imaging, any site, not otherwise specified [when billed for breast cancer screening]

References

1. American Cancer Society. (2022, Jan 14). *American Cancer Society Recommendations for the Early Detection of Breast Cancer*. Retrieved April 28, 2023, from <https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html>
2. American College of Radiology. ACR Practice Parameter for the Performance of Whole Breast Ultrasound for Screening and Screening and Staging.

- <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/USWholeBreast.pdf?la=en> Revised 2019.
3. American College of Radiology. ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination. Revised 2021.  
<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Breast-US.pdf>
  4. American College of Radiology. ACR Appropriateness Criteria Breast Cancer Screening.  
<https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria>. Updated 2020.
  5. American College of Radiology. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography.  
<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/screen-diag-mammo.pdf>
  6. American College of Radiology. Practice Parameter for the Performance of Contrast-Enhanced MRI of the Breast. Revised 2018.
  7. American College of Radiology. ACR Practice Parameter for the Performance of Molecular Breast Imaging Using a Dedicated Gamma Camera.  
<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MBI.pdf> Revised 2017.
  8. American College of Radiology. Practice Parameter for the Performance of a Breast Examination Ultrasound. Revised 2016.
  9. American College of Radiology. ACR Position Statement on Screening Mammography and Health Care Coverage. 2016.  
<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Screening-Mammography-and-Health-Care-Coverage>
  10. American College of Radiology (ACR), Society for Pediatric Radiology (SPR). ACR-SPR practice guideline for the performance of tumor scintigraphy (with gamma cameras). 2015. American Society of Breast Surgeons (ASBS).
  11. American College of Obstetricians and Gynecologists. Management of Women with Dense Breasts Diagnosed by Mammography.
  12. Brem RF, Tabár L, Duffy SW, et al. Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the Somolnsight Study. *Radiology*. 2015;274(3):663-73.
  13. Brem RF, Ruda RC, Yang JL, et al. Breast-Specific  $\gamma$ -Imaging for the Detection of Mammographically Occult Breast Cancer in Women at Increased Risk. *J Nucl Med*. 2016 May;57(5):678-84.
  14. 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. ECRI Institute. Hotline Service. Breast-Specific Gamma Imaging for Diagnosis and Screening of Breast Cancer. Updated March 2013.
  15. Friedewald SM, Rafferty EA, Rose SL, Durand MA, Plecha DM, Greenberg JS, Hayes MK, Copit DS, Carlson KL, Cink TM, Barke LD, Greer LN, Miller DP, Conant EF. Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA*. 2014 Jun 25;311(24):2499-507.



16. Freer PE, Slanetz PJ. Breast density and screening for breast cancer. UpToDate.com. Last reviewed May 2018.
17. Harvey JA, Mahoney MC, et al. ACR Appropriateness Criteria Palpable Breast Masses. *J Am Coll Radiol*. 2016 Nov;13(11S):e31-e42.
18. Mainiero MB, Lourenco A, et al. ACR Appropriateness Criteria Breast Cancer Screening. *J Am Coll Radiol*. 2016 Nov;13(11S):R45-R49.
19. FDA Update on the Safety of Silicone Gel-Filled Implants. June 2011. Centers for Devices and Radiological Health, US Food & Drug Administration.
20. Destounis S. Breast magnetic resonance imaging indications. *Top Magn Reson Imaging*. 2014 Dec;23(6):329-36.
21. Digital breast tomosynthesis from concept to clinical care. Kopans DB *AJR Am J Roentgenol*. 2014 Feb; 202(2):299-308.
22. Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening. *JAMA Oncol*. 2016 Jun 1;2(6):737-43. doi: 10.1001/jamaoncol.2015.5536.
23. Gilbert FJ, Tucker L, Gillan MG, et al. The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK NHS Breast Screening Programme -- a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. *Health Technol Assess*. 2015;19(4):i-xxv, 1-136.
24. Gu YL, Pan SM, et al. Role of Magnetic Resonance Imaging in Detection of Pathologic Complete Remission in Breast Cancer Patients Treated With Neoadjuvant Chemotherapy: A Meta-analysis. *Clin Breast Cancer*. 2017 Jan 11. pii: S1526-8209(16)30256-7.
25. Hellgren R, Dickman P, Leifland K, et al. Comparison of handheld ultrasound and automated breast ultrasound in women recalled after mammography screening. *Acta Radiol*. 2017 May; 58(5):515-520.
26. Hodgson R, et al. Systematic review of 3D mammography for breast cancer screening. *Breast* 2016 Jun;27:52-61. doi: 10.1016/j.breast.2016.01.002. Epub 2016 Mar 25.
27. Jung Hyun Yoon, Min Jung Kim, et al. Indications for breast MRI in the patient with newly diagnosed breast cancer. *J Natl Compr Canc Netw*. 2009 Feb;7(2):193-201.
28. 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;26(2):131-137.
29. Pisano ED, Yaffe MJ. Breast cancer screening: should tomosynthesis replace digital mammography? *JAMA*. 2014 Jun 25;311(24):2488-9.
30. National Comprehensive Cancer Network. (2022, June 2). *NCCN Guidelines Version 1.2022 Breast Cancer Screening and Diagnosis*. Retrieved from June 6, 2022 [https://www.nccn.org/professionals/physician\\_gls/pdf/breast-screening.pdf](https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf)
31. Siu AL; U.S. Preventive Services Task Force. Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2016 Feb 16;164(4):279-96.
32. Thompson A, Santucci G, Curcio M. The Impact of Preoperative Magnetic Resonance Imaging in Detecting Additional Disease in Breast Cancer Patients. *J Registry Manag*. 2016 Summer;43(2):87-9.

33. U.S. Preventive Services Task Force. (2016, Jan 11). *Breast Cancer: Screening. Final Recommendation Statement*. Retrieved April 28,, 2023 from <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#fullrecommendationstart>

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