Clinical Guideline



Oscar Clinical Guideline: Breast Imaging (CG027, Ver. 11)

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 magnetic resonance imaging (MRI) medically necessary as screening modalities in patients meeting certain risk criteria (described below). These modalities and breast positron emission tomography (PET) are also used as a diagnostic tool, typically for the purpose of breast cancer evaluation and staging.

Definitions

"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 cancer risk" refers to the estimated chance a person has of developing breast cancer over time. According to the 2024 American College of Radiology Appropriateness Criteria® for Female Breast Cancer Screening, breast cancer risk is most commonly grouped into three categories based on estimated lifetime risk: average, intermediate, and high.

- Average risk: A person at average risk typically has less than a 15% chance of developing breast cancer in their lifetime based on medical risk assessment tools.
- Intermediate risk: A person at intermediate risk has a 15-20% chance of developing breast cancer in their lifetime based on medical risk assessment tools.
- High risk: A person at high risk has a 20% or greater chance of developing breast cancer in their lifetime based on medical risk assessment tools.

"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.

"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.

"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.

"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.

A. Clinical Indications

- 1. Medical Necessity Criteria for Clinical Review
 - a. Indication-Specific Criteria
- 2. Experimental or Investigational / Not Medically Necessary
- B. Applicable Billing Codes
- C. References

Medical Necessity Criteria for Clinical Review

Indication-Specific Criteria

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.

As an additional indication to MCG Breast MRI (A-0048) criteria for medical necessity, the member may also meet for medical necessity for Breast MRI follow-up surveillance (e.g., up to 5 years) after completing therapy for breast cancer when ALL of the following are met:

- 1. The member had breast conserving therapy or unilateral mastectomy; and
- 2. The member has extremely dense breast tissue on mammography (Category D); and
- 3. The member is presenting with additional risk factor(s) in MCG Breast MRI (A-0048), under Breast cancer screening criteria.

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 breast MRI medically necessary 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.
- The Plan does NOT consider routine MRI surveillance medically necessary for asymptomatic members with a history of breast cancer who have successfully completed primary therapy with bilateral mastectomy.
- The National Comprehensive Cancer Network (NCCN) guidelines for breast cancer (Version 2.2024) state that the utility of MRI in the follow-up screening of most patients with prior breast cancer is undefined. However, annual MRI is recommended for patients with personal history and 1) were diagnosed ≤ 50 OR 2) have dense breasts. NCCN recommends mammograms every 12

- months for follow-up screening and the routine imaging of reconstructed breasts is not indicated.
- According to the American College of Radiology Appropriateness Criteria, breast MRI after mastectomy and breast reconstruction is "usually not appropriate."

Transillumination

• The Plan does NOT consider transillumination medically necessary 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 electrical impedance scanning medically necessary 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 magnetic resonance elastography or ultrasound elastography medically necessary 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 breast-specific gamma-imaging (BSGI)/scintomammography medically necessary as current studies do not provide conclusive evidence that BGSI can be relied on rather than biopsy, ultrasound (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. According to the 2025 American College of Radiology Appropriateness Criteria, Sestamibi molecular breast imaging is usually not appropriate for breast cancer screening. BSGI remains as a limited adjunctive tool to standard mammograms, US, and MRI.

Computer-Aided Detection for MRI and Ultrasound

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

Automated Breast Ultrasound

• The Plan does NOT consider automated breast ultrasound (ABUS) medically necessary for breast imaging. Although there are FDA-approved ABUS systems, based mainly on the safety of the technique, 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 PET-based imaging (e.g., PET, PET-CT, PET-MRI, etc.) medically necessary 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 do not list PET under breast cancer screening recommendations. PET imaging covering the skull base to mid thigh may be medically necessary for members who have already been diagnosed with breast cancer and require further workup or staging when the criteria outlined in MCG Tumor Imaging Positron Emission Tomography (PET) and PET-CT (A-0098) are met.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	Description
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

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	Description
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)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	Description
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
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
G0235	PET imaging, any site, not otherwise specified
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

Table 2	
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:	
Code	Description
C50.011 - C50.9292	Malignant neoplasms of breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Carcinoma in situ of breast
D24.1	Benign neoplasm of right breast
D24.2	Benign neoplasm of left breast
D48.60 - D48.62	Neoplasm of uncertain behavior of breast
N60.01 - N65.1	Disorders of breast
Q85.81 - Q85.89	Other phakomatoses, not elsewhere classified

Table 2	
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:	
Code	Description
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
Z40.01	Encounter for prophylactic removal of breast
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

Table 3	
CPT/HCPCS codes considered experimental or investigational:	
Code	Description
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral
76499	Unlisted diagnostic radiographic procedure Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: When this code is billed for Transillumination, Electrical Impedance Scanning, Scintimammography, it is considered experimental/investigational
A9591	Fluoroestradiol F-18, diagnostic, 1 millicurie
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)

Table 4	
CPT/HCPCS codes <u>not considered medically necessary</u> for breast cancer screening:	
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)

78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
G0219	PET imaging whole body; melanoma for noncovered indications
G0235	PET imaging, any site, not otherwise specified

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