Molina Clinical Policy
Breast MRI: Policy No. 649

Last Approval: 12/14/2022
Next Review Due By: December 2023

OHIO MEDICAID ADDENDUM: Ohio State regulation allows breast MRIs as a screening tool for women with dense breast tissue.

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Breast cancer is the most common malignancy diagnosed in women worldwide; it is the second leading cause of death among women worldwide. Approximately 266,120 women in the United States are diagnosed annually with invasive breast cancer – this accounts for one in eight women (12.4%). In situ breast cancer diagnoses account for 63,960 women. Among males, 2550 were diagnosed in 2018 with invasive breast cancer; 1 in 1000 men will have breast cancer during their lifetime. The incidence of breast cancer began to decrease in the United States – it has been attributed to fewer women using hormone replacement therapy (HRT) and the connection between HRT and increased breast cancer risk. In 2018, 40,920 American women died of breast cancer; a larger decrease occurs in women < age 50. Incidence of disease increases with age with 95% of new diagnoses found in women over age 40 (median age at diagnosis is 61). (Alkabban & Ferguson, 2022). Rates among racial and ethnic groups include:

- Non-Hispanic White: 128.1 in 100,000
- African American: 124.3 in 100,000
- American Indian / Alaska Native: 91.9 in 100,000
- Hispanic / Latina: 91.0 in 100,000
- Asian American / Pacific Islander: 88.3 in 100,000

Risk factors include genetic predisposition, increased age, reproductive history and hormone exposure, lifestyle factors, medical history, and radiation exposure. Additional breast abnormalities may be identified during screening that may or may not be accompanied by symptoms. Common signs and symptoms of breast cancer include palpable breast mass, axillary mass, nipple discharge, skin changes of the breast or nipple, asymmetric thickening or nodularity, breast pain, or signs and/or symptoms due to metastatic disease. The 5-year survival rate in the United States following diagnosis is 99% for women with localized disease, 85% for women with regional spread, and 27% for women with distant metastases. Risk of recurrence in women with estrogen receptor positive cancers treated with endocrine therapy is 13-41% within 5-20 years post-diagnosis. Prognosis may be impacted by a patient's tumor and disease characteristics, age, response to therapy, race and ethnicity, and body mass. (DynaMed, n.d.).

Magnetic resonance imaging (MRI) involves multiplanar imaging based on an interaction between radiofrequency electromagnetic fields and certain nuclei in the body (typically hydrogen nuclei) once a body has been placed in a strong magnetic field. MRI distinguishes between normal and abnormal tissues to give providers a sensitive examination to identify disease. The sensitivity is correlates with the high degree of inherent contrast due to variations in the magnetic relaxation properties of different tissues (normal and diseased), and the necessity of the MRI signal on tissue properties. ([1] ACR, 2022; Gunduru & Grigorian, 2022). Evaluation and diagnosis of breast cancer are based on a clinical breast exam and lymph node assessment plus imaging; confirmation of a diagnosis is made by pathological assessment of biopsy imaging. While not routinely recommended for diagnosis, MRI may be considered in patients with hereditary breast cancer associated with BRCA mutations, breast implants, lobular cancers, suspicion

of multifocality or multicentricity, or in case of discrepancies between conventional imaging and clinical examination (DynaMed, n.d.). Due to high sensitivity, MRI has been utilized more for the detection, assessment, and treatment monitoring of breast cancer. Appropriate indications, scanning technique, and interpretation are variable among facilities. Hormonal changes such as a patient's menstrual cycle and lactation may impact the accuracy of breast MRIs. Lactation and menopause status may also impact the MRI findings. MRI is contraindicated for patients who are pregnant, have implanted devices and foreign bodies, and/or a prior history of gadolinium allergy or diminished renal function. (Ghadimi & Sapra, 2022).

COVERAGE POLICY

Breast MRI **may be considered medically necessary** when the following criteria are met:

1. **Breast Implants**
   a. For suspected rupture of silicon (not saline) breast implants when mammography and breast ultrasound are indeterminate.
   b. Suspicious lesion in a patient who has had free silicone injected into breast.

2. **Recent or Known Diagnosis of Breast Cancer**
   a. New diagnosis of breast cancer.
   b. To detect local recurrence in Members who have distorted breast tissue from surgery, biopsy, or radiation treatments which render mammography or ultrasound difficult to interpret.
   c. To determine tumor extent in a post-operative patient with positive tissue margins.
   d. For evaluation of a suspicious mass seen on mammography or ultrasound in a Member with a prior history of breast cancer if needle biopsy of that mass is inconclusive or cannot be performed.
   e. For pre-operative planning in a Member with known breast cancer.
   f. For evaluation of Members with a biopsy showing lobular carcinoma (LCIS) or atypical ductal or lobular hyperplasia.
   g. For detection of a primary breast cancer in a Member with axillary lymph node metastases if mammography and breast ultrasound are negative or inconclusive.
   h. For advanced breast cancer to assess response after neoadjuvant (preoperative) chemotherapy.

3. **No Prior History of Breast Cancer**
   a. For evaluation of a suspicious lesion seen on imaging and biopsy could not be performed.
   b. Mammography was performed but was limited in diagnostic capability due to extremely dense breast tissue and breast ultrasound is inconclusive.
   c. Persistent reproducible single duct nipple discharge and mammography and ultrasound are inconclusive.

4. **Annual Screening**
   a. Greater than a 20% lifetime risk using a validated breast cancer risk assessment calculator (e.g. Gail, Claus, BRCAPRO, Tyer-Cuzik) and as follows:
      - Risk factor dependent on family history alone
        i. MRI studies to begin 10 years prior to when the youngest family member was diagnosed with breast cancer
        ii. Age 40 whichever comes first but not prior to age 25.

      OR

      - Risk factor dependent on genetic testing:
        iii. Known BRCA carrier.
        iv. First degree relative who has tested positive for BRCA gene and patient is untested.
        v. Not prior to age 25
        vi. Encourage genetic testing prior to MRI.

   b. History of extensive chest radiation prior to the age of 30 (to begin no sooner than 10 years after treatment).

   c. Personal history of or first-degree relative with Le-Fraumeni syndrome (TP53 mutation), Cowden syndrome (PTEN) or Bannayan-Riley-Ruvalcaba syndrome (BRRS).

Additional Critical Information

The above medical necessity recommendations are used to determine the best diagnostic study based on a Member's specific clinical circumstances. The recommendations were developed using evidence-based studies and current accepted clinical practices. Medical necessity will be determined using a combination of these recommendations as well as the Member's individual clinical or social circumstances.

- Tests that will not change treatment plans should not be recommended.
- Same or similar tests recently completed need a specific reason for repeat imaging.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

For peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

National and Specialty Organizations

The **American College of Radiology (ACR)** ([1] 2022, [1-3] 2021, 2018, 2017) published the following *Practice Parameters for the Performance of:*

- Contrast Enhanced Magnetic Resonance Imaging (MRI) of the Breast
- Diagnostic Breast Ultrasound Examination
- Magnetic Resonance Imaging – Guided Breast Interventional
- Molecular Breast Imaging (MBI) Using a Dedicated Gamma Camera
- Preoperative Image-Guided Localization in the Breast

The ACR ([2] 2022) also published the *ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI).* Guidance is provided on indications and contraindications for MRI, provider qualifications to perform MRI, specifications of the examination, proper documentation, equipment specifications, and safety guidelines. A section regarding quality control and improvement is also included with information on safety, infection control, and patient education.

The ACR (n.d.) published the following appropriateness criteria for MRI of the breast:

- Breast Cancer Screening
- Breast Implant Evaluation
- Imaging After Mastectomy and Breast Reconstruction
- Monitoring Response to Neoadjuvant Systemic Therapy for Breast Cancer
- Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women

Available *ACR Appropriateness Criteria and Procedures* can be found at ACR – search for "MRI breast".

The ACR also published *Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations from the ACR* (Monticciolo et al., 2018). Recommendations include mammographic screening starting at age 40 for women at average risk. Women at high risk are recommended to begin mammographic screening sooner as they may benefit from additional screening modalities. Supplemental screening with contrast-enhanced breast MRI is recommended for women with a genetics-based increased risk (and their untested first-degree relatives), with a calculated lifetime risk of 20% or more or a history of chest or mantle radiation therapy at a young age. Breast MRI is recommended for women with personal histories of breast cancer and dense tissue or those diagnosed by age 50. Additional imaging may be warranted for women with histories of breast cancer and women with atypia at biopsy, especially if other risk factors are present. Ultrasound may be considered for women who qualify for but cannot undergo MRI. All women (specifically Black women and women of Ashkenazi Jewish descent) should be evaluated for breast cancer risk by age 30 to identify high risk patients that may benefit from supplemental screening.

The **American Society of Breast Surgeons (ASBrS)** (2019) published a *Position Statement on Screening Mammography.* Women with high-than-average risk of breast cancer are recommended to have an annual MRI (3D if available) starting at age 25 if they have hereditary susceptibility or had prior chest wall radiation during the ages of 10-30. In addition, women with a higher risk are recommended to have an annual mammography (3D preferred) and access to additional imaging such as MRI, starting at age 35 as advised by their provider. Annual mammography is recommended for women with a prior history of breast cancer before age 50 or for women with dense breasts; access to additional imaging such as MRI is also recommended.

The ASBrS (2017) also published a *Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast*. Routine screening with MRI is not recommended for newly diagnosed patients except for those enrolled in a study. The ASBrS does recommend MRI for the following scenarios:

- To identify occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis if clinical examination and conventional breast imaging do not detect a primary breast cancer.
- To determine the degree of cancer or presence of multi-focal or multi-centric tumor or the presence of contralateral cancer in patients with a proven breast cancer and associated clinical or conventional indeterminate imaging findings suspicious for malignancy. Includes patients with invasive lobular carcinoma or extremely dense breast tissue (limiting mammographic sensitivity) or when there are substantial differences in the estimated tumor size as measured on clinical exam, mammogram, and ultrasound.
- To aid the assessment for eligibility and response to neoadjuvant endocrine therapy or chemotherapy before, during, or after treatment; MRI can identify patients who are candidates for breast conservation and assist in determining the extent of resection.
- To further evaluate suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations.
- To evaluate suspected breast implant rupture (especially patients with silicone implants) when MRI findings can aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants.

The ASBrS recommends annual MRI screening as according to guidelines published by the NCCN:

- Women aged 25 or older with a BRCA gene mutation (hereditary breast and ovarian cancer syndrome; BRCA1 and BRCA2) and their untested first-degree relatives, unless the patient has limited life expectancy from age and comorbid conditions.
- Women with other germline mutations known to predispose to a high risk of breast cancer: Li-Fraumeni (begin age 20-29), Cowden's disease (PTEN Hamartoma Tumor Syndrome-PT53) (begin age 30-35 or 5-10 years before earliest breast cancer in family), ATM (begin age 40), CDH1 (begin age 30), CHEK2 (begin age 40), NF1 (begin age 30), PALB2 (begin age 30), and STK11, unless the patient has limited life expectancy from age and comorbid conditions.
- Women with a history of chest irradiation, particularly if receiving mediastinal radiation for Hodgkin's disease between the ages of 10-30.
- Women with a > 20-25% estimated lifetime risk of breast cancer primarily based on mathematical models that are mostly based on family history such as the Claus, BRCAPRO, BOADICEA, and Tyrer-Cuzick models.

The **National Comprehensive Cancer Network (NCCN)** (2022) address the use of MRI in published guidelines titled *Breast Cancer Screening and Diagnosis.*

The **American College of Obstetricians and Gynecologists (ACOG)** (2017) published *Committee Opinion No. 723: Guidelines for Diagnostic Imaging During Pregnancy and Lactation.* The guidance provides an overview of the safety, necessity, and clinical usefulness of imaging studies for acute and chronic conditions during pregnancy. Ultrasound and MRI are the preferred choice of imaging for pregnant patients however these modalities should only be utilized when medically necessary. The risk of radiation exposure to the fetus is low as radiography, CT and nuclear medicine use lower doses of radiation. Further, patients do not need to stop breastfeeding if imaging studies are necessary.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy reviewed, no changes to criteria; updated Overview and Reference sections; added Summary of Medical Evidence section.
12/8/2021	Policy reviewed, no changes to criteria, updated references.
Review Dates	12/13/2018, 12/10/2019, 12/9/2020
12/13/2017	New policy.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

OHIO MEDICAID ADDENDUM: Ohio State regulation allows breast MRIs as a screening tool for women with dense breast tissue.