04-70540-09

Original Effective Date: 10/15/04

Reviewed: 01/23/20

Revised: 02/15/20

Subject: Magnetic Resonance Imaging (MRI) of the Breast

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Magnetic resonance imaging (MRI) of the breast is an imaging modality for the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization.Breast MRI should be bilateral except for individuals with a history of mastectomy or when the MRI is being performed expressly to further evaluate or follow findings in one breast. MRI findings should be correlated with clinical history, physical examination results, and the results of mammography and prior breast imaging. MRI of the breast is performed using MR scanners and intravenous magnetic resonance contrast agents. MRI examinations should be performed with a dedicated breast MRI coil unless obesity or other patient consideration requires modification of the imaging procedure.

POSITION STATEMENT:

Magnetic resonance imaging (MRI) of the breast **meets the definition of medical necessity** for the following indications:

Silicone Implants

- Confirmation of silicone gel-filled breast implant ruptures in symptomatic members, when this diagnosis cannot be confirmed by mammography or breast ultrasound
- Postoperative evaluation of silicone breast implant complications when other imaging is inconclusive

No History of Known Breast Cancer:

Screening examination to detect breast cancer in any of the following:

- Inconclusive screening mammogram when category 0 has been specifically assigned due to breast characteristics limiting the sensentivity of mammography (e.g., extremely or heterogeneously dense breasts, implants obscure breast tissue)
- A Breast Cancer Risk Assessment (by the Gail, or modified Gail risk or other validated breast cancer risk assessment models) that identifies the member as having a lifetime risk of 20% or greater of developing breast cancer (approve annually beginning 10 years prior to youngest family member's age at diagnosis but not before age 30)
- Members with histories of extensive chest irradiation (usually as treatment for Hodgkin's or other lymphoma), between ages 10 and 30). Begin ten years after radiation, but not prior to age 25
- Members with known BRCA mutation (approved annually starting at age 25)
- Member not yet tested for BRCA gene, but with known BRCA mutation in first degree relative (parents, siblings, children) (approve annually starting at age 25)
- Personal history of germline mutations known to predispose to a high risk of breast cancer: Li-Fraumeni syndrome (TP53 mutation)(begin at age 20-29), Cowden syndrome (PTEN) or Bannayan-Riley-Ruvalcaba syndrome (BRRS) (begin at age 30-35 or 5-10 years before earliest breast cancer in family), ATM (Ataxia-Telangiesctasia mutated) gene (begin at age 40), CDH1 gene (begin age 30), CHEK2 (checkpoint kinase 2) gene (begin at age 40), NF1 (neurofibromatosis type 1) gene (begin age 30), PALB2 (partner and localizer of the BRCA2) gene (begin at age 30)

Evaluation of identified lesion, mass or abnormality in breast for any of the following

- Evaluation of suspected breast cancer when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy could not be performed (e.g. seen only in single view mammogram without ultrasound correlation). Includes skin changes of suspected inflammatory breast cancer
- Inconclusive screening mammogram due to breast characteristics limiting the sensitivity of mammography (e.g., extremely or heterogeneously dense breasts, breast implants)
- When the presence of a palpable lesion is questionable (does not meet the criteria for biopsy by clinical exam) and remains indeterminate on mammography and ultrasound
- Evaluation of axillary node metastasis or adenocarcinoma with normal physical examination and normal breast mammogram
- Member diagnosed with biopsy-proven lobular neoplasia or ADH (atypical ductal hyperplasia)/ALH (atypical lobular hyperplasia)
- Spontaneous unilateral serous or bloody nipple discharge when conventional imaging is normal and there is no palpable mass
- Paget's disease of the nipple: to detect underlying ductal carcinoma when conventional imaging is normal and there is no palpable mass
- Follow-up of a probably benign (BI-RADS 3) lesion seen only on prior MRI (when prior mammogram and ultrasound did not show the abnormality)

History of known Breast Cancer

Staging, treatment, and surveillance of members with a known history of breast cancer

- Approve initial staging when conventional imaging is indeterminate in defining multifocal, multicentric, contralateral cancer or there is a discrepancy in estimated tumor size between physical exam and imaging
- **During or after treatment: To identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy (within three (3) months)**
- **Yearly surveillance in members with genetic or other risk factors placing them at high risk for a new cancer or recurrence**

Evaluation of identified lesion, mass or abnormality in breast in any of the following

- Evaluation of breast lesion, identifying whether single or multi-focal, in member with diagnosed breast cancer
- Evaluation of suspicious mass, lesion, distortion or abnormality of breast in member with history of breast cancer when other imaging is inconclusive

Pre-operative evaluation

- Pre-operative evaluation for known breast cancer when surgery planned within thirty (30) days

Post-operative/procedural evaluation:

- A follow-up study may be needed to help evaluate a member's progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested

Other

MRI as First-Line Screening Modality

Only recently has the use of MRI for screening been encouraged. It is now used for screening in member with increased risk for breast cancer due to certain factors (e.g., history of mediastinal irradiation for Hodgkin disease, mutation in a breast cancer susceptibility gene, and familial clustering of breast cancer). Certain mutations, including BRCA1 and BRCA2 genes confer significantly elevated risk of breast cancer. Even when a member tests negative for BRCA mutations, this member may still be at risk for breast cancer if the member has first degree relatives with a history of breast cancer or positive BRCA mutations.

MRI in Member with Normal Physical Examination and Normal Mammogram but with Clinical Signs of Breast Cancer

Metastatic spread in the axillary lymph nodes suggests the breast as the site of the primary cancer even when the results of a mammogram are normal. MRI is useful in detecting primary breast malignancies in these cases. A negative MRI may also be used to prevent an unnecessary mastectomy.

MRI during or after Neoadjuvant Chemotherapy

Dynamic contrast material-enhanced MRI may be used to monitor response of a tumor to neoadjuvant chemotherapy used to shrink the tumor before surgery. This is very important in clinical decision making as alternative therapies may be selected based upon the results obtained from the MRI. It may also be used to depict residual disease after neoadjuvant chemotherapy. MRI-compatible localization tissue markers should be placed prior to neoadjuvant chemotherapy to evaluate the location of the tumor in the event of complete response.

MRI and Breast Implants

MRI may be used in members with breast implants to evaluate breast implant integrity. It may also detect cancers arising behind an implant that may not be diagnosed with mammography.

MRI and Invasive Lobular Carcinoma

Invasive lobular carcinoma (ILC) is not the most common type of breast carcinoma but it is second to invasive ductal carcinoma. MRI is used in the evaluation of ILC and can measure the extent of the disease with high reliability.

Nipple Discharge

Nipple discharge is a common complaint with at least 80% of women having at least 1 episode. Discharge that is considered pathologic is unilateral, spontaneous, from one duct orifice and serous or bloody. Physiologic discharge will be bilateral, from multiple ducts, and white, green, or yellow in color. "In general, MRI should be considered in cases in which other approaches have failed to identify an underlying cause of pathologic nipple discharge. The sensitivities of breast MRI for detection of underlying cause of pathologic nipple discharge are 86% to 100% for invasive cancer and 40% to 100% for noninvasive disease". Ductography (galactography) has the ability to demonstrate very small lesions in the specific duct that is secreting the pathologic nipple discharge. However, it is invasive and may cause discomfort and pain. It can be time-consuming and technically challenging and the rate of incomplete ductography is as high as 15%. The discharge must be present on the day of the study so that a cannula can be placed in the appropriate duct. Failure to cannulate the discharging duct may occur and cannulation of the wrong duct may cause a false-negative ductogram.

BI-RADS 3 (probably benign) MRI and Follow-up

A follow-up MRI study may be indicated to confirm stability of a probably benign mass seen only on prior MRI.

BILLING/CODING INFORMATION:

CPT Coding

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

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment, radiographic study reports (e.g., mammography, breast ultrasound, MRI breast) and reason for magnetic resonance imaging of the breast.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note or treatment notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology Study Reports (e.g., mammography, breast ultrasound, MRI breast)	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

Reimbursement for computer-aided detection (0159T) is included in the allowance of the magnetic resonance imaging breast (77048 and77049).

Follow-up study

A follow-up study may be needed to help evaluate a member's progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

PROGRAM EXCEPTIONS:

Coverage for the radiology services referenced in this guideline performed and billed in an outpatient or office location will be handled through the BCBSF Radiology Management program for select products.

The National Imaging Associates (NIA) will determine coverage for these services for select products. Refer to member's contract benefits.

Federal Employee Plan (FEP): FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.

Medicare Advantage products:

No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date. The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Magnetic Resonance Imaging, (220.2) located at cms.gov.

DEFINITIONS:

Bannayan-Riley-Ruvalcaba syndrome: a rare congenital inherited disorder characterized by excessive growth before and after birth; an abnormally large head (macrocephaly) that is often long and narrow (scaphocephaly); normal intelligence or mild mental retardation; and/or benign tumor-like growths (hamartomas) that, in most cases, occur below the surface of the skin (subcutaneously). The symptoms of this disorder vary greatly from case to case.

Cowden syndrome: (also known as multiple hamartoma syndrome) is a genetic disorder characterized by the development of multiple benign tumor-like malformations (hamartomas) in various areas of the body. Affected individuals also have a predisposition to developing certain cancers, especially cancer of the breast, thyroid or mucous membrane lining the uterus (endometrium). The specific symptoms of Cowden syndrome vary from case to case.

Li-Fraumeni syndrome (LFS): a familial syndrome of early breast carcinoma associated with soft tissue sarcomas and other tumors.

RELATED GUIDELINES:

Genetic Testing for Hereditary Breast or Ovarian Cancer, 05-82000-30

OTHER:

None.

REFERENCES:

1. American Cancer Society recommendations for early breast cancer detection in women without breast symptoms, 10/20/15.
2. American College of Radiology ACR Appropriateness Criteria® Evaluation of Nipple Discharge, 2016.
3. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast, Revised 2018.
4. American Society of Breast Surgeons Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast, 06/22/17.
5. Berg WA, Zhang Z, Lehrer D et al. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. JAMA 2012; 307(13): 1394-1404.
6. Bruening W, Uhl S, Fontanarosa J et al. Noninvasive Diagnostic Tests for Breast Abnormalities: Update of a 2006 Review. Comparative Effectiveness Review No. 47. (Prepared by the ECRI Institute

Evidence-based Practice Center under Contract No. 290- 02-0019.) AHRQ Publication No. 12-EHC014-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2012.

7. Elsamaloty H, Elzawawi MS, Mohammad S et al. Increasing accuracy of detection of breast cancer with 3-T MRI. American Journal of Roentgenology 2009; 192(4): 1142-1148.
8. Godinez J, Mortellaro VE, Marshall J et al. Breast MRI in the evaluation of eligibility for accelerated partial breast irradiation. American Journal of Roentgenology 2008; 191(1): 272-277.
9. Houssami N, Ciattyo S, Martinelli F et al. Early detection of second breast cancers improves prognosis in breast cancer survivors. Annals of Oncology 2009; 20(9): 1505-1510.
10. Khatcheressian JL, Hurley P, Bantug E et al. Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update. Journal of Clinical Oncology 2013; 31(7): 961-965.
11. Mann RM, Hoogeveen YL, Blickman JG et al. MRI compared to conventional diagnostic work-up in the detection and evaluation of invasive lobular carcinoma of the breast: a review of existing literature. Breast Cancer Research and Treatment 2008; 107(1): 1-14.
12. National Imaging Associates, Inc. Breast MRI Clinical Guideline,2020.
13. National Cancer Institute Breast Cancer Risk Assessment Tool. Assessed 12/12/19.
14. National Cancer Institute Breast Cancer Screening (PDQ®), 10/30/19
15. National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology Breast Cancer Risk Reduction Version 1.2019-December 11, 2018.National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology ® Breast Cancer Screening and Diagnosis Version 1. -2019-May 17, 2019.
16. Rockhill B, Spiegelman D, Byrne C et al. Validation of the Gail et al. model of breast cancer risk prediction and implications for chemoprevention. Journal of National Cancer Institute 2001; 73(5): 358-366.
17. Saslow, D, Boetes C, Burke W, et al. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57: 75-89.
18. Siu AL, on behalf of the U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Annals of Internal Medicine 2016; 164(4): 279-296.
19. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, Plastic and Reconstructive Surgery Devices Branch, Division of General, Restorative, and Neurological Devices Offices of Device Evaluation-Guidance for Industry and FDA Staff, Saline, Silicone Gel, and Alternative Breast Implants, 11/17/06.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/23/20.

GUIDELINE UPDATE INFORMATION:

10/15/04	New Medical Coverage Guideline.
10/15/05	Annual review. Added detection of local tumor recurrence in individuals with breast cancer who have radiographically dense breasts or old scar tissue from previous breast surgery that compromises the ability of combined mammography and ultrasonography to when services are covered. Updated references.

08/15/06	Scheduled review. Added 0159T (July CPT update). Updated references.
01/01/07	HCPCS update. Deleted 76093 and 76094. Added 77058 and 77059.
07/01/07	Scheduled review; revised position statements; reformatted guideline; updated references.
11/15/07	Added Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or who have a first-degree relative with one of these syndromes to position statement. Updated definitions and references.
01/21/08	Updated Program Exceptions.
07/15/08	Revised position statement to indicate that MRI of breast may be considered medically necessary for the following indications for screening for breast cancer in the following patients: known BRCA1 or BRCA2 mutation in patient or relative; high risk (lifetime risk about 20 to 25 percent or greater) of developing breast cancer as identified by models that are largely defined by family history (breast, ovarian) annual screening 10 years after therapeutic chest irradiation; or Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or who have a first-degree relative with one of these syndromes. Added the following indications to the position statement (meets the definition of medical necessity): for evaluation of the contralateral breast in patients with a new diagnosis of breast cancer who have normal clinical and mammographic findings in the contralateral breast for preoperative tumor mapping of the involved (ipsilateral) breast to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy Deleted “in order to avoid biopsy” for the diagnosis of a suspicious breast lesion. Added “i.e., indeterminate breast lesion” for the diagnosis of a suspicious breast lesion. Added ipsilateral to the definitions section. Updated references.
09/15/08	Added criteria for detection of tumor recurrence.
05/21/09	Removed Federal Employee Plan (FEP) from BCBSF Radiology Management program exception statement. Added FEP program exception statement: FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.
07/01/09	Updated BCBSF Radiology Management program exception; added BlueSelect.
10/15/09	Revised position statement (experimental or investigational), to clarify diagnosis of suspicious breast lesion. Added position statement for evaluation of residual tumor with positive margins after lumpectomy. Updated description section. Updated references.
01/01/10	Revised BCBSF Radiology Management program exception section.
10/15/10	Annual review: Revised position statement regarding mass, distortion, etc; added “or abnormality in breast”. Added position statement for evaluation of a documented abnormality of the breast prior to obtaining an MRI-guided biopsy when there is documentation that other methods (e.g., palpation, ultrasound) are not able to localize the lesion for biopsy. Revised position statement regarding the evaluation of residual tumor in individuals found to have positive margins after lumpectomy, and deleted

	"when lumpectomy was performed as the definitive surgery". Updated references.
10/01/11	Revision; formatting changes.
10/15/11	Annual review; maintain position statements. Updated references.
06/15/12	Note added for MRI as first-line screening modality in women with increased risk for breast cancer.
01/15/13	Annual review; no change in position statements. Repositioned the statement for MRI a first-line screening modality in women with increased risk for breast (moved to the position statement section). Updated references.
01/01/14	Review. Updated program exception.
03/15/15	Annual review; revised position statement; updated description and references.
11/15/16	Revision; revised position statement. Added additional information related to breast MRI. Updated references.
06/15/18	Revision; revised position statement. Updated references.
01/01/19	Annual HCPCS code update. Deleted 77058, 77059 and 0159T. Added 77046, 77047, 77048 and 77049.
02/15/20	Review/revision. Revised criteria for silicone implants. Revised and added criteria for screening to detect breast cancer. Revised and add criteria for identified lesion, mass or abnormality in breast. Added indication and criteria for staging, treatment, and surveillance of members with a known history of breast cancer. Revised criteria for evaluation of identified lesion, mass or abnormality in breast. Updated references.