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Subject: Magnetic Resonance Imaging (MRI) of the Breast

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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 individual 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:

No history of known breast cancer:

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

- Breast cancer screening in members with high risk of breast cancer as defined by breast cancer risk assessment/clinical risk estimators (models) that are largely depenent on family history (e.g., Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA), Gail model, Tyrer-Cuzick, Claus), with calculated lifetime risk of 20% or greater of developing breast cancer

- Members with lifetime risk of 20% or greater of developing breast cancer based on history of lobular neoplasia (LCIS [lobular carcinoma in situ]/ ALH [atypical lobular hyperplasia]) or ADH [atypical ductal hyperplasia]
- Members with history of extensive chest irradiation (usually as treatment for Hodgkin's or other lymphoma), between ages 10 and 30)
- Members with known BRCA mutation (annually starting at age 25)
- Members not yet tested for BRCA gene, but with known BRCA mutation in first degree relative (parents, siblings, children) (annually starting at age 25).
- Personal history of germline mutations known to predispose to a high risk of breast cancer: LiFraumeni syndrome (TP53 mutation)(begin at age 20), Cowden syndrome (PTEN) or Bannayan-Riley-Ruvalcaba syndrome (BRRS) (begin at age 30), ATM (Ataxia-Telangiesctasia mutated) gene (begin at age 40), CDH1 gene (begin at age 30), CHEK2 (checkpoint kinase 2) gene (begin at age 40), NF1 (neurofibromatosis type 1) gene (begin at 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 if conventional imaging and skin biopsies are first performed and negative)
- Inconclusive or conflicting findings on a diagnostic mammogram or ultrasound when the finding is not a palpable or a discrete mass
- Evaluation of suspicious mass, lesion, distortion, or abnormality of the breast in member with history of breast cancer when other imaging is inconclusive
- Nipple inversion (new) when mammographic and sonographic findings are inconclusive and a biopsy cannot be performed
- Member diagnosed with biopsy-proven lobular neoplasia (i.e., LCIS/ALH (lobular carcinoma in situ/atypical lobular hyperplasia) or ADH (atypical ductal 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
- For a phylloides tumor diagnosed by biopsy, breast MRI may help determine extent of disease and resectability in selected cases. However routine use for surgical planning is controversial
- 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

MRI breast surveillance (annual) for any of the following:

- Members with history of breast cancer and dense breast tissue on mammography
- Members with personal history of breast cancer diagnosed before age 50
- Members with genetic or other risk factors placing them at high risk for a new cancer or recurrence.

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

- Initial staging when conventional imaging is indeterminate in defining the extent of cancer or presence of multifocal, multicentric, contralateral cancer or there is a discrepancy in estimated tumor size between physical exam and imaging
- Invasive lobular carcinoma that is poorly or inadequately defined by mammography, ultrasound, or physical exam
- To identify primary cancer in a member with axillary nodal adenocarcinoma and unidentified primary tumor
- Prior to treatment: To serve as a baseline for comparison prior to amember starting planned neoadjuvant chemotherapy
- During or after treatment: To identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy (within three (3) months).

Silicone implants

- Confirmation of silicone gel-filled breast implant ruptures in asymptomatic members, after an abnormal or indeterminate finding on mammography or breast ultrasound
- Postoperative evaluation of silicone breast implant complications 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.

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**.

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:

Federal Employee Plan (FEP): 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:

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14. National Imaging Associates, Inc. Breast MRI Clinical Guideline, 2022.
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18. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. Version 1.2021.
19. 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.
20. 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.
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22. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Guidance for Industry and Food and Drug Administration Staff:,Saline, Silicone Gel, and Alternative Breast Implants, 09/29/20.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 04/28/22.

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.
05/15/22	Review/revision. Revised and expanded criteria for: screening examination to detect breast cancer, identified lesion, mass or abnormality in breast, staging, treatment, and surveillance for known history of breast cancer. Expanded criteria for history of known breast cancer. Updated references.
07/01/22	Revision to Program Exceptions section.