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Medical Policy

Subject:	MRI of the Breast		
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Description/Scope

This document addresses the use of magnetic resonance imaging (MRI) of the breast. MRI is a diagnostic imaging modality that uses magnetic and radiofrequency fields to image body tissue non-invasively. MRI of the breast can be performed using MR scanners equipped with breast coils and intravenous MR contrast agents. MRI of the breast has been investigated for screening and diagnosis of breast cancer, and evaluation of breast implants.

Position Statement

Medically Necessary:

Annual screening MRI of the breast using scanners equipped with breast coils with the ability to provide needle localization for biopsy is considered **medically necessary** in the following clinical situations:

- Individuals with a BRCA1 or BRCA2 mutation; **or**
- Individuals who ~~are~~ have a first-degree relative ~~of~~ with a BRCA1 or BRCA2 mutation carrier, but who have not themselves been tested for BRCA1 or BRCA2 mutation; **or**
- Individuals with a lifetime risk for breast cancer that is 20–25% or greater, as defined by BRCAPRO or other models (for example, BOADICEA, Gail, Claus, Tyrer-Cuzick) that are largely dependent on family history; **or**
- Individuals who have had radiation therapy to the chest between the ages of 10 and 30 years old; **or**
- Individuals who have genetic variants known to predispose to a high risk of breast cancer or have a first-degree relative with a history of one of the syndromes (for example, TP53 [Li-Fraumeni syndrome], PTEN [Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome], CDH1, STK11, ATM, CHEK2, PALB2); **or**
- Individuals with both a personal history of breast cancer and dense breasts by mammography; **or**
- Individuals considered at high familial risk with any of the following family history:

- Two or more first degree relatives with breast cancer; **or**
- One first degree relative and two or more second degree or third degree relatives with breast cancer; **or**
- One first degree relative with breast cancer before the age of 45 years and one other relative with breast cancer; **or**
- One first degree relative with breast cancer and one or more relatives with ovarian cancer; **or**
- Two second degree or third degree relatives with breast cancer and one or more with ovarian cancer; **or**
- One second degree or third degree relative with breast cancer and two or more with ovarian cancer; **or**
- Three or more second degree or third degree relatives with breast cancer; **or**
- One first degree relative with bilateral breast cancer; **or**
- Breast cancer in ~~a male~~ relatives with XY chromosomes.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

A single repeat MRI of the breast using scanners equipped with breast coils with the ability to provide needle localization for biopsy is considered **medically necessary** 6 months following an MRI for individuals who have met criteria for MRI of the breast and the MRI revealed BIRADS 3 findings.

MRI of the breast using scanners equipped with breast coils with the ability to provide needle localization for biopsy is considered **medically necessary** as an alternative to screening mammography when all of the following criteria are met:

- The individual is appropriate for screening mammography based on recognized national guidelines; **and**
- There is documentation that screening mammogram was not able to be interpreted (for example, due to technical or individual factors such as scarring); **and**
- The MRI scan is not being used to merely follow-up on an indeterminate lesion rather than performing a biopsy; **and**
- None of the investigational and not medically necessary criteria below apply.

MRI of the breast using scanners equipped with breast coils is considered **medically necessary** for the following diagnostic or detection indications:

- For presurgical planning for those with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy. MRI may be performed before and after completion of neoadjuvant chemotherapy to permit tumor localization and characterization; **or**
- To determine the presence of pectoralis major muscle/chest wall invasion in individuals with posteriorly located tumors; **or**
- To detect a suspected occult breast primary for individuals with positive axillary nodes, but with a mammographically normal breast; **or**
- To evaluate the integrity of a breast implant when symptoms of implant rupture are present and ultrasound imaging is inconclusive; **or**
- To screen for asymptomatic rupture of a silicone breast implant beginning 3 years after implantation and every other year thereafter; **or**
- To evaluate the presence of multicentric disease for individuals with clinically localized breast cancer; **or**
- Evaluation of the contralateral breast in individuals within 12 months of a breast cancer diagnosis in the opposite breast is made.

MRI of the breast using scanners equipped with breast coils to evaluate a documented ~~breast abnormality~~microcalcification prior to obtaining an MRI guided biopsy in individuals who do not meet other criteria

for MRI of the breast (above) is considered **medically necessary** when there is documentation that other methods to guide biopsy, such as manual palpation or ultrasound, were not adequate to localize the lesion for biopsy.

Investigational and Not Medically Necessary:

Other applications of MRI of the breast are considered **investigational and not medically necessary** including, but not limited to the following:

- As a screening technique in average risk individuals;
- To further characterize indeterminate breast lesions identified by clinical exam, mammography or ultrasound;
- For the diagnosis of low suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow up;
- For the diagnosis of a suspicious breast lesion in order to avoid biopsy;
- To determine response *during* (as opposed to before and after) neoadjuvant chemotherapy for individuals with locally advanced breast cancer;
- For evaluation of residual tumor in individuals with positive margins after lumpectomy;
- ~~As a screening technique in average risk individuals;~~
- To further characterize suspicious microcalcifications;
- As routine surveillance in individuals who do not otherwise meet the medical necessity criteria above.

Rationale

General Considerations

MRI of the breast is considered more sensitive than mammography in detecting abnormalities of the breast, particularly in individuals with dense breasts. Breast MRI is also considered relatively non-specific, resulting in an increase in recall rates and unnecessary breast biopsies for benign conditions. Indications for screening MRI of the breast are generally focused on individuals considered at high risk of breast cancer, based on either family or clinical history, or genetic testing. The incidence of unnecessary biopsy is considered acceptable in these individuals with high pre-test possibility of breast cancer.

Evaluations of other indications for breast MRI are based on a consideration of how the test will be used to direct and ~~ultimately~~ improve medical management.

The following discussion is based on guidelines published by the American Cancer Society (ACS, 2017), the American Society of Clinical Oncology (ASCO, 2013), the American College of Radiology (ACR, 2016-~~2021~~2022) and the National Comprehensive Cancer Network® (NCCN, ~~2021~~2022). Additionally, a literature search was

conducted to identify any articles not considered by the various guidelines. A complete reference list is beyond the scope of this document. Additional references may be found in the referenced guidelines.

Screening MRI
The majority of the screening indications listed in the position statement above describe subjects considered at an increased risk of breast cancer resulting in an acceptable ratio of sensitivity and specificity as well as an acceptable recall or biopsy rate. The ACS issued guidelines for breast screening with MRI (Saslow, 2007), which included a review of six screening studies of MRI (Kriege, 2004; Kuhl, 2005; Leach, 2005; Lehman, 2005; Sardanelli, 2007; Warner, 2004). The ACS recommendations for annual screening MRI are as follows:

Recommendations for Breast MRI Screening as an Adjunct to Mammography
Recommend Annual MRI Screening (Based on Evidence)

- BRCA mutation;
- First-degree relative of BRCA carrier, ~~but untested;~~but not tested themselves;
- Lifetime risk 20–25% or greater, as defined by BRCAPRO or other models that are largely ~~dependent~~ based on family history.

Recommend Annual MRI Screening (Based on Expert Consensus Opinion)

- Radiation to chest between age 10 and 30 years;
- Li-Fraumeni syndrome and first-degree relatives;
- Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives.

Insufficient Evidence to Recommend for or Against MRI Screening

- Lifetime risk 15–20%, as defined by BRCAPRO or other models that are largely ~~dependent~~ based on family history;
- Lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH);
- Atypical ductal hyperplasia (ADH);
- Heterogeneously or extremely dense breast on mammography;
- Women with a personal history of breast cancer, including ductal carcinoma in situ (DCIS).

Recommend Against MRI Screening (Based on Expert Consensus Opinion)

- Women at less than 15% lifetime risk.

The 20224 National Comprehensive Cancer Network (NCCN) guidelines recommend annual MRI in addition to mammogram for those individuals with an increased risk of breast cancer, defined as those with a history suggestive of or known genetic predisposition for breast cancer, starting at age 25 and individuals who have received thoracic radiation therapy between 10 and 30 years of age.

A 2017 consensus guideline by the American Society of Breast Surgeons on diagnostic and screening magnetic resonance imaging of the breast also supports the use of MRI as a screening technique in women. The guideline particularly supportsrecommends annual screening women age 25 or older with a BRCA gene mutation, women with other germline mutations known to predispose to a high risk of breast cancer, women with a history of chest irradiation, and women with a 20%-25% or greater estimated lifetime risk of breast cancer based on models primarily based on family history.

MRI findings can be classified using the Breast Imaging Reporting and Data System (BIRADS) categories. A finding on an MRI which is determined to beMRI finding designated BIRADS 3 is probably a benign finding lesion; with a short-interval follow-up is appropriate. suggested. MRI findings assessed to be category 3 are highly unlikely for malignancy and should have a very high probability of being benign. However, observation with a short-interval follow-up of these lesions may be preferred over a biopsy (Eby, 2010).

MRI for Dense Breasts:
The majority of individuals with breasts dense enough to interfere with interpretation of a mammogram are those under the age of 40 for whom annual screening is not recommended except if they were at . MRI screening for these individuals would be appropriate for those at high risk. However, in individuals with a prior history of breast cancer, who are not otherwise at high risk, who also have dense breasts which interfere with interpretation of a mammogram, MRI may be able to identify additional disease.

The available dataevidence for routine screening of women using MRI imaging is inconclusive for its use for routine screening in women who are not at high risk. As noted above, the ACS guidelines specifically recommended against annual MRI screening in women at less than a 15% lifetime risk of breast cancer and stated that there was insufficient data to recommend for or against screening in women with a lifetime risk between 15-20%. In 2013, ASCO addressed routine screening as a surveillance technique for individuals with prior breast cancer. These guidelines stated that:

> Although screening breast MRI seems to be more sensitive than conventional imaging at detecting breast cancer in high-risk women, there is no evidence that breast MRI improves outcomes when used

as a breast cancer surveillance tool during routine follow-up in asymptomatic patients. The decision to use breast MRI in high-risk patients should be made on an individual basis depending on the complexity of the clinical scenario.

As noted above, mammography is ~~recognized as~~ the screening method of choice in women at average to intermediate risk of breast cancer. However, in a small subset of ~~these individuals~~women, the mammogram ~~is uninterpretable~~finding is ~~equivical~~equivocal~~. In this unusual situation~~ and~~,~~ MRI may be considered an appropriate alternative to mammography (the mammogram can be interpreted and a breast lesion has been evaluated, but the characteristics of the breast lesion itself are indeterminate for the presence of cancer)
. This indication must be ~~carefully~~ distinguished from MRI to further characterize indeterminate breast lesions, which is considered investigational when biopsy is possible (See further discussion below). ~~In this situation, the mammogram can be interpreted and a breast lesion has been evaluated, but the characteristics of the breast lesion itself are indeterminate for the presence of cancer.~~

MRI to Detect Breast Cancer in the Contralateral Breast in Individuals with Breast Cancer
Kim and colleagues (2013) reported a study of 1323 women with unilateral breast cancer who underwent mammography and ultrasound compared to 1771 women with unilateral breast cancer who underwent mammography, ultrasound and MRI. The incidence of cancer in the contralateral breast was compared between the two groups. Twenty-five contralateral cancers were additionally detected by MRI in the MRI group of women. The cumulative incidence of contralateral breast cancer was 0.5% at 45 months in the MRI group compared to 1.4% in the group without MRI scanning. The 2018 ACR guidelines state that screening of the contralateral breast for those with a new breast malignancy is indicated, and note that MRI can detect occult malignancy in the contralateral breast in at least 3-5% of those with breast cancer.

MRI for Indeterminate Breast Lesions
Validation for MR imaging of indeterminate breast lesions requires data comparing its diagnostic performance compared to breast biopsy, i.e. the gold standard. Considering the relative ease of breast biopsy, the sensitivity of breast MRI would have to be virtually 100% to confidently avoid breast biopsy. While MRI performs well, it is clear that the sensitivity is not 100%. False-negative results tend to occur particularly in certain subcategories, such as ductal carcinoma in situ. Invasive carcinoma may fail to enhance on MRI, leading to false-negative findings as well. The potential harm to health outcomes of failing to diagnose breast cancer or at least delaying the diagnosis of breast cancer is of significant concern.

The 2018 ACR Practice Guideline states:

> MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. Because MRI will miss some cancers that mammography will detect, it should not be used as a substitute for screening mammography. MRI should not be used in lieu of biopsy of a suspicious finding identifiable by mammography, ultrasound, or clinical examination.

Evaluation of suspicious microcalcifications is an example of one type of indeterminate lesions. Several studies have focused on whether or not MRI can help further characterize these lesions, but no study has specifically analyzed how this additional information could be used to direct treatment, specifically to determine whether an individual could forego ~~the gold standard of~~a biopsy. For example, Uematsu and colleagues (2007) performed MRI in 100 cases of microcalcifications detected with screening mammography. All participants underwent biopsy. The negative predictive value of MRI varied with the BI-RADS category of the mammography abnormality and ranged from 93-97%. The authors conclude that MRI may provide additional diagnostic information, but cannot replace biopsy. Bazzochi and colleagues (2006) performed MRI in 112 participants with microcalcifications, which were highly suspicious of cancer (that is, BI-RADs category IV and V). In this group of participants with a higher pretest probability of cancer, the negative predictive value of MRI was only 73%. The authors did not recommend the use of MRI to further characterize microcalcifications.

~~The above discussion notes that b~~Biopsy is recommended to further evaluate indeterminate breast lesions. However, as noted in the ACR Practice Guidelines (2018), biopsy is not possible in a small subset of these individuals; for example, due to distortion on only one mammographic view without a sonographic correlate. In this unusual situation, where biopsy can only be performed with MRI guidance, MRI may be performed.

MRI as a Technique to Evaluate Multicentric Disease

MRI ~~has been used in those with breast cancer~~is used to ~~evaluate~~ detect the presence of multicentric disease in persons with beast cancer and to ~~aid in decision making regarding~~help patients decide between breast conserving surgery ~~vs.~~and mastectomy. ~~Specifically, t~~The presence of multicentric disease may prompt the individual and physician to ~~seriously~~ consider mastectomy. Multiple studies have confirmed that MRI of the breast has a better sensitivity and specificity for identifying multicentric and multifocal breast tumors compared to mammography or ultrasound. ~~However, t~~There is no evidence that mastectomy ~~is associated with~~ achieves superior long term outcomes (i.e., recurrence or survival) in those with multicentric disease compared to breast conserving surgery with tumor bed radiation but~~. Specifically,~~ the pivotal trials that established the equivalency of the two procedures did not use MRI as part of the staging work-up, but rather relied on mammography, chest x-ray, liver enzymes and physical exam for pre-surgical staging.

~~Aside from contributing to the choice between mastectomy and breast conserving surgery~~ Detecting multicentric disease may also help guide the decision to perform ~~, the presence of multicentric disease may contribute to the decision regarding~~ axillary node dissection or the choice between partial breast and whole breast irradiation. Finally, MRI has been widely accepted as part of the preoperative work up for individuals with breast cancer.

The 2018 ACR Practice Guidelines state:

> Breast MRI may be useful to determine the extent of disease and the presence of multifocality and multicentricity in patients with invasive carcinoma and ductal carcinoma in situ … It remains to be shown conclusively, however, that this increased accuracy decreases posttreatment recurrence rates or surgical re-excision.

MRI to Determine Treatment Response in Individuals with Locally Advanced Breast Cancer Receiving Neoadjuvant Chemotherapy

Compared with conventional methods of evaluating tumor size and extent (i.e., mammography, clinical exam or ultrasound), MRI of the breast provides an estimation of tumor size and extent that is at least as good as or better than that based on alternatives. Drew and colleagues (2001) found MRI to be 100% sensitive and specific for defining residual tumor after chemotherapy. Conversely, mammography achieved 90% sensitivity and 57% specificity and clinical exam was only 50% sensitive and 85% specific. Similarly Partridge et al (2002) reported correlation of residual tumor size on MRI of 0.89 and clinical exam of 0.60. Knowledge of the response to chemotherapy is important to determine further therapy options.

A 2013 ASCO Clinical Practice Guideline Update for breast cancer follow-up and management after primary treatment does not recommend MRI of the breast in asymptomatic individuals with no specific findings on clinical exam (Khatcheressian, 2013).

The role of MRI to assess response *during* a course of neoadjuvant chemotherapy is less clear. The most important use would be to reliably identify individuals whose tumors are not responding to neoadjuvant chemotherapy to avoid the added morbidity of continued ineffective chemotherapy. Such chemotherapy may be discontinued or changed to an alternative and potentially effective regimen. MRI would be harmful when it falsely suggests a lack of response and leads to premature discontinuation of effective chemotherapy. There is insufficient evidence to determine whether breast MRI can reliably predict lack of response to neoadjuvant chemotherapy (Le-Petross, 2010).

MRI to Evaluate Suspected Chest Wall Involvement

Morris and colleagues (2000) prospectively studied 19 subjects with posteriorly located breast tumors suspected to involve the pectoralis major muscle based on either mammography or clinical exam. Thirteen of these tumors were thought to be fixed to the chest wall on clinical exam and 12 appeared to have pectoral muscle involvement on mammography. Results of MRI were compared with surgical and pathological findings. The presence of abnormal enhancement within the pectoralis major muscle on MRI was 100% sensitive and 100% specific for identifying the 5 tumors that actually involved the pectoralis major muscle. Given the high level of diagnostic accuracy for MRI as compared with reference standard and conventional alternative techniques, ~~the evidence is considered sufficient to permit conclusions that breast MRI improves net health outcome.~~ we conclude that MRI improves outcomes in this setting.

MRI To Detect a Suspected Occult Breast Primary in Individuals with Positive Axillary Nodes
This indication for MRI represents a small subgroup of individuals, but the adjunctive use of breast MRI allows individuals to avoid the morbidity of mastectomy in a substantial portion of those with an acceptable risk of unnecessary biopsy (Orel, 1999). The use of positive MRI findings to guide breast-conserving surgery instead of presumptive mastectomy appears to offer the substantial benefit of breast conservation in true positive MRI cases.

MRI to Evaluate Residual Tumor after Lumpectomy with Positive Surgical Margins
For those considering breast-conserving surgery, complete removal of all gross tumor has been associated with improved local control. Therefore, re-excision may be considered if the initial lumpectomy specimen has positive surgical margins. Imaging to detect residual disease has been investigated as a technique to refine the selection criteria for re-excision. However, due to postoperative inflammation any type of imaging technique is limited. MRI has been investigated in this setting, with evaluation of different optimal postoperative time frames. For example, Frei and colleagues studied different time frames for MRI and reported that the negative predictive value was highest (86%) 35 days after surgery (Frei, 2000). It is not clear whether an 86% negative predictive value would be adequate ~~to deselect individuals~~obviated the need for ~~from~~ re-excision.

MRI as a Technique to Evaluate the Integrity of Breast Implants
Imaging techniques to detect implant rupture include mammography and ultrasonography. When these techniques are inconclusive, studies have shown that MRI can detect implant integrity for these circumstances (Ahn, 1994). In 2011, the U.S. Food and Drug Administration (FDA) issued the FDA Update on the Safety of Silicone Gel-Filled Breast Implants. This publication provides the following guidance for MRI imaging in those individuals with silicone breast implants:

Recommendations for Health Care Providers:

1. Provide women with copies of patient brochures and informed consent so that they have access to the critical information needed to make informed decisions about receiving and caring for breast implants. Labeling for Approved Breast Implants for patients and for physicians is available on FDA's breast implant website.
2. Maintain medical vigilance through follow-up and post-approval studies so that the long-term effects of silicone gel-filled breast implants can be better understood. Your contributions provide data that are used to evaluate how new surgical techniques, patient characteristics, and implant characteristics influence the cosmetic and health outcomes of patients undergoing breast implantation.
3. Screen for silent rupture using MRI. Women with silicone gel-filled breast implants should undergo MRI screening for silent implant ruptures at 3 years post-implantation, and every 2 years thereafter.
4. Report breast implant associated adverse events and deaths to FDA via MedWatch.

The FDA considered the following for its conclusions:

- Preliminary data from the post-approval studies; and
- A summary and analysis of adverse events reported to FDA since approval; and
- A review and analysis of recent clinical publications about the safety and effectiveness of silicone gel-filled breast implants.

The ACR, in its *Practice Guideline for the Performance of Contrast Enhanced Magnetic Resonance Imaging (MRI) of the Breast*, addresses the appropriate MRI equipment required for breast MRI studies.

Background/Overview

MRI is a non-invasive imaging modality that uses magnetic and radiofrequency fields to image body tissue producing very detailed, cross-sectional pictures of the body. Unlike CT, MRI uses no ionizing radiation and is generally a safe procedure. Nonetheless, the strong magnetic fields and radio pulses can affect metal implants within the body. MRI is sometimes used in combination with mammography.

Definitions

Asymptomatic: The absence of signs or symptoms of disease.

Bannayan-Riley-Ruvalcaba Syndrome: Familial disorder associated with development of variety of benign/malignant tumors and fast-flow vascular anomalies.

BRCAPRO: A computer-based Bayesian probability model that uses first- and second-degree family history of breast or breast/ovarian cancers to determine the probability that a BRCA1 or BRCA2 gene mutation accounts for these cancers (Weitzel et al, 2007).

Breast Imaging Reporting and Data System (BIRADS): http://www.acr.org/Quality-Safety/Resources/BIRADS/About-BIRADS

Contralateral: Taking place or originating in a corresponding part on the opposite side of the body.

Cowden Syndrome: A rare autosomal dominant inherited disorder characterized by multiple tumor-like growths called hamartomas and an increased risk of certain forms of cancer.

Gail Model: A computer based risk analysis tool that uses personal and family history to estimate a woman's chance of developing breast cancer; it does not have the capacity to analyze detailed family histories including first-degree and second-degree relatives on both the maternal and paternal sides.

Li-Fraumeni Syndrome: A family predisposition to multiple cancers, caused by a mutation in the p53 tumor-suppressor gene.

Lumpectomy: The surgical removal of a small tumor in the breast which may be benign or malignant; a lumpectomy differs from a mastectomy in which the breast is removed.

Microcalcification: A tiny deposit of calcium in the breast that cannot be felt but can be detected on a mammogram; a cluster of these very small specks of calcium may indicate that cancer is present.

Multicentric breast cancer: Breast cancer in which there is more than one tumor, all of which have formed separately from one another; tumors are likely to be in different quadrants (sections) of the breast.

Multifocal breast cancer: Breast cancer in which there is more than one tumor, all of which have arisen from one original tumor; the tumors are likely to be in the same quadrant (section) of the breast.

Neoadjuvant chemotherapy: Initial use of chemotherapy for those with localized cancer in order to decrease the tumor burden prior to treatment by other modalities.

Relative, first-degree: A 50% genetic link to the individual; examples are parents, brothers, sisters, or children of an individual.

Relative, second-degree: A 25% genetic link to the individual; examples are aunts, uncles, nieces, nephews, and grandparents of an individual.

Relative, third-degree: A 12.5% genetic link to the individual; examples are first cousins, great grandparents, great grandchildren, of an individual.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time for service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

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

HCPCS

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

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:
For the codes listed above when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

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   - Breast Imaging of Pregnant and Lactating Women (2018).
   - Breast Implant Evaluation (2018).
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Document History

Status	Date	Action
Revised	11/10/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Position Statement and changed "male relative" to "relatives with XY chromosomes"; "breast abnormality" to "mircrocalcification"; and reordered investigational and not medically necessary bullets. Updated References and Website sections.
Reviewed	11/11/2021	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Updated Rationale, References, and Website sections.
Reviewed	11/05/2020	MPTAC review. Updated Rationale, References, and Website sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	11/08/2018	MPTAC review.
Reviewed	10/31/2018	Hematology/Oncology Subcommittee review. Updated Rationale and References sections. Updated Coding section with 01/01/2019 CPT and HCPCS changes; added CPT 77046-77049, codes 77058, 77059, C8904, C8907 deleted 12/31/2018.
Revised	11/02/2017	MPTAC review.

Revised	11/01/2017	Hematology/Oncology Subcommittee review. Updated Rationale and References sections. Added additional genetic variations to Position Statement. The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	11/03/2016	MPTAC review.
Reviewed	11/02/2016	Hematology/Oncology Subcommittee review. Updated Rationale and References sections.
Revised	11/05/2015	MPTAC review.
Revised	11/04/2015	Hematology/Oncology Subcommittee review. Updated Rationale and Reference sections. Clarifications to Position Statement. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review.
Reviewed	11/12/2014	Hematology/Oncology Subcommittee review. Updated Rationale and Reference sections.
Reviewed	11/14/2013	MPTAC review.
Reviewed	11/13/2013	Hematology/Oncology Subcommittee review. Updated Rationale and Reference sections.
Revised	11/08/2012	MPTAC review. Medically necessary Position Statement updated to include a six month follow-up MRI when previous MRI results showed BIRADS 3. Updated Rationale and Definition sections.
Revised	11/07/2012	Hematology/Oncology Subcommittee review. Updated Rationale and Reference.
Revised	11/17/2011	MPTAC review.
Revised	11/16/2011	Hematology/Oncology Subcommittee review. Medically Necessary criteria updated to address the FDA guidance for MRI imaging in those with silicone breast implants. Medically necessary criteria for familial risk/family history clarified. Rationale, Definitions and Reference sections updated.
Reviewed	05/19/2011	MPTAC review.
Reviewed	05/18/2011	Hematology/Oncology Subcommittee review. Medically Necessary criteria clarified for dense breasts. Rationale, Definitions and Reference sections updated.
Reviewed	05/13/2010	MPTAC review.
Reviewed	05/12/2010	Hematology/Oncology Subcommittee review. Rationale, Definitions and Reference sections updated.
Revised	05/21/2009	MPTAC review.

Revised	05/20/2009	Hematology/Oncology Subcommittee review. Criteria updated for microcalcifications, MRI indications for dense breasts and inclusion of the Gail model. Rationale, Background, Definitions and Reference sections updated.
Reviewed	05/15/2008	MPTAC review.
Reviewed	05/14/2008	Hematology/Oncology Subcommittee review. Definitions added. References and Coding sections updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
	11/15/2007	American Cancer Society (ACS) statement corrected in rationale.
Revised	05/17/2007	MPTAC review.
Revised	05/16/2007	Hematology/Oncology Subcommittee review. Criteria revised; Rationale and Reference sections updated.
Revised	03/08/2007	MPTAC review. MRI criteria clarified, rationale updated. References updated.
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes; removed CPT 76093, 76094 deleted 12/31/2006.
Reviewed	03/23/2006	MPTAC review. References updated.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc. Scientific Statement and AMWMR UM Criteria (Historical)	UM RAD 004 01/14/2005 Historical on 02/11/2005	UM guideline RAD 004	MRI of the Breast
WellPoint Health Networks, Inc	09/23/2004	4.01.15	MRI of the Breast