Guidelines for Medical Necessity Determination for Breast MRI

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information MassHealth needs to determine medical necessity for breast magnetic resonance imaging (MRI). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 431.000 (independent diagnostic testing facility services), 433.000 (physician services) and 450.000 (administrative and billing regulations), Subchapter 6 of the *Independent Diagnostic Testing Facility Manual*, and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements applicable to this service. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) or a MassHealth-contracted integrated care organization (ICO) should refer to the MCO's or ICO's medical policies for covered services.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

Magnetic resonance imaging (MRI) of the breast is a computerized imaging tool that can generate detailed, multidimensional images of the breast(s) to detect and characterize disease. Breast MRIs may be used as an adjunct to mammography and breast ultrasound to screen high-risk patients for breast cancer and other abnormalities. This tool may also be used to evaluate the extent of disease in patients with newly diagnosed breast cancer, to monitor treatment response, to detect silicone implant ruptures, and as guidance for biopsy or pre-operative wire-guided localization. Breast MRI is not a replacement for mammogram, ultrasound, or biopsy. MassHealth considers approval for coverage of breast MRIs on an individual, case-by-case basis, in accordance with 130 CMR 450.204.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for breast MRI on a combination of clinical data and the presence of indicators that would affect the relative risks and benefits of the procedure. These criteria include, but are not limited to, the following:

1. Medical necessity for screening breast MRI adjunct to mammography can be demonstrated by meeting one or more of the following criteria:

    a. The member is a known carrier of a deleterious or suspected deleterious BRCA gene mutation.

b. The member has a first-degree relative (e.g., parent, sibling, or child) with a deleterious or suspected deleterious BRCA gene mutation and the member has not been tested.

c. The member has a lifetime breast cancer risk of 20% or greater as estimated with a validated risk assessment model (such as BRCAPRO, Gail, Tyrer-Cuzick, Claus or other similar models).

d. The member has a history of radiation to the chest under the age of 30 years for tumors such as Hodgkin disease.

e. The member has a personal history of or first-degree relative with Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome.

f. The member has silicone gel-filled breast implants (this does not include saline-filled implants) and is symptomatic.

2. Medical necessity for diagnostic breast MRI can be demonstrated by meeting one or more of the following criteria:

   a. to detect an occult malignancy of the contralateral breast in a member with a new breast malignancy;

   b. to determine the extent of disease and the presence of multifocality and multicentricity in a member with invasive carcinoma and ductal carcinoma in situ (DCIS);

   c. to evaluate treatment response before, during, and after chemotherapy and the extent of disease before surgery;

   d. to locate the primary tumor in a member with metastatic disease and/or axillary adenopathy and no mammographic or physical findings of primary breast carcinoma;

   e. to further evaluate a member with a prior history of breast cancer and suspicion of recurrence when clinical exam, mammography, and ultrasound are inconclusive;

   f. to evaluate residual disease in members whose pathology specimens demonstrate close or positive margins;

   g. to confirm rupture of silicone breast implant(s) in a symptomatic patient (does not include saline-filled implants);

   h. to define the relationship of the tumor to the fascia and its extension into the pectoralis major, serratus anterior, and/or intercostal muscles before surgical treatment; and

   i. for lesion characterization when clinical exam, mammography and ultrasound are inconclusive for the presence of breast cancer and a biopsy cannot be performed.

B. NONCOVERAGE

MassHealth does not consider breast MRIs to be medically necessary under circumstances that include, but are not limited to, the following:

1. Breast MRI as a screening tool to detect breast cancer in women who do not otherwise meet one or more of the criteria in Section II. A.1. above. There is insufficient evidence to recommend screening breast MRI in women with the following:

   a. a lifetime breast cancer risk of less than 20% as estimated with a validated risk assessment model (such as BRCAPRO, Gail, Tyrer-Cuzick or similar models)

b. lobular carcinoma in situ (LCIS)

c. atypical ductal hyperplasia (ADH) or atypical lobular hyperplasia (ALH)

d. heterogeneously or extremely dense breasts on mammography

e. a personal history of breast cancer that is not related to a hereditary cancer

2. Breast MRI as an alternative to mammogram or ultrasound, or in lieu of biopsy of a suspicious finding on mammography or ultrasound.

3. Breast MRI as a screening tool to detect breast cancer in men.

4. Breast MRI is not the least costly, medically appropriate alternative.

5. Computer aided detection (CAD) as an aid for radiologists to interpret contrast-enhanced breast MRI is not medically necessary as clinical evidence has not yet demonstrated that its use provides a positive clinical benefit.

3 SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for breast MRIs must be submitted by a MassHealth provider of imaging services and accompanied by clinical documentation supplied by the oncologist or primary care provider that supports the medical necessity for this procedure. If technical and professional components are to be paid separately, each must be requested on a separate line with the appropriate modifiers (TC and 26) added. The request must specify whether the procedure is for screening or diagnostic purposes.

A. Documentation of medical necessity for breast MRIs must include the following, and any other pertinent clinical information that MassHealth may request:

1) **Screening** Breast MRI
Documentation of medical necessity must include one or more of the following, as applicable:

a. results of genetic testing of the member;

b. documentation that the member has a first-degree relative (e.g., parent, sibling, or child) with a deleterious BRCA gene mutation, suspected deleterious BRCA gene mutation and the member has not been tested;

c. documentation of the member's calculated lifetime breast cancer risk as estimated with a validated risk assessment model including a description of the model used (see section II.A.1.c above). Documentation must explain all known risk factors used to calculate lifetime risk (including personal and/or family history);

d. documentation describing the member's history of radiation to chest (documentation must include medical condition and age at first exposure);

e. documentation describing the member's personal and/or family history of Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome;

f. documentation of the date that the member received silicone gel-filled implants, the date(s) of any previous screening breast MRIs, and symptomatology present.

2) **Diagnostic** Breast MRI
Documentation of medical necessity must include the following:

a. reason for performing the breast MRI (see Section II A.2.a-i.);

b. pathology report with diagnosis, if applicable; and

c. reports of most recent diagnostic studies and their results including most recent mammogram, and, if applicable, most recent MRI, ultrasound, and biopsy results

Note: Breast biopsy performed under MRI guidance does not require prior authorization as the breast MRI portion of the procedure is included in the procedure code for the MRI-guided procedure.

B. Clinical information must be submitted by a MassHealth provider of imaging services. *Providers are strongly encouraged to submit requests electronically.* Providers must submit all information pertinent to the diagnosis using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at www.mass.gov/masshealth) and attaching pertinent documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions regarding POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

C. Addendum: CPT codes. The following table includes the most up-to-date CPT codes for this procedure at the time of the writing or most recent revision of this document. Codes must be used when requesting a PA and the most up-to-date codes must be used.

Code	*Description*	*Date*
77058	Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral	June 2016
77059	Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral	June 2016

SELECT REFERENCES

1. American College of Radiology (ACR). ACR practice guideline for the performance of contrast-enhanced magnetic resonance imaging (MRI) of the breast. Amended 2014. Accessed March 2016. Available at: http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/MRI_Breast.pdf

2. ACR. ACR Appropriateness Criteria. Breast Cancer Screening. 2012. Accessed March 2016. Available at: http://www.acr.org/~/media/ACR/Documents/AppCriteria/Diagnostic/BreastCancerScreening.pdf.

3. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC). Special Report: Screening Asymptomatic Women with Dense Breasts and Normal Mammograms for Breast Cancer. April 2014. Accessed March 2016. Available at http://www.bcbs.com/cce/vols/28/special-report-screening.html

4. Charlot M, Beatrix O, Chateau F, et al. Pathologies of the male breast. *Diagn Interv Imaging*. 2013 Jan; 94(1):26-37.

5. Cutuli B1, de La Rochefordière A, Dhermain F, Borel C, Graic Y, de Lafontan B, Dilhyudy JM, Mignotte H, Tessier E, Tortochaux J, N'Guyen T, Bey P, Le Mevel-Le Pourhier A, Arriagada R. Bilateral breast cancer after Hodgkin disease. Clinical and pathological characteristics and therapeutic possibilities: an analysis of 13 cases. *Cancer Radiother.* 1997; 1(4):300-6.

6. Dorrius, M, Jansen-van der Weid, M, Van Ooijen, P, Pinjnappel, R, Oodkerk, M. Computer-aided detection in breast MRI: a systematic review and meta-analysis. Eur Radiol. 2011 Aug; 21(8): 1600–1608. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3128262/

7. Harris JR, Lippman, ME, Morrow M, Osborne, CK. *Diseases of the Breast*. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2010.

8. Iuanow E, Kettler M, Slanetz PJ. Spectrum of disease in the male breast. AJR Am J Roentgenol. 2011 Mar; 196(3): W247-59.

9. Kerlikowske K, Zhu WW, Tosteson A, Sprague BL, Tice JA, Lehman CD, Miglioretti DL. Identifying women with dense breasts at high risk for interval cancer. *Ann Intern Med.* 2015 May; 162:673-681.

10. Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *J Am Coll Radiol.* 2010; 7(1):18-27.

11. Lehman CD, DeMartini W, Anderson BO, Edge SB. Indications for breast MRI in the patient with newly diagnosed breast cancer. *J Natl Compr Canc Netw.* 2009; 7(2): 193-201.

12. McCarthy CM, Pusic AL, Kerrigan CL. Silicone breast implants and magnetic resonance imaging screening for rupture: do U.S. Food and Drug Administration recommendations reflect an evidence-based practice approach to patient care? *Plast Reconstr Surg.* 2008; 121(4): 1127-34.

13. National Comprehensive Cancer Network (NCC). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Breast Cancer Screening and Diagnosis. Version 2.2015. Accessed March 2016. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

14. Patterson SK, Helvie MA, Aziz K, Nees AV. Outcome of men presenting with clinical breast problems: the role of mammography and ultrasound. Breast J. 2006 Sep-Oct. 12(5):418-23. Samphao S, Wheeler AJ, Rafferty E, et al. Diagnosis of breast cancer in women age 40 and younger: delays in diagnosis result from underuse of genetic testing and breast imaging. *Am J Surg.* 2009; 198(4): 538-43.

15. 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(2):75-89.

16. Silverstein MJ, Recht A, Lagios MD, et al. Special Report: Consensus conference III. Image-detected breast cancer: state-of-the-art diagnosis and treatment. *J Am Coll Surg.* 2009; 209(4): 504-20.

17. Sung JS, Lee CH, Morris EA, et al. Screening Breast MR Imaging in Women with a History of Chest Irradiation. Radiology. 2011; 259(1):65-71.

18. Taylor AJ, Taylor RE. Surveillance for breast cancer after childhood cancer. JAMA. 2009; 301(4): 435-6. Weinstein SP, Localio R, Conant EF, Rosen M, Thomas KM, Schnall MD. Multimodality screening of high-risk women: a prospective cohort study. *J Clin Oncol.* 2009; 27(36): 6124-8.

19. Terenziani M1, Casalini P, Scaperrotta G, Gandola L, Trecate G, Catania S, Cefalo G, Conti A, Massimino M, Meazza C, Podda M, Spreafico F, Suman L, Gennaro M. Occurrence of breast cancer after chest wall irradiation for pediatric cancer, as detected by a multimodal screening program. *Int J Radiat Oncol Biol Phys.* 2013 Jan 1;85(1):35-9.

20. U.S. Food and Drug Administration (FDA). Silicone Gel-Filled Implants. Accessed March 2016. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063871.htm

21. U.S. Preventive Services Task Force (USPSTF). Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2009; 151: 716-726.

These Guidelines are based on review of the medical literature and current practice in breast MRI. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products or services. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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