IEHP UM Subcommittee Approved Authorization Guidelines

**MRI of the Breast**

**Policy:**

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

1. To plan pre-surgically in patients 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;
2. To determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors;
3. To detect a suspected occult primary breast mass in patients with positive axillary nodes or more distant metastatic sites, but with a mammographically normal breast;
4. To evaluate the integrity of a breast implant when ultrasound imaging is inconclusive;
5. To check for silent rupture of silicone gel implants no more frequently than every 2 years and to begin 3 years after implant placement;
6. To evaluate the presence of multicentric disease in patients with clinically localized breast cancer;
7. To image the contralateral breast in individuals within 12 months of a breast cancer diagnosis in the opposite breast;
8. To guide localization of breast lesions to perform needle biopsy when suspicious lesions exclusively detected by contrast enhanced MRI cannot be visualized with mammogram or ultrasound;
9. To detect suspected local tumor recurrence in Members with breast cancer who have undergone mastectomy and breast reconstruction with an implant;
10. To detect extent of residual cancer in recently post operative breast with positive pathological margins after incomplete lumpectomy when Member still desires breast conservation and local re-excision is planned;
11. To detect 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.
Annual 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;
- Individuals who are a first-degree relative of a BRCA1 or BRCA2 mutation carrier but have not been tested for BRCA1 or BRCA2 mutation;
- Individuals with a lifetime risk for breast cancer of 20–25% or greater, as defined by BRCAPRO or other models (e.g., BOADICEA, Claus, Tyrer-Cuzick) that are largely dependent on family history;
- Individuals who have had radiation therapy to the chest between the ages of 10 and 30 years;
- Individuals who have Li-Fraumeni syndrome (mutations of TP53 gene), Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome (mutations of PTEN gene), or a first-degree relative with a history of one of these syndromes;
- Individuals considered as high familial risk with **ONE** of the following:
  - 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 relative.

**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:

1. Further characterization of indeterminate breast lesions identified by clinical exam, mammography or ultrasound;
2. Diagnosis of low suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow up;
3. Diagnosis of a suspicious breast lesion in order to avoid biopsy;
4. Determination of response *during* (as opposed to before and after) neoadjuvant chemotherapy in patients with locally advanced breast cancer;
5. Screening in average risk patients;
6. Individuals with heterogeneously or extremely dense breasts on mammography and no personal history of breast cancer.

Rationale:
The available data for MRI imaging is inconclusive for its use for routine screening in asymptomatic individuals. The American Cancer Society, in their American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography stated that Breast MRI Screening as an adjunct to mammography is indicated under the following conditions:

Recommend Annual MRI Screening (Based on Evidence*)
- BRCA mutation;
- First-degree relative of BRCA carrier, but untested;
- Lifetime risk ~20–25% or greater, as defined by BRCAPRO or other models that are largely dependent 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 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 <15% lifetime risk.

*Evidence from non-randomized screening trials and observational studies.
† Based on evidence of lifetime risk for breast cancer.
‡ Payment should not be a barrier. Screening decisions should be made on a case-by-case basis, as there may be particular factors to support MRI. More data on these groups is expected to be published soon.
Background:

Magnetic resonance imaging (MRI) is non-invasive imaging modality that uses magnetic and radiofrequency fields to image body tissue.¹ These radio frequency emissions are received and a tomographic image can be constructed that will represent the tissue being analyzed and the environment surrounding it. MRI uses no ionizing radiation and is unimpeded by bone. It is designed to identify anatomical abnormalities and to provide information on the characteristics of tissue. MRI of the breast has been investigated as a clinical tool for several applications.

When MRI of the breast is used for annual screening in appropriate individuals, it should be performed with a mammogram.

Effective Date:  May 27, 2009

Reviewed Annually:  November 9, 2016
Revised:
August 22, 2012
May 11, 2016

Bibliography:

1.  Anthem Blue Cross MRI of the Breast; RAD.00036

Disclaimer

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.