Magnetic Resonance Imaging (MRI), formerly called nuclear magnetic resonance (NMR), is a non-invasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or computed tomography (CT) scans, in which the image is produced by x-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MRI image production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, and the relaxation times, and the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. General Clinical Utility
Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body. Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and Food and Drug Administration (FDA) approval of new paramagnetic contrast agents for MRI which allow even better visualization in some instances. Multi-slice imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses...
do not cause distortion of MR images, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

Indications and Limitations of Coverage

B. Nationally Covered MRI Indications

1. MRI

Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection C), MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific covered indications. Coverage is limited to MRI units that have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. In addition, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

a) Effective November 22, 1985:
   a. MRI is useful in examining the head, central nervous system, and spine.
   b. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are visible.
   c. The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology.

b) Effective November 22, 1985:
   a. MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses, including abnormalities of the large vessels such as aneurysms and dissection.
   b. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals, and pelvic organs without the use of radiological contrast materials. When MRI is considered reasonable and necessary, the use of paramagnetic contrast materials may be covered as part of the study.
   c. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and
d. to evaluate disorders of cancellous bone and soft tissues.
e. It may also be used in the detection of pericardial thickening.
f. Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early stage and monitored with MRI.
g. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect the early stages of infection of the bone to which the prosthesis is attached.

c) Effective March 22, 1994:
   a. MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

d) Effective March 4, 1991:
   a. MRI with gating devices and surface coils, and gating devices that eliminate distorted images caused by cardiac and respiratory movement cycles are now
considered state of the art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

C. Contraindications and Nationally Non-Covered Indications

1. Contraindications
   The MRI is not covered when the following patient-specific contraindications are present:
   MRI is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms unless the Medicare beneficiary meets the provisions of the following exceptions:
   Effective July 7, 2011, the contraindications will not apply to pacemakers when used according to the FDA-approved labeling in an MRI environment

2. Nationally Non-Covered Indications
   CMS has determined that MRI of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Act, and are therefore non-covered.

D. Other
   Effective June 3, 2010, all other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local MAC discretion.
NIA CLINICAL GUIDELINE FOR BREAST MRI:

INTRODUCTION:

Magnetic resonance imaging (MRI) of the breast is a useful tool 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 women 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 any other prior breast imaging.

INDICATIONS FOR BREAST MRI FOR WOMEN:

Silicone Implants:
- Confirmation of silicone gel-filled breast implant ruptures, when this diagnosis cannot be confirmed by mammography or breast ultrasound.
- For postoperative evaluation of silicone breast implant complications.

No History of Known Breast Cancer

For screening examination to detect breast cancer in any of the following situations:
- A Breast Cancer Risk Assessment (by the Gail risk or other validated breast cancer risk assessment models) that identifies the patient as having a lifetime risk of 20% or greater of developing breast cancer (Approve annually).
- Two or more first degree relatives (parents, siblings, and children) have history of breast cancer.
- Women with histories of extensive chest irradiation (usually as treatment for Hodgkin’s or other lymphoma.) Approve annually starting at age 30.
- Patients with known BRCA mutation. Approve annually starting at age 30.
- Patients not yet tested for BRCA gene, but with known BRCA mutation in first degree relative. Approve annually starting at age 30.

For evaluation of identified lesion, mass or abnormality in breast in any of the following situations:
- Two or more first degree relatives (parents, siblings, and children) have history of breast cancer.
- 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).
- Previous positive breast biopsy within the previous four (4) months and no intervening previous breast MRI.
- Inconclusive mammogram due to breast characteristics limiting the sensitivity of mammography (e.g., extremely dense breasts, implants).
- Evaluation of palpable lesion on physical examination and not visualized on ultrasound or mammogram and MRI guided biopsy considered.
- For evaluation of axillary node metastasis or adenocarcinoma with normal physical examination and normal breast mammogram.
- Patients diagnosed with biopsy-proven lobular neoplasia or ADH (atypical ductal hyperplasia).
- Personal history of or first-degree relative with Le-Fraumeni syndrome (TP53 mutation), Cowden syndrome (PTEN) or Bannayan-Riley-Ruvalcaba syndrome (BRRS).

**History of Known Breast Cancer**

**For screening examination to detect breast cancer in any of the following situations:**
- Patients with a known history of Breast Cancer: Approve Initial staging, with treatment [within three (3) months], and yearly surveillance for detection of recurrence or a new cancer.

**For evaluation of identified lesion, mass or abnormality in breast in any of the following situations:**
- For evaluation of breast lesion, identifying whether single or multi-focal, in patient with diagnosed breast cancer.
- For evaluation of suspicious mass, lesion, distortion or abnormality of breast in patient with history of breast cancer.

**Pre-operative:**
- For preoperative evaluation for known breast cancer when surgery planned within thirty (30) days.
- Evaluation of more than two (2) lesions to optimize surgical planning when requested by surgeon or primary care provider on behalf of surgeon who has seen the patient.

**ADDITIONAL INFORMATION RELATED TO BREAST MRI:**

**Request for a follow-up study** - A follow-up study may be needed to help evaluate a patient’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.

**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

**MRI as First-Line Screening Modality** – Only recently has the use of MRI for screening been encouraged. It is now used for screening in women 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 woman tests negative for BRCA mutations, she may still be at risk for breast cancer if she has first degree relatives with a history of breast cancer or positive BRCA mutations.
MRI in Women with Normal Physical Examination and Normal Mammogram but with Clinical Signs of Breast Cancer – Metastatic spread in the axillary lymph nodes suggest 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 and Breast Implants – MRI may be used in patients 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.
REFERENCES


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