“FOR CMS (MEDICARE) MEMBERS ONLY”

NATIONAL COVERAGE DETERMINATION (NCD) FOR MAGNETIC RESONANCE IMAGING:

Item/Service Description
A. General
1. Method of Operation
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 LOWER EXTREMITY MRI:

INTRODUCTION:

Magnetic resonance imaging shows the soft tissues and bones. With its multiplanar capabilities, high contrast and high spatial resolution, it is an accurate diagnostic tool for conditions affecting the joint and adjacent structures. MRI has the ability to positively influence clinicians’ diagnoses and management plans for patients with conditions such as primary bone cancer, fractures, and abnormalities in ligaments, tendons/cartilages, septic arthritis, and infection/inflammation.

INDICATIONS FOR LOWER EXTREMITY MRI (FOOT, ANKLE, KNEE, LEG or HIP) (plain radiographs must precede MRI evaluation):

Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis):
- Initial evaluation of suspicious mass/tumor found on an imaging study, and needing clarification, or found by physical exam and remains non-diagnostic after x-ray or ultrasound is completed.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Surveillance: One follow-up exam if initial evaluation is indeterminant and lesion remains suspicious for cancer. No further surveillance unless tumor is specified as highly suspicious, or change was found on last imaging.

Evaluation of known cancer:
- Initial staging of known cancer in the lower extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected lower extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Cancer surveillance: Once per year (last test must be over 10 months ago before new approval) for surveillance of known cancer.

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- With abnormal physical, laboratory, and/or imaging findings.
- Known or suspected (based upon initial workup including x-ray) of septic arthritis or osteomyelitis.

For evaluation of suspected (AVN) avascular necrosis (i.e. aseptic necrosis, Legg-Calve-Perthes disease in children):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.

For evaluation of suspected or known Auto Immune Disease, (e.g. rheumatoid arthritis):
- Known or suspected auto immune disease and non-diagnostic findings on prior imaging.

For evaluation of known or suspected fracture and/or injury:
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Suspected fracture when imaging is negative or equivocal.
• Determine position of known fracture fragments/dislocation.

**For evaluation of persistent pain and initial imaging (e.g. x-ray) has been performed:**
• Chronic (lasting 3 months or greater) pain and/or persistent tendonitis unresponsive to conservative treatment*, which include - medical therapy (may include physical therapy or chiropractic treatments) and/or - physician supervised exercise** of at least four (4) weeks, OR with progression or worsening of symptoms during the course of conservative treatment.

**Pre-operative evaluation.**

**Post-operative/procedural evaluation:**
• When imaging, physical or laboratory findings indicate joint infection, delayed or non-healing or other surgical/procedural complications.
• 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.

**Other indications for a Lower Extremity (Foot, Ankle, Knee, Leg or Hip) MRI:**
• Abnormal bone scan and x-ray is non-diagnostic or requires further evaluation.
• MR arthrogram.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, treated osteochondral defects where physical or imaging findings suggest its presence.

**Additional indication specific for FOOT or ANKLE MRI**
• Accompanied by physical findings of ligament damage such as an abnormal drawer test of the ankle or significant laxity on valgus or varus stress testing and/or joint space widening on x-rays.

**Additional indications specific for KNEE MRI:**
• Accompanied by blood in the joint (hemarthrosis) demonstrated by aspiration.
• Presence of a joint effusion.
• For evaluation of suspected Baker’s cyst or posterior knee swelling with ultrasound requiring further evaluation.
• Accompanied by physical findings of a meniscal injury determined by physical examination tests (McMurray’s, Apley’s) or significant laxity on varus or valgus stress tests.
• Accompanied by physical findings of anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) ligamental injury determined by the drawer test or the Lachman test.

**Additional indications specific for HIP MRI:**
• For evaluation of suspected slipped capital femoral epiphysis with non-diagnostic imaging.
• For any evaluation of patient with hip prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging.
• Suspected labral tear of the hip with signs of clicking and pain with hip motion especially with hip flexion, internal rotation and adduction which can also be associated with locking and giving way sensations of the hip on ambulation.

ADDITIONAL INFORMATION RELATED TO A LOWER EXTREMITY MRI:

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.

*Conservative Therapy: (musculoskeletal) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, injections (bursal, and/or joint, not including trigger point), and diathermy, can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care. NOTE: for joint and extremity injuries, part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

**Home Exercise Program - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with information provided regarding completion of HEP (after suitable 4 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

MRI and Knee Trauma - MRI is an effective means of evaluating internal derangements of the knee with a very high accuracy for detection of meniscal injury. On MRI of the knee, meniscal injury may appear “free-floating”, corresponding to a meniscal avulsion or detachment from the tibial plateau. The floating meniscus seen on MRI is a result of significant trauma. It may also be associated with significant ligamentous injury. The results of the MRI are valuable to the surgeon as he plans to reattach the meniscus to the tibial plateau.

MRI and Osteonecrosis – Osteonecrosis is a complication of knee surgery which may be accompanied by new or persistent pain after meniscal surgery. It can be detected by MRI with subcortical low signal intensity of T1-weighted images with or without central high signal intensity on T2-weighted images. Osteonecrosis can result in collapse of the articular surface.
MRI and Legg-Calvé-Perthes Disease (LPD) – This childhood condition is associated with an insufficient blood supply to the femoral head which is then at risk for osteonecrosis. Clinical signs of LPD include a limp with groin, thigh or knee pain. Flexion and adduction contractures may develop as the disease progresses and eventually movement may only occur in the flexion-extension plane. This condition is staged based on plain radiographic findings. MRI is used in identifying the early stage of LPD when normal plain films are normal. It is also used in preoperative planning to diagnose “hinge abduction” (lateral side of the femoral head contacts the acetabular margin and femoral head does not slide as it should). However, MRI is not used as a standard diagnostic tool.

MRI and Septic Arthritis – Young children and older adults are the most likely to develop septic arthritis in the hip joint. Early symptoms include pain in the hip, groin, or thigh along with a limping gait and fever. It is sometimes hard to differentiate this condition from transient synovitis, a less serious condition with no known long-term sequelae. MRI may help in the differential diagnosis of these two conditions. Coronal T1-weighted MRI, performed immediately after contrast administration, can evaluate blood perfusion at the femoral epiphysis.

MRI and Slipped Capital Femoral Epiphysis – This condition, where the femoral head is displaced in relation to the femoral neck, is the most common hip disorder in adolescents and it is more common in obese children. Its symptoms include a limping gait, groin pain, thigh pain and knee pain. Most cases are stable and the prognosis is good with early diagnosis and treatment. Unstable slipped capital femoral epiphysis may lead to avascular necrosis. MRI is used for diagnosis of slipped capital femoral epiphysis. Its image can be oriented to a plane orthogonal to the plane of the physic to detect edema in the area of the physis.

MRI and Tarsal Coalition – This is a congenital condition in which two or more bones in the midfoot or hindfoot are joined. It usually presents during late childhood or late adolescence and is associated with repetitive ankle sprains. Mild pain, deep in the subtalar joint and limited range of motion is clinical symptoms. Tarsal coalition is detectable on oblique radiographs, but these are not routinely obtained at many institutions. Clinical diagnosis is not simple; it requires the expertise of skilled examiners. MRI is valuable in diagnosing tarsal coalition because it allows differentiation of osseous from non-osseous coalitions and also depicts the extent of joint involvement as well as degenerative changes. It may also detect overgrowth of the medial aspect of the talus that may be associated with talocalcaneal coalitions.

MRI and Ankle Fractures – One of the most frequently injured areas of the skeleton is the ankle. These injuries may include ligament sprains as well as fractures. A suspected fracture is first imaged with conventional radiographs in anteroposterior, internal oblique and lateral projections. MRI is normally not used in the initial imaging of suspected ankle fractures; MRI is more specific for ligamentous injuries. MRI may identify ankle ligament injuries associated with problematic subsets of ankle fracture.
REFERENCES


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