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 LUMBAR SPINE MRI:

INTRODUCTION:

Magnetic resonance imaging (MRI) is used in the evaluation, diagnosis and management of spine related conditions, e.g., degenerative disc disease, cauda equine compression, radiculopathy, infections, or cancer in the lumbar spine. MRI provides high quality multiplanar images of organs and structures within the body without the use of x-rays or radiation. In the lumbar area where gonadal exposure may occur, MRI's lack of radiation is an advantage.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LUMBAR SPINE MRI:

For evaluation of neurologic deficits:
- With any of the following new neurological deficits: lower extremity weakness; abnormal reflexes; abnormal sensory changes along a particular dermatome (nerve distribution) as documented on exam; evidence of Cauda Equina Syndrome; bowel or bladder dysfunction; new foot drop.

For evaluation of chronic back pain with any of the following:
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months
- With progression or worsening of symptoms during the course of conservative treatment*
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality

For evaluation of new onset of back pain:
- Failure of conservative treatment*, for at least six (6) weeks
- With progression or worsening of symptoms during the course of conservative treatment*
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality

For evaluation of trauma or acute injury within past 72 hours:
- Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
- With progression or worsening of symptoms during the course of conservative treatment*.

For evaluation of known tumor, cancer or evidence of metastasis:
- For staging of known tumor.
- For follow-up evaluation of patient undergoing active treatment.
- Presents with new signs or symptoms (e.g., laboratory and/or imaging findings) of new tumor or change in tumor.
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality
• With evidence of metastasis on bone scan or previous imaging study.
• With no imaging/restaging within the past ten (10) months.

For evaluation of suspected tumor:
• Prior abnormal or indeterminate imaging that requires further clarification.

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance OR evaluation of suspected metastases:
• ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected infection, abscess, or inflammatory disease:
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, lymphoma:
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For post-operative / procedural evaluation of surgery or fracture occurring within past six (6) months:
• 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.
• Changing neurologic status post-operatively.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• Surgical infection as evidenced by signs/symptoms, laboratory or prior imaging findings.
• Delayed or non-healing fracture as evidenced by signs/symptoms, laboratory or prior imaging findings.
• Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

Other indications for a Lumbar Spine MRI:
• For preoperative evaluation.
• Tethered cord, known or suspected spinal dysraphism.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Ankylosing Spondylitis - For diagnosis when suspected as a cause of back or sacroiliac pain and completion of the following initial evaluation:
  o History of back pain associated with morning stiffness
  o Sedimentation rate and/or C-reactive protein
  o HLA B27
o Non-diagnostic or indeterminate x-ray

- Known Arnold-Chiari syndrome.

**COMBINATION OF STUDIES WITH LUMBAR SPINE MRI:**

**Cervical/Thoracic/Lumbar MRIs:**
- Any combination of these for scoliosis survey in infant/child.
- Any combination of these for spinal survey in patient with metastasis.
- For evaluation of spinal abnormalities associated with Chiari Malformation.

**ADDITIONAL INFORMATION RELATED TO LUMBAR SPINE 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* (spine) 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, acupuncture and/or stimulators, medications, injections (epidural, facet, 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.

**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 documentation provided regarding completion of HEP (after suitable 6 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 Back Pain** – MRI is the initial imaging modality of choice in the evaluation of complicated low back pain. Contrast administration may be used to evaluate suspected inflammatory disorders, e.g., discitis, and it is useful in evaluating suspected malignancy. Radiculopathy, disease of the nerve roots, is the most common indication for MRI of patients with low back pain. The nerve roots become irritated and inflamed, due to direct pressure from degenerative changes in the lumbar spine, creating pain and numbness. Symptoms of radiculopathy also include muscle weakness. MRI is indicated for this condition if the symptoms do not improve after conservative treatment over six weeks. MRI is also performed to evaluate Cauda equina syndrome, severe spinal compression.

**Tethered spinal cord syndrome** - a neurological disorder caused by tissue attachments that limit the movement of the spinal cord with the spinal column. Although this condition is rare, it can continue undiagnosed into adulthood. The primary cause is myelomeningocele and lipomyelomeningocele; the following are other associations that vary in severity of symptoms and treatment.
- Dermal sinus tract (a rare congenital deformity)
- Diastematomyelia (split spinal cord)
- Lipoma
- Tumor
- Thickened/tight filum terminale (a delicate filament near the tailbone)
- History of spine trauma/surgery
- Arnold Chiari Malformation

Magnetic resonance imaging (MRI) can display the low level of the spinal cord and a thickened filum terminale, the thread-like extension of the spinal cord in the lower back. Treatment depends upon the underlying cause of the tethering. If the only abnormality is a thickened, shortened filum then limited surgical treatment may suffice.

**Back Pain with Cancer History** - Radiographic (x-ray) examination should be performed in cases of back pain when a patient has a cancer history. This can make a diagnosis in many cases. This may occasionally allow for selection of bone scan in lieu of MRI in some cases. When radiographs do not answer the clinical question, then MRI may be appropriate after a consideration of conservative care.

For example, bone metastases occur in a minority of all breast cancer patients. Low stage breast cancer patients are very unlikely to have bone metastases (Coleman RE et al). Radiographic (X-ray) evaluation prior to MRI is appropriate. A trial of conservative care in back pain is also indicated and appropriate in these low stage patients.

Advanced stage breast cancer patients do develop bone metastases in a slight majority of cases (Coleman RE et al). Back pain in advanced stage breast cancer patients should still be initially evaluated with X-ray (which has the chance of demonstrating cause of pain, or identifying multiple metastases, and may change the subsequent imaging choice for optimal staging). However, these patients should, in most cases, not undergo a trial of conservative care.”
REFERENCES


ACR-AIUM-SPR-SRU Practice Parameter For The Performance of AN Ultrasound Examination Of The Neonatal And Infant Spine (2016)
http://www.acr.org/~/media/222a9d4cb54409ba108b8929a56d1d9.pdf


Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer