“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.

b) 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 CERVICAL SPINE MRI:

INTRODUCTION:

Magnetic resonance imaging (MRI) produces high quality multiplanar images of organs and structures within the body without radiation. It is the preferred modality for evaluating the internal structure of the spinal cord, providing assessment of conditions such as degenerative disc pathology, osteomyelitis and discitis.

INDICATIONS FOR CERVICAL SPINE MRI:

For evaluation of known or suspected multiple sclerosis (MS):
- Evidence of MS on recent baseline Brain MRI.
- Suspected MS with new or changing symptoms consistent with cervical spinal cord disease.
- Follow up to known Multiple Sclerosis.
- Follow up to the initiation or change in medication for patient with known Multiple Sclerosis.

For evaluation of neurologic deficits:
- With any of the following new neurological deficits: extremity weakness; abnormal reflexes; or abnormal sensory changes along a particular dermatome (nerve distribution) as documented on exam.

For evaluation of suspected myelopathy:
- Progressive symptoms including hand clumsiness, worsening handwriting, difficulty with grasping and holding objects, diffuse numbness in the hands, pins and needles sensation, increasing difficulty with balance and ambulation (unsteadiness, broad-based gait), increased muscle tone, weakness and wasting of the upper and lower limbs; diminished sensation to light touch, temperature, proprioception, vibration; bowel and bladder dysfunction in more severe cases)

For evaluation of chronic or degenerative changes, e.g., osteoarthritis, degenerative disc disease:
- 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 radicular symptoms are present.
For evaluation of new onset of neck 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 radicular symptoms are present.

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 (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 radicular symptoms are present.
- 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.
  - Cancer surveillance excluding small cell lung cancer: Every six (6) months for the first two (2) years then annually thereafter.
  - Cancer surveillance – small cell lung cancer: Up to every 3 months for the first two years then annually thereafter.

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

For evaluation of immune system suppression, e.g., HIV, chemotherapy, leukemia, lymphoma:
- As evidenced by signs/symptoms, laboratory or prior imaging findings.
- For post-operative / procedural evaluation: 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 radicular symptoms are present.
• Surgical infection as evidence by signs/symptoms, laboratory or prior imaging findings.
• Delayed or non-healing as evidence 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.

For post-operative / procedural evaluation for surgery or fracture occurring within the 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 radicular symptoms are present.
• Surgical infection as evidence by signs/symptoms, laboratory or prior imaging findings.
• Delayed or non-healing as evidence 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 Cervical Spine MRI:
• For preoperative evaluation.
• Suspected cord compression with any of the following neurological deficits: extremity weakness; abnormal gait; asymmetric reflexes.
• Known arnold-chiari syndrome.
• Syrinx or syringomyelia.

COMBINATION OF STUDIES WITH CERVICAL 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 metastases.

Cervical MRI/CT
• For unstable craniocervical junction.

Brain MRI/Cervical MRI –
• For evaluation of arnold chiari malformation.
• For follow-up of known multiple sclerosis (MS).

ADDITIONAL INFORMATION RELATED TO CERVICAL SPINE MRI:

*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).

Cervical myelopathy: Symptom severity varies and a high index of suspicion is essential for making the proper diagnosis in early cases. Symptoms of pain and radiculopathy may not be present. The natural history of myelopathy is characterized by neurological deterioration. The most frequently encountered symptom is gait abnormality (86%) followed by increased muscular reflexes (79.1%), pathological reflexes (65.1%), paresthesia of upper limb (69.8%) and pain (67.4%) Vitzthum, Hans-Ekkehart, Dalitz, Kristina

MRI for Evaluation of Discitis – Discitis is a known complication of cervical discography. Postoperative discitis in the cervical spine does not occur frequently but result from accidental inoculation of bacteria into the disc space intra-operatively by a contaminated spinal needle being used as a radiological marker. There may be other causes for postoperative discitis, e.g., esophageal perforation, hematogenous spread, inoculation of bacteria during surgery. Patients with an alteration in the nature of their symptoms after cervical discectomy and fusion may have discitis. Symptoms may include complaints of mild paresthesia in extremities and neck pain. MRI may be performed to reveal feature of discitis with associated abscesses and may help to confirm the diagnosis and decide on the further management.

MRI for Cervical Radiculopathy – MRI is a useful test to evaluate the spine because it can show abnormal areas of the soft tissues around the spine: it addition to the bones, it can also show pictures of the nerves and discs and is used to find tumors, herniated discs or other soft-tissue disorders. MRI has a role both in the pre-operative screening and post-operative assessment of radicular symptoms due to either disc or osteophyte.

MRI and Multiple Sclerosis (MS) – MRI is a sensitive method of detecting the white matter lesions of MS. These plaques on MRI generally appear as multiple, well demarcated, homogenous, small ovoid lesions which lack mass effect and are oriented perpendicular to the long axis of the lateral ventricles. Sometimes they present as large, space occupying lesions that may be misinterpreted as tumors, abscesses or infarcts.

MRI and Neck Pain – Neck pain is common in the general population and usually relates to musculoskeletal causes but it may also be caused by spinal cord tumors. When neck pain is accompanied by extremity weakness, abnormal gait or asymmetric reflexes, spinal MRI may be performed to evaluate the cause of the pain. MRI may reveal areas of cystic expansion within the spinal cord. Enhancement with gadolinium contrast may suggest that the lesion is neoplastic.
REFERENCES


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