National Imaging Associates, Inc.

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“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 BRAIN (HEAD) MRI:

INTRODUCTION:

Brain (head) MRI is the procedure of choice for most brain disorders. It provides clear images of the brainstem and posterior brain, which are difficult to view on a CT scan. It is also useful for the diagnosis of demyelinating disorders (disorders such as multiple sclerosis (MS) that cause destruction of the myelin sheath of the nerve). The evaluation of blood flow and the flow of cerebrospinal fluid (CSF) is possible with this non-invasive procedure.

INDICATIONS FOR BRAIN MRI:

For evaluation of suspected multiple sclerosis (MS):
- For evaluation of patient with neurological symptoms or deficits within the last four (4) weeks.

For evaluation of known multiple sclerosis (MS):
- Stable condition with no prior imaging within the past ten (10) months.
- Exacerbation of symptoms or change in symptom characteristics such as frequency or type and demonstrated compliance with medical therapy.
- For repeat follow up and no prior imaging within the past ten (10) months (unless for exacerbation of symptoms) for patients taking Tysabri (Natalizumab).

For evaluation of known or suspected seizure disorder:
- New onset of a seizure.
- Medically refractory epilepsy.

For evaluation of suspected Parkinson's disease:
- For evaluation of suspected Parkinson's disease as a baseline study.

For evaluation of known Parkinson's disease:
- For evaluation of new non-Parkinson symptoms complicating the evaluation of the current condition.

For evaluation of neurological symptoms or deficits:
- Acute, new or fluctuating neurologic symptoms or deficits such as tingling (paresthesia), numbness of one side, spastic weakness (hemiparesis) of one side, paralysis, loss of muscle control, inability to speak, lack of coordination or mental status changes.

For evaluation of cognitive assessment:
- Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status exams showing at least mild cognitive impairment AND a completed basic metabolic workup (such as thyroid function testing, liver function testing, complete blood count, etc).

For evaluation of known or suspected trauma:
- Known or suspected trauma or injury to the head with documentation of one or more of the following acute, new or fluctuating:
  - Focal neurologic findings
  - Motor changes
  - Mental status changes
- Amnesia
- Vomiting
- Seizures
- Signs of increased intracranial pressure
- Headache
- Known or suspected skull fracture by physical exam and positive x-ray.

**For evaluation of headache:**
- Chronic headache with a change in character/pattern (e.g. more frequent, increased severity or duration).
- Sudden onset (within the past 3 months) of a headache described by the patient as the worst headache of their life OR a “thunderclap” type headache. *(Concerned with aneurysm).* Note: The duration of a thunderclap type headache lasts more than 5 minutes. A headache that lasts less than 5 minutes in duration is not neurological.
- New severe unilateral headache with radiation to or from the neck. Associated with suspicion of carotid or vertebral artery dissection.
- Acute, sudden onset of headache with personal or family history (parent, sibling or child of patient) of stroke, brain aneurysm or AVM (arteriovenous malformation).
- Patient with history of cancer or HIV with new onset of headache.
- New onset of headache in pregnancy.

**For evaluation of known or suspected brain tumor/metastasis:**
- Known tumor and new onset of headache.
- Follow up for known tumor *without* any acute, new or fluctuating neurologic, motor or mental status changes.
- With any acute, new or fluctuating neurologic, motor or mental status changes.
- Known or suspected pituitary tumor with corroborating physical exam (galactorrhea), neurologic findings and/or lab abnormalities.
- Known lung cancer, or rule out metastasis and/or preoperative evaluation.
- Evaluation of metastatic melanoma (not all melanomas).

**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.

**For evaluation of known or suspected stroke:**
- Symptoms of transient ischemic attack (TIA) (episodic neurologic symptoms) (may be tumor or Multiple Sclerosis [MS]).
- Known or rule out stroke with any acute, new or fluctuating neurologic, motor or mental status changes.

**For evaluation of known or suspected aneurysm or arteriovenous malformation (AVM):**
- Presents with new onset of headache or any acute, new or fluctuating neurologic, motor or mental status changes.

**For evaluation of known or suspected infection or inflammatory disease (i.e., meningitis, abscess):**
• Intracranial abscess or brain infection with acute altered mental status OR positive lab findings (such as elevated WBC’s) OR follow up assessment during or after treatment completed.
• Inflammatory disease (i.e. vasculitis), sarcoid or infection for patient presenting with a fever, stiff neck and positive lab findings (such as elevated white blood cells or abnormal lumbar puncture fluid exam).
• Meningitis with positive physical findings (such as fever, stiff neck and positive lab findings (such as elevated white blood cells or abnormal lumbar puncture fluid exam.)
• Suspected encephalitis with a severe headache, altered mental status OR positive lab finding. (such as elevated WBC’s).
• Endocarditis with suspected septic emboli.

For evaluation of known or suspected congenital abnormality (such as hydrocephalus, craniosynostosis):
• Treatment planned within four (4) weeks for congenital abnormality (such as placement of shunt or problems with shunt: surgery).
• Known or rule out congenital abnormality with any acute, new or fluctuating neurologic, motor or mental status changes.
• Evaluation of macrocephaly with child >6 months of age or microcephaly.
• Follow up shunt evaluation within six (6) months of placement or one (1) year follow up and/or with neurological symptoms.
• Suspected normal pressure hydrocephalus, (NPH) with symptoms.

Pre-operative evaluation for brain surgery:

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.

Indications for a Brain MRI with Internal Auditory Canal (IAC):
• Tinnitus (constant ringing in one or both ears), hearing loss and an abnormal audiogram.
• Suspected acoustic neuroma (Schwannoma) or cerebellar pontine angle tumor with any of the following signs and symptoms: unilateral hearing loss by audiometry, headache, disturbed balance or gait, tinnitus, facial weakness, altered sense of taste.
• Suspected cholesteotoma
• Suspected glomus tumor.
• Acute onset or asymmetrical sensory neurological hearing loss.

Other indications for a Brain MRI:
• Evaluation of suspected acute Subarachnoid Hemorrhage (SAH).
• Initial imaging of a suspected or known Arnold Chiari Malformation.
• Optic Neuritis.
• Initial brain evaluation for a known syrinx or syringomyelia.
• Vertigo associated with headache, blurred or double vision, or a change in sensation after full neurologic examination and initial work-up.
• Abnormal eye findings on physical or neurologic examination (Papilledema, nystagmus, ocular nerve palsies, visual field deficit etc).
• Anosmia (loss of smell) (documented by objective testing).
• Follow up for known hemorrhage, hematoma or vascular abnormalities.
• For evaluation of known or suspected cerebrospinal fluid (CSF) leakage.
• Developmental delay.

**Indications for combination studies:**

- **Brain MRI/Neck MRA** –  
  - Confirmed carotid occlusion of >60%, surgery or angioplasty candidate *(significant lesion can flip off emboli, looking for stroke).*

- **Brain MRI/Cervical MRI** –  
  - For evaluation of Arnold Chiari Malformation.
  - For follow-up of known Multiple Sclerosis (MS).

- **Brain MRI/Orbit MRI** –  
  - For approved indications as noted above and being performed in a child under 3 years of age who will need anesthesia for the procedure.

**ADDITIONAL INFORMATION RELATED TO BRAIN MRI:**

The MMSE has been the most commonly used measure of cognitive function in dementia research, but researchers have recognized that it is relatively insensitive and variable in mildly impaired individuals.

MoCA differs from the MMSE mainly by including tests of executive function and abstraction, and by putting less weight on orientation to time and place. Ten of the MMSE’s 30 points are scored solely on the time-place orientation test, whereas the MoCA assigns it a maximum of six points.

The MoCA also puts more weight on recall and attention-calculation performance, while de-emphasizing language skill.

**MoCA** - The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

**MMSE** - The Mini Mental State Examination (MMSE) is a tool that can be used to systematically and thoroughly assess mental status. It is an 11-question measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment. The MMSE takes only 5-10 minutes to administer and is therefore practical to use repeatedly and routinely.

**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.
Combination MRI/MRA of the Brain – This is one of the most misused combination studies and these examinations should be ordered in sequence, not together. Vascular abnormalities can be visualized on the brain MRI.

MRI for Headache - Generally, magnetic resonance imaging is the preferred imaging technique for evaluating the brain parenchyma and CT is preferable for evaluating subarachnoid hemorrhage. CT is faster and more readily available than MRI and is often used in urgent clinical situations. Neurologic imaging is warranted in patients with headache disorders along with abnormal neurologic examination results or predisposing factors for brain pathology. Contrast enhanced MRI is performed for evaluation of inflammatory, infectious, neoplastic and demyelinating conditions.

MRI for Macrocephaly or Microcephaly - Consider ultrasound for child <6 months of age for Macrocephaly or Microcephaly.

MRI and Positron Emission Tomography (PET) for Chronic Seizures – When MRI is performed in the evaluation of patients for epilepsy surgery, almost a third of those with electrographic evidence of temporal lobe epilepsy have normal MRI scans. Interictal positron emission tomography (PET) may be used to differentiate patients with MRI-negative temporal lobe epilepsy.

MRI and Multiple Sclerosis – Current advances in MRI improve the ability to diagnose, monitor and understand the pathophysiology of MS. Different magnetic resonance methods are sensitive to different aspects of MS pathology and by the combining of these methods, an understanding of the mechanisms underlying MS may be increased.

MRI and Vertigo – Magnetic resonance imaging is appropriate in the evaluation of patients with vertigo who have neurologic signs and symptoms, progressive unilateral hearing loss or risk factors for cerebrovascular disease. MRI is more appropriate than CT for diagnosing vertigo due to its superiority in visualizing the posterior portion of the brain, where most central nervous system disease that causes vertigo is found. MRI is helpful in diagnosing vascular causes of vertigo.
REFERENCES


