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 ORBIT MRI:

INTRODUCTION:

Magnetic resonance imaging (MRI) is a noninvasive and radiation free radiologic technique used in the diagnosis and management of ocular and orbital disorders. Common uses include the evaluation of suspected optic nerve involvement in patients suspected of having multiple sclerosis and assessment of tumor invasion of the orbit. MRI is used in the evaluation of hyperthyroid related exophthalmos as well as in identifying the structural causes of unilateral proptosis. It is a sensitive method for showing soft tissue abnormalities which makes it a useful technique in evaluating orbital disorders, e.g., orbital pseudotumor.

INDICATIONS FOR ORBIT MRI:

- For assessment of proptosis (exophthalmos).
- For evaluation of progressive vision loss.
- For evaluation of decreased range of motion of the eyes.
- For screening and evaluation of ocular tumor, especially melanoma.
- For screening and assessment of suspected hyperthyroidism (such as Graves’ disease).
- For assessment of trauma.
- For screening and assessment of known or suspected optic neuritis.
- For evaluation of unilateral visual deficit.
- For screening and evaluation of suspected orbital Pseudotumor.
- Papilledema

COMBINATION OF STUDIES WITH ORBIT MRI:

- **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 and there is a suspicion of concurrent intracranial tumor (e.g. “trilateral retinoblastoma”)*
  - Unilateral papilledema: to distinguish a compressive lesion on the optic nerve or optic disc swelling associated with acute demyelinating optic neuritis in multiple sclerosis from nonarteritic anterior ischemic optic neuropathy (AION), central retinal vein occlusion or optic nerve infiltrative disorders.

ADDITIONAL INFORMATION RELATED TO ORBIT 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 and Optic Neuritis – MRI is useful in the evaluation of patients who have signs and symptoms of optic neuritis. These signs and symptoms may be the first indications of demyelinating disease, e.g., multiple sclerosis (MS). MRI findings showing the presence of three or more bright spots in brain white matter on T2-weighted images are indicative of MS and may be used as a criterion for initiating treatment.

MRI and Exophthalmos (Proptosis) – Proptosis is characterized by a bulging of one or two eyes and may be caused by hyperthyroidism (Grave’s disease) or it may be caused by other conditions, e.g., orbital tumors, infection and inflammation. The degree of exophthalmos in thyroid-associated ophthalmopathy is related to the orbital fatty tissue volume. MRI is able to define orbital soft tissues and measure the volumetric change in orbital fatty tissues.

MRI and Orbit Tumors – The most common intraocular malignant tumor is choroidal melanoma. Most choroidal melanomas can be evaluated by ophthalmoscopy and ultrasonography. MRI may be used to differentiate the types of mass lesions and to define their extent.

*Retinoblastoma and intracranial tumors* Histologically similar tumors may occur in the pineal, suprasellar or parasellar regions of patients with ocular retinoblastoma, also known as “trilateral retinoblastoma”. The incidence of these intracranial tumors in either unilateral or bilateral retinoblastoma patients is 1.5%-5%.

Unilateral papilledema: The most common causes of unilateral optic disc edema are nonarteritic anterior ischemic optic neuropathy (AION), optic neuritis (termed papillitis when disc swelling is present), and orbital compressive lesions. Idiopathic intracranial hypertension (pseudotumor cerebri) and central retinal vein occlusive lesions can also present with unilateral papilledema.

Nonarteritic anterior ischemic optic neuropathy (NAION) - Nonarteritic anterior ischemic optic neuropathy (NAION) is the most common form of ischemic optic neuropathy. It is an idiopathic, ischemic insult of the optic nerve head characterized by acute, monocular, painless visual loss with optic disc swelling. The pathophysiology for reduction in blood flow to the optic nerve is controversial.
REFERENCES


