“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.

b) 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 NECK MRI:

INTRODUCTION:

Magnetic resonance imaging (MRI) is used in the evaluation of head and neck region tumors. The soft-tissue contrast among normal and abnormal tissues provided by MRI permits the exact delineation of tumor margins in regions, e.g., the nasopharynx, oropharynx, and skull base regions. MRI is used for therapy planning and follow-up of head and neck neoplasms. It is also used for the evaluation of neck lymphadenopathy, tracheal stenosis, and vocal cord lesions.

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 NECK MRI:

For evaluation of known tumor, cancer or mass:
- Evaluation of neck tumor, mass or cancer for patient with history of cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of skull base tumor, mass or cancer.
- Evaluation of tumors of the tongue, larynx, nasopharynx, or salivary glands.
- Evaluation of parathyroid tumor when:
  - CA > normal and PTH > normal WITH
  - Previous nondiagnostic ultrasound or nuclear medicine scan AND
  - Surgery planned.

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 – Active monitoring for recurrence as clinically indicated.

For evaluation of suspected tumor, cancer or mass:
- Evaluation of neck tumor, mass or with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of palpable lesions in mouth or throat.
- Evaluation of non-thyroid masses in the neck when persistent, greater than one month, and ≥/≤ to 1 cm or associated with generalized lymphadenopathy.

For evaluation of known or suspected inflammatory disease or infections:
- Evaluation of lymphadenopathy in the neck when greater than one month, and ≥/≤ to 1 cm or associated with generalized lymphadenopathy.

Pre-operative evaluation.
Post-operative/procedural evaluation (e.g. post neck dissection/exploration):
- 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 Neck MRI:
- For evaluation of vocal cord lesions or vocal cord paralysis.
- For evaluation of stones of the parotid and submandibular glands and ducts.
- Brachial plexus dysfunction (Brachial plexopathy/Thoracic Outlet Syndrome).

Indications for combination studies:
- Abdomen CT/Pelvis CT/Chest CT/Neck MRI/Neck CT with MUGA – known tumor/cancer for initial staging or evaluation before starting chemotherapy or radiation treatment.

ADDITIONAL INFORMATION RELATED TO NECK 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.

MRI and Brachial Plexus – MRI is the only diagnostic tool that accurately provides high resolution imaging of the brachial plexus. The brachial plexus is formed by the cervical ventral rami of the lower cervical and upper thoracic nerves which arise from the cervical spinal cord, exit the bony confines of the cervical spine, and traverse along the soft tissues of the neck, upper chest, and course into the arms.

MRI and Neck Tumors – MRI plays a positive role in the therapeutic management of neck tumors, both benign and malignant. It is the method of choice for therapy planning as well as follow-up of neck tumors. For skull base tumors, CT is preferred but MRI provides valuable information to support diagnosis of the disease.

MRI and Vocal Cord Paralysis or Tumors – MRI helps in the discovery of tumors or in estimating the depth of invasion of a malignant process. It provides a visualization of pathological changes beneath the surface of the larynx. MRI scans may indicate the presence or absence of palsy and possible reasons for it. If one or both vocal cords show no movement during phonation, palsy may be assumed.

MRI and Cervical Lymphadenopathy – MRI can show a conglomerate nodal mass that was thought to be a solitary node. It can also help to visualize central nodal necrosis and identify nodes containing metastatic disease. Imaging of the neck is not done just to evaluate lymphadenopathy, but is performed to evaluate a swollen lymph node and an unknown primary tumor site. Sometimes it is necessary to require a second imaging study using another imaging modality, e.g., a CT study to provide additional information.
MRI and Submandibular Stones – Early diagnosis and intervention are important because patients with submandibular stones may eventually develop sialadenitis. MRI provides excellent image contrast and resolution of the submandibular gland and duct and helps in the evaluation of stones.
REFERENCES


