**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 ABDOMEN MRI:

INTRODUCTION:

Abdominal magnetic resonance imaging (MRI) is a proven and useful tool for the diagnosis, evaluation, assessment of severity and follow-up of diseases of the abdomen. It is more expensive than computed tomography (CT) but it avoids exposing the patient to ionizing radiation. MRI may be the best imaging procedure for patients with allergy to radiographic contrast material or renal failure. It may also be the procedure of choice for suspected lesions that require a technique to detect subtle soft-tissue contrast and provide a three dimensional depiction of a lesion. Abdominal MRI studies are usually targeted for further evaluation of indeterminate or questionable findings, identified on more standard imaging exams such as Ultrasound (US) and CT.

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 ABDOMEN MRI:

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:
- Initial evaluation of suspicious abdomen masses/tumors found only in the abdomen by physical exam or imaging study, such as Ultrasound (US).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the abdomen. No further surveillance unless tumor(s) are specified as highly suspicious, or change was found on last follow-up.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as Ultrasound (US) and CT:
- Initial staging of known cancer
  - All cancers, excluding the following:
    - Basal Cell Carcinoma of the skin,
    - Melanoma without symptoms or signs of metastasis.
- Three (3) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected abdominal metastasis based on a sign, symptom or an abnormal lab value.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated

For evaluation of suspected infection or inflammatory disease:
- Suspected acute appendicitis (or severe acute diverticulitis) if abdominal pain and tenderness to palpation is present, with at LEAST one of the following:
  - WBC elevated
- Fever
- Anorexia or
- Nausea and vomiting.
- Suspected peritonitis (from any cause) if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - Rebound, rigid abdomen, or
  - Severe tenderness to palpation present over entire abdomen.
- Suspected pancreatitis.
- Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.
- Suspected cholecystitis or retained gallstones with recent equivocal ultrasound.
- Suspected infection in the abdomen.

**For evaluation of known infection or inflammatory disease follow up:**
- Complications of diverticulitis with severe abdominal pain or severe tenderness or mass, not responding to antibiotic treatment, (prior imaging study is not required for diverticulitis diagnosis).
- Pancreatitis by history, (including pancreatic pseudocyst) with abdominal pain suspicious for worsening, or re-exacerbation.
- Known inflammatory bowel disease, (Crohn’s or ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
- Any known infection that is clinically suspected to have created an abscess in the abdomen.
- Any history of fistula limited to the abdomen that requires re-evaluation, or is suspected to have recurred.
- Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
- Hepatitis C/hepatoma evaluation with elevated alpha-fetoprotein (AFP) and equivocal ultrasound results.
- Known infection in the abdomen.

**Pre-operative evaluation:**
- For abdominal surgery or procedure.

**Post-operative/procedural evaluation:**
- Follow-up of suspected or known post-operative complication involving only the abdomen.
- A follow-up study 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.

**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.
Other Indications for an Abdominal MRI:

- To provide an alternative to abdominal CT when CT would be limited due to allergy to radiographic contrast material.
- To provide an alternative to follow-up of an indeterminate abdomen CT when previous CT/Ultrasound was equivocal.
- Suspected adrenal mass or pheochromocytoma based on diagnostic testing/imaging results, and/or a suspicious clinical presentation.

ADDITIONAL INFORMATION RELATED TO ABDOMINAL 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 of the liver — The liver is a common site of metastatic spread. Patients with a history of known or suspected malignancy, especially tumors from the colon, lung, pancreas and stomach, are at risk for developing hepatocellular carcinoma. Patients with chronic liver disease are also at risk for developing liver cancer and undergo periodic liver screening for focal liver lesion detection, usually with ultrasonography (US). Extra-cellular gadolinium chelate contrast-enhanced MRI is used for evaluating patients with an abnormal US. Patients with hepatic metastases being considered for metastasectomy undergo contrast-enhanced MRI using tissue-specific contrast agents.

MRI of the adrenal glands — The adrenal glands are susceptible for metastases from various tumors, especially of lung or breast. Adrenal lesions may also represent primary tumors of the adrenal cortex of medulla, both benign and malignant. MRI may be done to distinguish between benign and malignant lesions. Metastases are predominantly hypointense on T1-weighted images and hyperintense on T2-weighted images. Benign lesions, which have high lipid content, exhibit clear suppression of the signals.

MRI of the pancreas — The most common pancreatic endocrine tumors, accounting for up to 50% of all cases, are insulinomas, which are usually benign. The next most common is gastrinomas. Patients with gastrinomas generally present with recurrent, multiple or ‘ectopic’ peptic ulceration, the Zollinger-Ellison syndrome. After a diagnosis of gastrinomas has been confirmed, imaging should be done to localize and stage the disease. Other pancreatic endocrine tumors are rare and often associated with genetic disorders such as the multiple endocrine neoplasia type 1 (MEN 1). MRI is the preferred imaging for follow-up in patients with MEN 1 where repeated imaging may be required to assess the response to therapy.

MRI of the kidney — MRI in renal imaging has been used to differentiate benign lesions versus malignant lesions in patients unable to undergo CT scanning with contrast media or in cases where the CT findings were questionable. Initial evaluation of renal lesions is often undertaken with ultrasound. MRI can have additional diagnostic value in the evaluation of lesions with minimal amounts of fat or with intracellular fat. MRI may have a higher accuracy than CT in the evaluation of early lymph node spread. Although MRI of the
kidney has not yet found broad clinical application, it may have an increasing role in the management of patients with renal disease.

**MRI of the spleen** – Among some radiologists, the spleen is considered a ‘forgotten organ’ although it is included and demonstrated on every abdominal CT and MRI. Malignant tumors of the spleen are rare; malignant lymphomas are the most common and are usually a manifestation of generalized lymphoma. Splenic metastases are predominantly hypointense on T1-weighted images and hyperintense on T2-weighted images and MRI is used for the detection of necrotic or hemorrhagic metastases.

**MRI to diagnose abdominal aortic aneurysm** - MRI can be useful in the diagnosis of aortic aneurysms in patients with chronic aortic disease. The advantages include: safety, noninvasive nature (except for intravenous contrast), wide field of view, multi-planar imaging and 3D relationship viewing. MRI, unlike CT, does not require large volumes of iodinated contrast. ECG-gated spin-echo MRI is the basis for many MRI imaging algorithms for diagnosing abdominal aortic disease. A rapid breath holds MRI, a more recent development, allows more comprehensive examination of the aorta and defines many types of aortic pathology.

**MRI for the evaluation of vascular abnormalities such as renal artery stenosis and celiac/superior mesenteric artery stenosis (in chronic mesenteric ischemia)** - Doppler Ultrasound, MRA or CTA should be considered as the preferred imaging modalities.
REFERENCES


