“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 PELVIS MRI:

INTRODUCTION:

Magnetic resonance imaging of the pelvis is a noninvasive technique for the evaluation, assessment of severity, and follow-up of diseases of the male and female pelvic organs. MRI provides excellent contrast of soft tissues and provides multiplanar and 3D depiction of pathology and anatomy. Patients undergoing MRI do not have exposure to ionizing radiation or iodinated contrast materials.

INDICATIONS FOR PELVIC MRI:

For known or suspected prostate cancer and for recurrence workup:

- Initial treatment by radical prostatectomy:
  - Failure of PSA to fall to undetectable levels or PSA detectable and rising on at least 2 subsequent determinations
- Initial treatment radiation therapy:
  - Post-RT rising PSA or positive digital exam and is candidate for local therapy
- In patients without confirmed diagnosis of prostate cancer (with persistently elevated or rising PSA and prior negative biopsy).
- Prostatic cancer with:
  - PSA greater than twenty
  - Gleason score of seven or greater.

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:

- Initial evaluation of suspicious pelvic masses/tumors found only in the pelvis 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 pelvic. No further surveillance unless tumor(s) are specified as highly suspicious, or change was found on last follow-up new/changing sign/symptoms or abnormal lab values.

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:
    - Excluding Basal Cell Carcinoma of the skin,
    - Excluding Melanoma without symptoms or signs of metastasis.
- Three (3) month follow-up of known pelvic cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known pelvic 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 pelvic metastasis based on a sign, symptom or an abnormal lab value.
- Cancer surveillance: Once per year last test must be over ten (10) months ago before new approval for surveillance of known cancer.

For evaluation of suspected infection or inflammatory disease:
- Suspected acute appendicitis (or severe acute diverticulitis) if pelvic pain and tenderness to palpation is present, with at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
- Suspected complications of diverticulitis (known to be limited to the pelvis by prior imaging) with pelvic pain or severe tenderness, not responding to antibiotic treatment.
- Suspected infection in the pelvis.

For evaluation of known infection or inflammatory disease follow up:
- Complications of diverticulitis with severe abdominal pain or severe tenderness, not responding to antibiotic treatment, (prior imaging study is not required for diverticulitis diagnosis).
- 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 pelvis.
- Any history of fistula limited to the pelvis that requires re-evaluation, or is suspected to have recurred.
- Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
- Known infection in the pelvis.

Pre-operative evaluation:
For pelvic surgery or procedure.

For post-operative/procedural evaluation:
- Follow-up of known or suspected post-operative complication involving the hips or the pelvis.
- 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.

Indications for Musculoskeletal Pelvic MRI:
- Initial evaluation of suspicious mass/tumor of the bones, muscles or soft tissues of the pelvis found on an imaging study, and needing clarification, or found by physical exam and remains non-diagnostic after x-ray or ultrasound.
- Evaluation of suspected fracture and/or injury when initial imaging is inconclusive or needs further evaluation.
- For evaluation of known or suspected aseptic/avascular necrosis of hip(s).
- Sacroilitis (infectious or inflammatory)
- Sacroiliac Joint Dysfunction:
  - Persistent back and/or sacral pain unresponsive to four (4) weeks of conservative treatment, received within the past six (6) months, including physical therapy or physician supervised home exercise plan (HEP).
• Persistent Pain:
  o For evaluation of persistent pain unresponsive to four (4) weeks of conservative treatment received within the past six (6) months.

• Pelvic floor failure:
  o For evaluation of incontinence and anatomical derangements including, but not limited to uterine prolapse, rectocele, cystocele.
  o For further evaluation of congenital anomalies of the sacrum and pelvis and initial imaging has been performed.

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

**Other Indications for a Pelvic MRI:**

• For location or evaluation of undescended testes in adults and in children, including determination of location of testes, where ultrasound has been done previously.

• To provide an alternative to follow-up of an indeterminate pelvic CT when previous CT/Ultrasound was equivocal and needed to clarify a finding a CT could not.

• For evaluation and characterization of uterine and adnexal masses, (e.g., fibroids, ovaries, tubes and uterine ligaments), or congenital abnormality where ultrasound has been done previously.

• For evaluation of uterus prior to embolization.

• For evaluation of endometriosis.

• Prior to uterine surgery if there is abnormality suspected on prior ultrasound.

• For evaluation of known or suspected abnormality of the fetus noted on prior imaging and no prior pelvis MRI.

**ADDITIONAL INFORMATION RELATED TO PELVIC MRI:**

*Conservative Therapy - Sacroiliac Joint Dysfunction* 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
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 Undescended Testes – The most common genital malformation in boys is undescended testis. The timely management of undescended testis is important to potentially minimize the risk of infertility and less the risk of malignancy. MRI is used as a diagnostic tool in the detection of undescended testes and can reveal information for both anatomic and tissue characterization. It is noninvasive, non-ionizing, and can obtain multiplanar images.

MRI and Adnexal Masses – MRI is used in the evaluation of adnexal masses in pregnancy. It can identify and characterize different neoplastic and nonneoplastic abnormalities, e.g., exophytic leiomyoma, endometrioma, dermoid cyst, and ovarian edema. It is a useful adjunct when sonography is inconclusive in the evaluation of adnexal masses in pregnancy.

MRI and Endometriosis – MRI manifestations of endometriosis vary including endometrioma, peritoneal endometrial implant, adhesion and other rare features. The data obtained from imaging must be combined with clinical data to perform preoperative assessment of endometriosis.

MRI and Prostate Cancer – Although prostate cancer is the second leading cause of cancer in men, the majority of cases do not lead to a prostate cancer related death. Aggressive treatment of prostate cancer can have side effects such as incontinence, rectal injury and impotence. It is very important to do an evaluation which will assist in making decisions about therapy or treatment. MRI can non-invasively assess prostate tissue, functionally and morphologically. MRI evaluation may use a large array of techniques, e.g., T1-weighted images, T2-weighted images, and dynamic contrast enhanced T1-weighted images.

Prostate Cancer – For symptomatic patients and/or those with a life expectancy of greater than 5 years, a bone scan is appropriate for patients with T1 to T2 disease who also have a PSA greater than 20ng/mL or a Gleason score of 8 or higher. Patients with a T3 to T4 disease or symptomatic disease should also receive a bone scan. Pelvic computed tomography (CT) or magnetic resonance imaging (MRI) scanning is recommended if there is T3 or T4 disease, or T1 or T2 disease and a nomogram indicates that there is greater than 20% chance of lymph node involvement, although staging studies may not be cost effective until the chance of lymph node positively reaches 45%. Biopsy should be considered for further evaluation of suspicious nodal findings. For all other patients, no addition imaging is required for staging.

Men who suffer a biochemical recurrence following prostatectomy fall into two groups: (1) those whose PSA level fails to fall to undetectable levels after surgery, or (2) those who achieve an undetectable PSA after surgery with a subsequent detectable PSA level that increases on two or more laboratory determinations. Since PSA elevation alone does not necessary lead to clinical failure, the workup for both of these groups focuses on the
assessment of distant metastasis. The specific tests depend on the clinical history, but potentially include a bone scan, biopsy, PSA doubling time assessment, CT/MRI or radioimmunologic scintigraphy. (i.e. ProstaScint scan). Bone scans are appropriate when patients develop symptoms or when the PSA level is increasing rapidly. In one study, the probability of a positive bone scan for a patient not on ADT after radical prostatectomy was less than 5% unless the PSA increased to 40 to 45 ng/mL.

Further work up is indicated in patients who are considered candidates for local therapy. These patients include those with original clinical stage T1-2, a life expectancy of greater than 10 years, and a current PSA of less than 10ng/mL. Work up includes a prostate biopsy, bone scan and additional tests as clinically indicated such as abdominal/pelvic CT, MRI or radioimmunologic scintigraphy. (i.e. ProstaScint scan).

A negative biopsy following post-radiation biochemical recurrence poses clinical uncertainties. Observation, ADT, or enrolling in clinical trials is viable options. Alternatively, the patients may undergo more aggressive workup, such as repeat biopsy, MR spectroscopy, and or endorectal MRI.

Fusion imaging of multi-parametric magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) to guide prostate biopsy is not covered.

**MRI and Rectal Cancer** – MRI is used in the evaluation of rectal cancer to visualize not only the intestinal wall but also the surrounding pelvic anatomy. MRI is an excellent imaging technique due to its high soft-tissue contrast, powerful gradient system, and high resolution. It provides accurate evaluation of the topographic relationship between lateral tumor extent and the mesorectal fascia.
REFERENCES


