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 MRCP:**

**INTRODUCTION:**

Magnetic resonance cholangiopancreatography (MRCP) is a non-invasive radiologic technique for imaging the biliary and pancreatic ducts, and it is used to evaluate patients with cholestatic liver function tests, right upper quadrant pain, and recurrent pancreatitis. The MRCP uses magnetic resonance imaging (MRI) to produce detailed pictures of the pancreas, liver and bile ducts. MRCP is reliable for the diagnosis of ductal abnormalities, e.g., pancreas divisum. It is also used to diagnose bile duct stones and assess the level of obstruction. MRCP is especially useful when a noninvasive exam is desired.

**INDICATIONS FOR MRCP:**

- For evaluation of suspected congenital anomaly of the pancreaticobiliary tract, e.g., aberrant ducts, choledochal cysts, pancreas divisum or related complications.
- For evaluation of chronic pancreatitis or the complications related to such (pseudocysts and bile duct strictures).
- Preoperative evaluation: Prior to surgery or other invasive procedure.
- Post operative evaluation: For evaluation of suspected biliary abnormalities after surgery or invasive procedure.
- For further evaluation of inconclusive abnormalities identified on other imaging (ultrasound, CT, or MRI).
- For evaluation of abnormality related to the biliary tree based on symptoms or laboratory findings and initial imaging has been performed.

**ADDITIONAL INFORMATION RELATED TO MRCP:**

**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.

**Ultrasound** - Ultrasound is the initial imaging technique used for screening suspected biliary or pancreatic disease, but it has limited ability to characterize abnormalities in the biliary and pancreatic ducts.

**Endoscopic retrograde cholangiopancreatography (ERCP)** – ERCP can combine diagnosis with therapeutic intervention, e.g., removal of stones, but it is an invasive procedure that carries significant risk of complications, e.g., pancreatitis. ERCP is also technically challenging in patients with post-surgical biliary and/or surgical anastomoses.
**Magnetic resonance Cholangiopancreatography (MRCP)** – MRCP is a noninvasive method for depicting biliary and pancreatic ducts and assessing the level of obstruction. It is also used to evaluate congenital anomalies of these structures. In clinical practice MRCP is often combined with conventional MRI imaging of the liver and pancreas. MRCP does not require the use of any contrast materials. Unlike ERCP, it does not combine diagnosis with therapeutic intervention. MRCP is not cost effective if the patient will need ERCP mediated intervention after the MRCP. MRCP is preferred over ERCP when a noninvasive examination is needed or when there is a very small likelihood that the patient will need therapeutic intervention afforded by ERCP. Secretin-enhanced MR Cholangiopancreatography has been recently developed to improve the diagnostic quality of MRCP images.

**Cystic Pancreatic neoplasms**: In the evaluation of cystic neoplasms, MRP is more sensitive than ERCP in differentiating mural nodules from mucin globules (40–44). It also consistently demonstrates the internal architecture of the main duct and the extent of IPMN (Intraductal Papillary Mucinous Neoplasms) better than ERCP. (ACG-GL)

**Biliary strictures**: Approximately 15% of biliary strictures in the western world are benign. 80% are related to previous surgery, usually an injury during gallbladder surgery. After liver transplantation anastomotic strictures usually develop 3-6 months after surgery. Rare causes of stricture formation include infectious agents such as TB, parasites and viruses. Other etiologies include recurrent pyogenic cholangitis, Mirizzi syndrome with external compression of the bile duct by an inflamed gallbladder, blunt trauma and an even smaller number of strictures of unknown etiology also occur.

**PSC (primary sclerosing cholangitis)**: Magnetic resonance cholangiography is increasingly available but does not yet visualize the intrahepatic bile ducts sufficiently to replace direct cholangiography. Neither liver histology nor cholangiography alone will reliably reflect the severity of the disease. They must be used together with symptoms, physical findings, blood tests, and imaging or upper endoscopy tests that indicate the presence and severity of portal hypertension. (Insights into Imaging)
REFERENCES


