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Cohere Medicare Advantage Policy -Magnetic Resonance Imaging (MRI), Lower Extremity

Clinical Guidelines for Medical Necessity Review

Version:1Effective Date:October 3, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging **Guideline Name:** Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Lower Extremity

Date of last literature review: 10/2/2024 Document last updated: 10/3/2024 Type: [X] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.¹

<u>National Coverage Determination (NCD). Magnetic resonance imaging</u>
 (MRI)(220.2)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is segmented into joint and non-joint distribution and may be performed without or with contrast (intravenous or intra-articular). Metal hardware in the bone can limit certain exams and is generally inappropriate for imaging by 3 Tesla scanners. Based on the clinician and supervising radiologist's discussion, alternate modalities may sometimes be more clinically appropriate.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the lower extremities. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²⁻³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁵

The clinical benefits of using these criteria include:

- Analyzing soft tissue: MRI is the "gold standard" for imaging of lower extremity soft tissue and detection of abnormal tissue.⁶
- Ability to quantify changes: MRI can detect changes in the musculoskeletal system following a spinal cord injury.⁶
- Diagnosis of low back pain: MRI aids in the diagnosis of radiculopathy that does not respond to conservative management, neurogenic claudication, myelopathy, or when "red flag" symptoms are present.²
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care. In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- → Magnetic resonance imaging (MRI), lower extremity is considered appropriate if ANY of the following is TRUE:
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication), including ANY of the following:
 - Malignant or aggressive primary musculoskeletal tumor⁸;
 OR
 - Malignant or aggressive primary soft tissue tumor^z; **OR**
 - Malignant or aggressive bone tumor⁸; **OR**
 - Nonsuperficial (deep) soft tissue mass⁹; **OR**
 - Soft tissue mass⁹; **OR**
 - A primary bone tumor is suspected with ANY of the following¹⁰:
 - Lesion is suspected on plain radiograph; OR
 - "Incidental" osseous lesion on MRI or CT of another region and not fully evaluated by other imaging; OR
 - Presence of a mass with **ANY** of the following⁹:
 - Absence of trauma; **OR**
 - Rapid growth; **OR**
 - Recurrence after prior surgery; **OR**
 - Non-diagnostic ultrasound or other inconclusive imaging; OR
 - Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on initial imaging study⁹⁻¹⁰; OR
 - Known malignancy with localized lower extremity pain or swelling and **ANY** of the following are required:
 - Monitor response to treatment; OR
 - Surveillance after treatment or surgery; **OR**
 - Persistent palpable abnormality with a non-diagnostic radiograph or ultrasound; **OR**
 - Routine surveillance of known malignancy; OR

- Acute traumatic lower extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and ANY of the following is TRUE:
 - Bony injury and **ANY** of the following is **TRUE**:
 - Acute injury with occult fracture suspected; OR
 - Joint dislocation or instability; OR
 - Internal derangement; OR
 - Stress/insufficiency fracture (known) and follow-up imaging needed; OR
 - Stress/insufficiency fracture (suspected) with negative radiographs; OR
 - Suspected soft tissue injury (e.g., peroneal tendon injury, meniscal tear); OR
- Chronic injury with ongoing symptoms for greater than or equal to 6 weeks and ALL of the following is TRUE:
 - The patient has failed conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**
 - Radiographs are negative for osseous injury, and an alignment injury is suspected based on physical exam, including **ANY** of the following:
 - Dislocation; OR
 - Syndesmotic injury; **OR**
 - Other ligamentous or soft tissue injury; **OR**
- Infection or an infectious disorder, including **ANY** of the following:
 - Septic arthritis is suspected with initial radiographs that are normal or with findings suggestive of joint effusion or soft tissue swelling¹¹⁻¹²; OR
 - Osteomyelitis, suspected^{11,13}; **OR**
 - Soft tissue infection suspected with **ANY** of the following¹:
 - Normal initial radiographs or with findings suggestive of joint effusion or soft tissue swelling; OR
 - History of puncture wound with possible retained foreign body; OR
 - High clinical suspicion of necrotizing fasciitis; **OR**
- Vascular conditions, known or suspected, including ANY of the following:

- Osteonecrosis, known or suspected, with negative radiographs¹⁴; OR
- Vascular malformation (with or without pain) and ANY of the following findings of physical deformity are suspected¹⁵:
 - Diffuse or focal enlargement; OR
 - Discoloration; **OR**
 - Soft-tissue mass; OR
 - Ulceration; OR
 - Vascular bruit or thrill; **OR**
- Neuropathy, nerve entrapment, or nerve lesion with ANY of the following¹¹⁶:
 - Clinically suspected nerve entrapment and **ALL** of the following are **TRUE**:
 - Abnormal EMG; AND
 - MRI is to assist in diagnosis and treatment options; OR
 - Known peripheral nerve sheath tumor or syndrome and **ANY** of the following:
 - Enlarging mass; OR
 - New or worsening localized pain; OR
 - Recurrence after prior resection; **OR**
 - Persistent symptoms following conservative treatment and localized EMG abnormality; OR
 - Trauma/ injury with suspected nerve injury or laceration based on site of injury and associated neurological deficits; OR
- Pre and post-intervention evaluation (including the diagnosis of postoperative complications) when ANY of the following is TRUE:
 - Imaging after hip arthroplasty and ANY of the following is TRUE¹⁷:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - Aseptic loosening; OR
 - ♦ Instability; OR
 - ♦ Osteolysis; **OR**
 - Periprosthetic fracture; OR
 - History of acute injury; OR

- Metal-on-metal prosthesis with an adverse reaction to metal debris; OR
- Trunnionosis (corrosion or metallosis), suspected; **OR**
- Imaging after knee arthroplasty and **ANY** of the following are suspected (with or without pain)¹³:
 - Hardware fracture; **OR**
 - Infection; OR
 - Periprosthetic fracture; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ♦ Aseptic loosening; OR
 - ♦ Instability; OR
 - ♦ Osteolysis; OR
 - Acute injury with suspected extensor mechanism involvement; OR
- Evaluation of ANY of the following uncategorized/miscellaneous symptoms when applicable¹⁸:
 - Marrow abnormalities¹⁴; **OR**
 - Pain or weakness of a lower extremity as indicated by **ALL** of the following:
 - Joint-specific orthopedic evaluation and maneuvers suggesting ANY of the following:
 - ♦ Tear; OR
 - ♦ Tendonitis; OR
 - Other abnormality; **OR**
 - Other injury; **AND**
 - Radiographs and/or ultrasound are nondiagnostic or indeterminate; AND
 - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; AND
 - Concern for rupture or high-grade tear based on **ALL** of the following:
 - Clinical history; AND
 - Physical exam; OR
 - Screening, surveillance, or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹²; OR

- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if ANY of the following is TRUE:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- → Magnetic resonance imaging (MRI), lower extremity may not be considered appropriate if ANY of the following is TRUE:
 - If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; OR
 - The patient has metallic clips on vascular aneurysms¹; OR
 - Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); OR
 - Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; OR
 - Imaging of cortical bone and calcifications¹; OR
 - Procedures involving spatial resolution of bone and calcifications.¹

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.¹

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73718	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast

	material(s)
73719	Magnetic resonance imaging (MRI) (e.g., proton),of lower extremity (other than joint); with contrast material(s)
73720	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73721	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material
73722	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; with contrast material(s)
73723	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material(s) followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Drake et al. (2022) conducted a systematic review and meta-analysis of observational studies comparing medical imaging (specifically magnetic resonance imaging [MRI]) of adults with plantar heel pain. A total of 42 studies were included. Patients with PHP had higher rates of thickened plantar fascia (greater than 4 mm) as well as abnormal plantar fascia tissue, a thicker loaded plantar heel fat pad on ultrasound, and a plantar calcaneal spur on plain film x-ray. Continued research is needed on high-quality imaging to increase the accuracy of MRI.¹⁹

Lansdown and Ma (2020) review the clinical utility of advanced imaging of the knee. MRI excels in sensitivity and specificity for diagnosing injuries such as ligament, meniscus, and full-thickness cartilage defects in the knee. High-resolution qualitative assessment ensures accurate detection and characterization of these conditions. Utilizing compositional MRI sequences enables an assessment of the biochemical characteristics of cartilage, meniscus, and ligaments, providing additional insights into pathology beyond traditional imaging. Progress in image processing, shape modeling, and dynamic studies is an innovative approach to assess conditions of the lower extremities and to track post-treatment outcomes.²⁰

Warner et al. (2019) conducted a study to compare the diagnostic efficacy of injury (non-stress) and stress radiographs vs MRI to identify deep deltoid ligament ruptures among patients with operative supination-external rotation (SER) ankle fractures. The medial clear space (MCS) was considered to be positive if measurements exceeded 5 mm on either injury or stress mortise radiographs. Compared to intra-operative visualization, MCS measurements and MRI exhibited differential diagnostic capabilities for identifying deep deltoid ruptures. When MCS measured less than 5 mm on injury radiographs with subsequent stress testing, MCS assessments proved less accurate than MRI in predicting deltoid ruptures (46% vs 79%, respectively), with a notably high false positive rate (80%). An MCS exceeding 5 mm on injury radiographs strongly correlated with deep deltoid rupture diagnosis (accuracy of 95%). In contrast, to direct intra-operative visualization of the deltoid ligament, these findings advocate for surgical intervention when MCS measures greater than 5 mm on injury radiographs without necessitating additional stress tests or advanced imaging. However, MRI analysis is recommended when MCS measures less than 5 mm because of its heightened accuracy and reduced false positive rates. Enhanced diagnostic capabilities promise more effective management of patients with SER ankle fractures.²¹

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024			
Review History			