Cohere Medicare Advantage Policy - Computed Tomography (CT), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Computed Tomography (CT), Lower Extremity
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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), 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.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1]

- National Coverage Determination (NCD) 220.1. Computed Tomography

Recommended Clinical Approach

Computed tomography (CT) of the lower extremity for trauma and fracture generally does not require contrast. IV contrast should be used at the request of the ordering provider with guidance from the radiologist. Common indications for administering contrast include infectious and inflammatory conditions, as well as fractures, tumors, palpable abnormalities, and concern for malignancy of the soft tissues. CT scan coverage can be modified to include the region of clinical suspicion. Intra-articular contrast may be useful in patients for whom internal joint derangement or cartilage loss is suspected, but in whom MR is not possible (e.g., incompatible pacemaker, unable to tolerate MR exam, metallic artifact).

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 CT of the lower extremity. 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:

- Computed tomography imaging employs ionizing radiation in the form of x-rays, and while such routine x-rays use low levels of ionizing radiation, this form of radiation is known to increase the risk of cancer.[2]
- Young children are more sensitive to radiation than adults and even the low-dose radiation of CT may pose a significant cancer risk to pediatric patients. In growing children, the thyroid gland, breast tissue, and gonads are particularly sensitive to radiation.[3,4]
- The contrast agent, or dye, employed in some lower extremity CT scans has been linked to a renal dysfunction called contrast-induced nephropathy. Patients undergoing consecutive scans, or patients with cirrhosis, hypotension, or peritoneal carcinomatosis may be predisposed to contrast-induced nephropathy.[5]
- Contrast agents may also produce adverse anaphylactoid or nonanaphylactoid reactions. Women, infants, older adults, and Individuals with medical conditions such as diabetes, asthma, or thyroid disorders may be predisposed to contrast induced allergic reactions.[6]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- As a component of a whole-body trauma study, CT may aid in surgical planning by enabling triage through the simultaneous consideration of extremity and intracavitary injuries.[7]
- Computed tomography is more sensitive to lower extremity fractures than conventional radiographic examinations, while delivering an equivalent dose of radiation.[8]
- For patients for whom magnetic resonance imaging is unavailable or contraindicated, CT can serve as an alternative when an occult proximal femoral fracture is suspected.[9]
- Computed tomography scans can visualize anatomical structures, including the posterior cruciate ligament, allowing for better soft tissue protection in surgical procedures such as total knee arthroplasty.[10]

- 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

➔ **Computed tomography (CT), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses and mass-like conditions) requiring evaluation (e.g., for treatment planning, treatment response, or prognostication) and **ANY** of the following is **TRUE**[10-13]:
  - Malignant or aggressive primary bone tumor[11]; **OR**
  - Malignant or aggressive primary soft tissue tumor[11]; **OR**
  - Metastatic lesions of the lower extremity; **OR**
  - Nonsuperficial (deep) soft tissue mass[12]; **OR**
  - Soft tissue mass and MRI or ultrasound is unable to be performed or is contraindicated[12]; **OR**
  - A primary bone tumor is suspected, and radiographs indicate **ANY** of the following[13]:
    - Radiograph is negative; **OR**
    - Benign features (osteoid osteoma is not suspected); **OR**
    - Osteoid osteoma is suspected; **OR**
    - Lesion is present on plain radiographs; **OR**
    - Indeterminate or aggressive appearance for malignancy; **OR**

        - "Incidental" osseous lesion on MRI or CT scan for unrelated indication; **OR**
    - Presence of a mass with **ANY** of the following[12]:
        - 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 the initial radiologic exam, including radiograph, ultrasound, magnetic resonance (MR), and nuclear medicine studies[13]; **OR**
    - Known malignancy with unexpected, localized lower extremity pain or swelling; **OR**
    - Persistent palpable abnormality with non-diagnostic imaging (e.g., radiograph, 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**[14,15]:
    - Bony injury and **ANY** of the following is **TRUE**[14]:
        - Fracture (known) and additional detail needed; **OR**
        - Acute injury with occult fracture suspected; **OR**
        - Joint dislocation or instability; **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) and MRI or ultrasound is unable to be performed or is contraindicated; **OR**
- Chronic injury with ongoing symptoms and **ALL** of the following is **TRUE**[16,17]:
    - 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, an alignment abnormality is suspected based on physical examination, or the injury requires additional detail than is available with plain radiographs and **ALL** of the following are **TRUE**:
    - MRI and/or ultrasound are contraindicated or cannot be performed; **AND**
    - Radiographs that suggest **ANY** of the following:
        - Dislocation; **OR**
        - Syndesmotic injury; **OR**
        - Other ligamentous injury; **OR**

- The patient requires a CT with arthrogram for a knee meniscal tear, and **ALL** of the following is **TRUE**:
    - Concern for rupture or high-grade tear based on clinical history, imaging, or physical exam; **AND**
    - Joint-specific orthopedic evaluation and maneuvers suggest a tear; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
    - Detection, screening, surveillance, and follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)[18]; **OR**
    - Osteonecrosis, known or suspected, with negative radiographs[19]; **OR**
    - MRI and/or ultrasound are contraindicated or cannot be performed, and the patient requires evaluation for vascular malformation (with or without pain) due to **ANY** of the following findings[20]:
        - Diffuse or focal enlargement; **OR**
        - Discoloration; **OR**
        - Soft-tissue mass; **OR**
        - Ulceration; **OR**
        - Vascular bruit or thrill; **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 **TRUE**[21]:
        - Hardware 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**
        - Pain with **ANY** of the following (infection excluded):
            - Aseptic loosening; **OR**
            - Instability; **OR**
            - Osteolysis; **OR**
        - Periprosthetic fracture; **OR**
    - Imaging after knee arthroplasty and **ANY** of the following are suspected (with or without pain)[22]:
        - Hardware fracture; **OR**
        - Infection; **OR**
        - Pain with **ANY** of the following (infection excluded):
            - Aseptic loosening; **OR**
            - Instability; **OR**
            - Osteolysis; **OR**
        - Periprosthetic fracture; **OR**
        - Concern for injury to extensor mechanism; **OR**
- Infection or an infectious disorder including **ANY** of the following:
    - Septic arthritis with **ANY** of the following:
        - Elevated laboratory markers (e.g., ESR/CRP, white blood cell count); **OR**
        - Findings are suggestive of joint effusion or soft tissue swelling[23]; **OR**
        - Clinical history of **ANY** of the following:
            - Adjacent infection; **OR**
            - Diabetes; **OR**
            - IV drug use; **OR**
            - Previous surgery on the suspected joint of concern (e.g., joint replacement/ ligament, labral, meniscus repair); **OR**
        - Physical exam that supports suspicion of septic arthritis; **OR**
        - Positive joint aspiration; **OR**
        - Septic arthritis is suspected with normal initial radiographs[23]; **OR**
    - Osteomyelitis, suspected[22,23]; **OR**

- Soft tissue infection suspected with a history of puncture wound with possible retained foreign body (radiographs normal)[23]; **OR**
- Soft tissue infection suspected with high clinical suspicion of necrotizing fasciitis[23]; **OR**

◆ Evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when MRI is contraindicated or cannot be performed, and the patient requires evaluation[24]:

- Marrow abnormalities[24]; **OR**
- Pain or weakness of a lower extremity as indicated by **ALL** of the following:
  - Nondiagnostic or indeterminate imaging (e.g. radiographs, US); **AND**
  - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months; **AND**
  - Concern for rupture or high-grade tear based on **ALL** of the following:
    - ◆ Clinical history; **AND**
    - ◆ Physical exam; **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

➔ **Computed tomography (CT), lower extremity** is not considered appropriate if **ANY** of the following is **TRUE**[25]:

◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.
**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.
***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[26,27]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[26,27]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[26,27]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[26,27]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
73700	Computed tomography (CT), lower extremity; without contrast material
73701	Computed tomography (CT), lower extremity; with contrast material
73702	Computed tomography (CT), lower extremity; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

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

Medical Evidence

Dreizin et al. (2022) review the role of computed tomography (CT) and computed tomography angiography (CTA) in trauma and salvaging a threatened or mangled extremity. When reviewing CT scans to assess complications around the amputation site, attention should focus on signs such as surgical wound opening, ulceration, infection, post-surgical blood collections, lingering bone fragments, abnormal bone growth, excessive scarring, and the maintenance of vascular function. Damage control techniques involve swift actions to manage bleeding and restore blood circulation. Early implementation of fasciotomies may be required, along with immediate temporary realignment and stabilization using splints, traction, or external fixation. The measures aim to safeguard the repaired blood vessels and ensure a smooth connection without tension.[7]

Allen et al. (2020) performed an observational study to evaluate the incidence of fractures and ligament injuries among patients presenting with an acute ankle injury and normal findings on radiographic examination while also exploring optimal examination protocols. A total of 100 patients were enrolled in the study - 19 were diagnosed with major fractures, and 42 had small avulsion fractures. Further, 42 patients exhibited ankle effusions, alongside a notable occurrence of soft tissue injuries. CT scans and ultrasound can identify fractures and soft tissue injuries yet may be utilized less frequently in standard clinical practice. The authors also discuss advances in imaging techniques. Research indicates that cone beam CT surpasses ultrasound examination and the traditional combination of clinical assessment and radiography in fracture detection sensitivity. Despite this heightened sensitivity, cone beam CT maintains a radiation exposure level comparable to conventional radiography, suggesting it is a safer and more precise imaging alternative.[8]

Kellock et al. (2019) conducted a meta-analysis on the diagnostic accuracy of CT to identify occult proximal femoral fractures. The authors report 13 studies of varied reporting quality that included 1248 patients (496 with hip fractures, 752 without) with MRI or clinical follow-up serving as the reference standard. Fifty false-negative examinations were identified. The pooled sensitivity estimate was 94%, with specificity reaching 100%. The authors conclude that when clinical suspicion arises for occult proximal femoral fracture, and MRI is either contraindicated or inaccessible, CT represents a viable option. In cases where clinical concern persists despite normal CT results, MRI may be indicated.[9]

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Clinical Guideline Revision History/Information

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