

**American College of Radiology  
ACR Appropriateness Criteria®  
Sudden Onset of Cold, Painful Leg**

**Variant 1: Sudden onset of cold, painful leg. Suspected vascular compromise. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Arteriography lower extremity	Usually Appropriate	☼☼
MRA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate	○
CTA lower extremity with IV contrast	Usually Appropriate	☼☼☼
CTA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate	☼☼☼☼
US duplex Doppler lower extremity	May Be Appropriate	○
MRA abdomen and pelvis with bilateral lower extremity runoff without IV contrast	May Be Appropriate	○
MRA lower extremity without and with IV contrast	May Be Appropriate	○
MRA lower extremity without IV contrast	May Be Appropriate	○
US duplex Doppler aorta abdomen	Usually Not Appropriate	○
US intravascular aorta and iliofemoral system	Usually Not Appropriate	○

## SUDDEN ONSET OF COLD, PAINFUL LEG

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### Summary of Literature Review

#### **Introduction/Background**

Acute onset of a cold, painful leg, also known as acute limb ischemia (ALI), describes the sudden loss of perfusion to the lower extremity and carries significant risk of morbidity and mortality. The pathophysiology primarily relates to acute arterial ischemia, in which there is often insufficient vascular collateralization to perfuse the lower extremity. A minority of cases may be related to a severe presentation of venous thrombotic disease. Known as *phlegmasia cerulea dolens*, this condition presents with lower extremity dusky discoloration, massive swelling, and pain. These clinical differences allow for differentiation from acute arterial ischemia.

ALI requires rapid identification and treatment. The objectives of diagnostic imaging include confirmation of diagnosis, identifying the location and extent of vascular occlusion, and preprocedural/presurgical planning. The published literature regarding imaging of peripheral artery disease (PAD) focuses almost exclusively on patients with chronic PAD. This includes asymptomatic PAD, leg pain with exertion (ie, intermittent claudication), and critical limb ischemia (defined as chronic leg or foot pain at rest, skin ulceration, or gangrene). By comparison, the literature on imaging patients with ALI is very limited. Consequently, the following discussion relies heavily on studies of patients with chronic PAD. This document has separated imaging appropriateness based on the clinical scenario of suspected ALI for which signs and symptoms may include pain, pallor, paresthesia/paralysis, poikilothermia, and pulselessness, or more rarely with symptoms of *phlegmasia cerulea dolens* as described above, acknowledging that some patients may present with any combination of the above or other comorbidities that may require imaging. Additionally, compartment syndrome also induces acute ischemia via a separate mechanism of tissue pressurization within a fixed volume, often in the setting of trauma or other injury. This entity may manifest overlapping symptomatology with ALI and should be excluded clinically before consideration of imaging modalities.

The management of ALI is inherently driven by clinical considerations. Given the potentially emergent nature of this clinical entity, multidisciplinary consultation is recommended as soon as suspicion of ALI is raised and before obtaining imaging. Decisions regarding revascularization strategy for individual patients are nuanced and depend in part on comorbidities, anatomy, functional status, conduit availability, presence of suitable bypass target, and other factors. Endovascular revascularization is performed by physicians across a variety of disciplines including vascular surgeons—the only specialty providing both endovascular and open surgical intervention—interventional radiologists, interventional cardiologists, and others [1]. The decision to operate immediately versus imaging preoperatively is highly dependent on the clinical scenario—for example, a patient with frank paresis/paralysis may be a candidate for an immediate operation, whereas a patient with mild pain and paresthesia may be more suitable for preoperative imaging and testing.

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## Special Imaging Considerations

Additional pertinent modalities of physiologic testing include echocardiography, measurement of ankle-brachial index (ABI), pulse volume recording, segmental blood pressures, Doppler waveforms, handheld Doppler, pulse-volume recordings, and transcutaneous oxygen pressure measurement. Transthoracic echocardiography and transesophageal echocardiography are generally not part of the initial workup but may be useful if patient symptoms could be from cardiac embolization, particularly in patients with known atrial fibrillation [2]. A detailed discussion of this workup can be found in the ACR Appropriateness Criteria® topic on “[Workup of Noncerebral Systemic Arterial Embolic Source](#)” [3]. Segmental studies, transcutaneous oxygen pressure measurement, and exercise treadmill testing are of little use in the diagnosis and management of ALI [4]. However, ABI measurement, pulse volume recordings of the ankle and foot, and handheld Doppler are simple, rapid, and reliable methods to confirm arterial occlusion as the etiology of sudden onset of cold leg when the cause is not obvious. ABI, pulse volume recording, and handheld Doppler can also serve as objective baseline tests to follow the patient after intervention [4].

Linear gadolinium-based agents used in contrast-enhanced MRI have previously been associated with nephrogenic systemic fibrosis (NSF) in patients with underlying renal dysfunction. However, in patients with acute kidney injury or stage 4/5 chronic kidney disease with current generation macrocyclic and linear agents (group II, ie, gadobenate dimeglumine, gadobutrol, gadoterate meglumine, gadoteridol, gadoxetic acid disodium) the risk of NSF is suggested to be so low that the potential harm of delaying or withholding contrast is likely to outweigh the risk of NSF in most clinical situations [5]. Group III agents (ie, gadoxetic acid disodium) have thus far demonstrated no unconfounded cases of NSF, although evidence is still limited. Of note, there is increasing evidence that gadolinium deposition occurs within the brain parenchyma, namely, within the dentate nuclei and globus pallidus, although with unknown clinical significance; this remains a topic of interest within MRI contrast safety [6].

Contrast-enhanced ultrasound (US) using microbubble-based intravenous (IV) contrast is being applied to a growing number of scenarios to demonstrate findings typically seen on contrast-enhanced CT and MRI. Early evidence has suggested the potential use of contrast-enhanced 3-D US to create targeted volumetric mapping of patent lower extremity arteries [7]. Using CT angiography (CTA), novel techniques such as 3-D fluoroscopy-CT fusion software have demonstrated potential to augment intraprocedural arterial navigation [8]. Investigations into combined noncontrast CT and MR angiography (MRA) fusion have also been undertaken, combining the vessel wall detail of CT with the luminal detail of MRI in preprocedural vessel mapping [9]. However, evidence remains limited for these techniques in the diagnosis of ALI.

For the purposes of distinguishing between CT and CT angiography (CTA), ACR Appropriateness Criteria topics use the definition in the [ACR–NASCI–SIR–SPR Practice Parameter for the Performance and Interpretation of Body Computed Tomography Angiography \(CTA\)](#) [10]:

*“CTA uses a thin-section CT acquisition that is timed to coincide with peak arterial or venous enhancement. The resultant volumetric dataset is interpreted using primary transverse reconstructions as well as multiplanar reformations and 3-D renderings.”*

All elements are essential: 1) timing, 2) reconstructions/reformats, and 3) 3-D renderings. Standard CTs with contrast also include timing issues and reconstructions/reformats. Only in CTA, however, is 3-D rendering a **required** element. This corresponds to the definitions that the CMS has applied to the Current Procedural Terminology codes.

### Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

- There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient’s care)

OR

- There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient’s care).

## **Discussion of Procedures by Variant**

### **Variant 1: Sudden onset of cold, painful leg. Suspected vascular compromise. Initial imaging.**

#### **Arteriography Lower Extremity**

Catheter arteriography (digital subtraction angiography [DSA]) performed with iodinated contrast remains the definitive method for anatomic evaluation of lower extremity peripheral arterial disease, providing dynamic, time-resolved evaluation of vascular anatomy and vascular flow [11]. However, noninvasive cross-sectional angiography techniques (ie, CTA and MRA) are increasingly performed to confirm disease with a high degree of accuracy before the decision to catheterize and perform angiographic intervention [12-18]. Catheter arteriography is typically performed in the intraprocedural setting for interventional planning and imaging confirmation of therapeutic objectives [19,20].

The main disadvantages of arteriography are related to the invasive nature of the procedure, which imparts risks of vascular injury, infection, bleeding, and other complications [11,21], and which may require additional interventions and prolonged hospital stay. Arteriography has been criticized for its imperfect evaluation of outflow vessels, specifically for limited visualization of pedal vasculature and patent distal vessels beyond significant obstructive lesions [22]. Preprocedural examinations including duplex US, MRA, or CTA may provide useful information given these considerations and to inform preprocedural/presurgical planning [8].

#### **CTA Abdomen and Pelvis with Bilateral Lower Extremity Runoff With IV Contrast**

CTA is useful in the diagnosis of ALI and peripheral arterial disease [12-18]. CTA in multiple meta-analyses has demonstrated sensitivity and specificity for detecting hemodynamically significant arterial stenosis of up to 96% and 96%, respectively, relative to DSA [15,18,23,24]. This cross-sectional imaging technique has several advantages over catheter arteriography via the manipulation of acquired imaging data, which includes thin axial, multiplanar, 3-D volume rendering, and maximum intensity projection reconstructions [25]. Additionally, poststenotic or postocclusive vascular anatomy and collateralization may be better demonstrated using CTA than by catheter arteriography.

Compared to MRA, CTA demonstrates superior spatial resolution and shorter scan time, contributing to lower likelihood of motion degradation. CTA generally also is less susceptible to severe image degradation due to metal artifact.

A major disadvantage of CTA is its limited ability to depict the lumen in heavily calcified arteries. Artifact induced by calcium can lead to an overestimation of stenosis [26]. Dual-energy CTA can be employed to reduce beam-hardening artifact from calcium or vascular stents [27,28].

CTA of the abdomen and pelvis can be obtained in addition to the lower extremity when aortoiliac disease is a concern or if the aorta and iliac arteries have not already been imaged and to assess for vascular suitability before endovascular intervention. CTA is considered the diagnostic reference standard over catheter angiography for aortic imaging [29,30].

#### **CTA Lower Extremity with IV Contrast**

CTA is useful in the diagnosis of ALI and peripheral arterial disease [12-18]. CTA in multiple meta-analyses has demonstrated sensitivity and specificity for detecting hemodynamically significant arterial stenosis of up to 96% and 96%, respectively, relative to DSA [15,18,23,24]. This cross-sectional imaging technique has several advantages over catheter arteriography via the manipulation of acquired imaging data, including thin axial, 3-D volume rendering, and maximum intensity projection reconstructions [25]. Additionally, poststenotic or postocclusive vascular anatomy and collateralization may be better demonstrated using CTA than by catheter arteriography.

Compared to MRA, CTA demonstrates superior spatial resolution and shorter scan time, contributing to lower likelihood of motion degradation. CTA generally also is less susceptible to severe image degradation due to metal artifact.

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CTA of the abdomen and pelvis can be obtained in addition to the lower extremity when aortoiliac disease is a concern or if the aorta and iliac arteries have not already been imaged. The lack of visualization of the abdominal

aorta and iliac vessels precludes evaluation for suitability before endovascular intervention or if pathology extends cranially beyond the lower extremities.

### **MRA Abdomen and Pelvis with Bilateral Lower Extremity Runoff With IV Contrast**

The widespread adoption of 3T magnets has allowed for higher spatial resolution and signal-to-noise ratio acquisitions. In multiple meta-analyses and prospective studies, contrast-enhanced MRA for the detection of hemodynamically significant arterial stenosis has yielded a sensitivity and specificity up to 97% and 96%, respectively, when compared to DSA [31-34].

Compared to CTA, MRA does not suffer from artifact related to calcium within small vessels. In addition, time-resolved sequences allow for dynamic visualization and separation of arterial and venous flow, allowing for increased diagnostic accuracy. In a study comparing to DSA, contrast-enhanced, time-resolved MRA at 3T with calf compression to prevent venous contamination demonstrated superior visualization of below-the-knee arterial vasculature than DSA [35]. Contrast-enhanced MRA may be an optimal imaging modality for patients at high risk for calcification of the distal arterial vessels, particularly patients with suspected significant arterial calcific plaque burden [16,36].

The imaging-related disadvantages of MRA include low signal-to-noise ratio, limited spatial resolution, longer acquisition times, and a greater potential for artifact-related image degradation, namely, from motion and susceptibility from metal stents and orthopedic hardware; techniques have been developed to address some of these issues [37-40]. Safety risks inherent to MRI should also be considered, such as magnetic field bioeffects.

MRA of the abdomen and pelvis can be obtained in addition to bilateral lower extremity runoff when aortoiliac disease is a concern or if the aorta and iliac arteries have not already been imaged and to assess for vascular suitability before endovascular intervention.

### **MRA Abdomen and Pelvis with Bilateral Lower Extremity Runoff Without IV Contrast**

Noncontrast MRA techniques have been in use for decades in the form of 2-D and 3-D time-of-flight. However, noncontrast MRA is rarely used in the setting of PAD or ALI because of long acquisition times relative to contrast-enhanced MRA and CTA. However, hardware advances and faster, novel sequences such as quiescent interval slice-selective MRA and flow-sensitive dephasing have demonstrated comparable diagnostic accuracies to contrast-enhanced MRA in the evaluation of PAD in multiple prospective studies and trials [41-43].

The imaging-related disadvantages of MRA relative to CTA include lower signal-to-noise ratio, limited spatial resolution, longer acquisition times, and a greater potential for artifact-related image degradation, namely, from motion and susceptibility from metal stents and orthopedic hardware; techniques have been developed to address some of these issues [37-40].

MRA of the abdomen and pelvis can be obtained in addition to bilateral lower extremity runoff when aortoiliac disease is a concern or if the aorta and iliac arteries have not already been imaged and to assess for vascular suitability for endovascular intervention.

### **MRA Lower Extremity Without and With IV Contrast**

The widespread adoption of 3T magnets has allowed for higher spatial resolution and signal-to-noise ratio acquisitions. In multiple meta-analyses and prospective studies, contrast-enhanced MRA for the detection of hemodynamically significant arterial stenosis has yielded a sensitivity and specificity up to 97% and 96%, respectively, when compared to DSA [31-34].

Compared to CTA, MRA does not suffer from artifact related to calcium within small vessels. In addition, time-resolved sequences allow for dynamic visualization and separation of arterial and venous flow, allowing for increased diagnostic accuracy. In a study comparing to DSA, contrast-enhanced, time-resolved MRA at 3T with calf compression to prevent venous contamination demonstrated superior visualization of below-the-knee arterial vasculature than DSA [35]. Contrast-enhanced MRA may be an optimal imaging modality for patients at high risk for calcification of the distal arterial vessels, particularly patients with suspected significant arterial calcific plaque burden [16,36].

The imaging-related disadvantages of MRA relative to CTA include lower signal-to-noise ratio, limited spatial resolution, longer acquisition times, and a greater potential for artifact-related image degradation, namely, from motion and susceptibility from metal stents and orthopedic hardware; techniques have been developed to address some of these issues [37-40].

MRA of the abdomen and pelvis can be obtained in addition to bilateral lower extremity runoff when aortoiliac disease is a concern or if the aorta and iliac arteries have not already been imaged. The lack of visualization of the abdominal aorta and iliac vessels precludes evaluation for suitability before endovascular intervention or if pathology extends cranially beyond the lower extremities.

#### **MRA Lower Extremity Without IV Contrast**

The imaging-related disadvantages of MRA relative to CTA include lower signal-to-noise ratio, limited spatial resolution, longer acquisition times, and a greater potential for artifact-related image degradation, namely, from motion and susceptibility from metal stents and orthopedic hardware; numerous techniques have been developed to address some of these issues [37-40].

Compared to MRA abdomen and pelvis with bilateral lower extremity runoff without IV contrast, the lack of visualization of the abdominal aorta and iliac vessels precludes evaluation for suitability for possible endovascular intervention or if pathology extends cranially beyond the lower extremities.

#### **US Duplex Doppler Aorta Abdomen**

Duplex Doppler US is a noninvasive, portable imaging modality that can be quickly performed and repeated without potential risk. Duplex Doppler US of the aorta and abdomen may suggest evidence of a proximal cause of sudden onset, cold, painful leg, for example, due to an acute aortic dissection or aortic thrombus; however, there is no relevant literature to support its use as an initial imaging modality to diagnose ALI.

#### **US Duplex Doppler Lower Extremity**

Duplex Doppler US is a noninvasive, portable imaging modality that can be quickly performed and repeated without potential risk. Duplex Doppler US of the lower extremity is potentially useful as an initial imaging procedure to confirm the absence of distal arterial flow in cases of suspected ALI. However, it is limited in diagnostic accuracy, poor accessibility of vessels, and shadowing from vascular calcifications [14,44,45], and is not useful as a standalone examination. The lack of visualization of the abdominal aorta and common iliac vessels precludes evaluation of pathology extending cranially beyond the lower extremities.

#### **US Intravascular Aorta and Iliofemoral System**

Intravascular US has demonstrated potential use as an adjunctive imaging modality in an increasing diversity of intraprocedural scenarios, for example, to characterize and measure plaque burden [46], and to guide angioplasty [47]. However, there is no relevant literature to support its use as an initial imaging modality to diagnose ALI.

#### **Summary of Recommendations**

- **Variant 1:** Arteriography of the lower extremity, MRA of the abdomen and pelvis with bilateral lower extremity runoff with IV contrast, CTA of the abdomen and pelvis with bilateral lower extremity runoff with IV contrast, or CTA of the lower extremity with IV contrast are usually appropriate for initial imaging in a patient with sudden onset of a cold, painful leg suspected of vascular compromise. However, given the potentially emergent nature of this clinical entity, multidisciplinary consultation is recommended as soon as there is suspicion of acute limb ischemia and before obtaining imaging. Although these procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care), the appropriate choice of modality ultimately depends on the patient's clinical status and revascularization strategy.

#### **Supporting Documents**

The evidence table, literature search, and appendix for this topic are available at <https://acsearch.acr.org/list>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to [www.acr.org/ac](http://www.acr.org/ac).

## Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

## Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document [48].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	0 mSv	0 mSv
⊕	<0.1 mSv	<0.03 mSv
⊕⊕	0.1-1 mSv	0.03-0.3 mSv
⊕⊕⊕	1-10 mSv	0.3-3 mSv
⊕⊕⊕⊕	10-30 mSv	3-10 mSv
⊕⊕⊕⊕⊕	30-100 mSv	10-30 mSv

\*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.