Lower Extremity Angiography

ACG: A-0002 (AC)
Link to Codes

MCG Health
Ambulatory Care
30th Edition

This MCG care guideline may overlap CMS guidance located in CMS statutes and regulations that are not currently part of MCG's Medicare Compliance content. For Medicare Advantage beneficiaries, before referring to MCG care guidelines, users should first follow all guidance related to this topic located in CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and other statutes and regulations. Content used in MCG care guidelines may be used to supplement but does not replace, modify, or supersede existing Medicare regulations or applicable NCDs or LCDs.

Clinical Indications

- Lower extremity angiography may be indicated for **1 or more** of the following(1):
  - Arterial disease of lower extremity, as indicated by **ALL** of the following(6):N
    - Arterial disease signs or symptoms, as indicated by **1 or more** of the following(7):
      - Acute limb (ie, lower extremity) ischemia(8)(9)
      - Aneurysm or dilatation
      - Arterial entrapment syndrome
      - Dissection
      - Intramural hematoma
      - Thromboembolic disease
      - Ulcerated or necrotic lesion(10)
      - Vasculitis
    - CT or MR angiography contraindicated or not available, or results indeterminate

- Intermittent claudication, as indicated by **ALL** of the following(1)(11)(12):N
  - Ankle-brachial index less than or equal to 0.9, or other noninvasive documentation of obstructive occlusive disease[A](19)(20)
  - Functional impairment from pain(21)
  - Sufficient mobility to benefit from treatment, without other disease that further precludes walking (eg, severe heart failure)
- Limb ischemia (critical), as indicated by **1 or more** of the following(22)(23):N
  - Ankle-brachial index of 0.40 or less, or documentation of significant occlusive disease by noninvasive testing
  - Arterial insufficiency ulcer
  - Consistent pain in foot, relieved by dependency and aggravated by elevation
  - Gangrene
- Mass or tumor, suspected, as indicated by **ALL** of the following(26)(27)(28):N
  - Arterial blood supply evaluation needed
  - Patient is candidate for therapeutic intervention (eg, surgery, embolization).

- Postoperative or postprocedural evaluation of complications when immediate intervention is needed or when vascular ultrasound findings are nondiagnostic(2)N
- Preoperative or preprocedural planning needed prior to lower extremity surgical or endovascular procedure (eg, microsurgical free flap reconstructive procedure, endovascular intervention)(12)(18)(29)(30)(31)N

- Previous vascular surgery or endovascular procedure and **ALL** of the following(1):N
  - Ankle-brachial index less than or equal to 0.9, interval decrease in ankle-brachial index of 0.15 from postprocedure value, or documentation of significant occlusive disease by Doppler ultrasonography(17)
  - Symptom recurrence(2)
- Trauma to vasculature of lower extremity, as indicated by **1 or more** of the following(33)(34)(35)(36)(37):N
  - Abnormal ankle-brachial index
  - Expanding hematoma
  - History of massive hemorrhage
  - Knee dislocation(46)
  - Need for localization of injury found on duplex ultrasound
  - Neurologic deficit of lower extremity in association with trauma

- Vascular abnormality of lower extremity, suspected (eg, arteriovenous malformation, fistula, aneurysm, vascular compression by adjacent masses), and CT or MR angiography contraindicated or not available, or results indeterminate(6)(47)(48)N

- Repeat evaluation of specific area or structure with same imaging modality, and **ALL** of the following:
  - Clinical need for repeat imaging, as indicated by **1 or more** of the following:
    - Change in clinical status (eg, worsening symptoms or new associated symptoms), and findings may impact treatment
    - Need for interval reassessment that may impact treatment plan
    - Need for re-imaging either prior to or after performance of invasive procedure
  - Prior imaging results of specific area or structure with same imaging modality documented and available for comparison

Evidence Summary

Background

Digital subtraction angiography is the gold standard for imaging lower extremity arteries. However, it is invasive, uses ionizing radiation, and carries the risk of allergy and nephrotoxicity from contrast material. Other potential adverse effects of catheter angiography include transient or permanent neurologic complications,

femoral artery injury and inguinal hematoma, and retroperitoneal hematoma.(2)(3)(4)(5) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 37 published peer reviewed articles, 7 specialty society or other evidence-based guidelines, and 2 book sections.

For arterial disease of the lower extremity, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Digital subtraction angiography is the gold standard for imaging lower extremity arteries.(2)(3) **(EG 2)** A specialty society guideline notes that contrast angiography provides detailed information about lower extremity arterial anatomy and may be useful for anatomic assessment in patients with lifestyle-limiting claudication for whom revascularization is being considered, particularly when noninvasive testing is unavailable.(1) **(EG 2)**

For intermittent claudication, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Digital subtraction angiography may be used for definitive visualization of arteries in the lower extremities; however, angiography is usually not necessary for initial diagnosis, which is suggested by clinical evaluation and measurement of the ankle-brachial index.(1) **(EG 2)** CTA or MRA may also be used for visualization of arteries; selection of which test to perform depends on local availability and experience for performance and interpretation.(13) **(EG 2)** Although the use of CTA or MRA has largely displaced that of digital subtraction angiography in clinical practice, digital subtraction angiography may still be used for combined diagnostic and therapeutic purposes, as when an interventional approach is planned in patients with known focal disease.(1)(6) **(EG 2)** A systematic review and meta-analysis of studies comparing use of CTA with digital subtraction angiography in patients with intermittent claudication found overall sensitivity and specificity of up to 95% and 96%, respectively, for detection of stenotic lesions of 50% or greater. Summary sensitivities and specificities for different anatomic regions were determined to be the following: 96% and 98%, respectively, for the aortoiliac arteries, 97% and 94%, respectively, for the femoropopliteal arteries, and 95% and 91%, respectively, for the tibial arteries.(14) **(EG 1)** In a systematic review and meta-analysis of 12 CTA studies (of which 49% of CTA patients for whom disease status was available had intermittent claudication and 51% had critical limb ischemia) and 30 contrast-enhanced MRA studies (of which 69% of MRA patients for whom disease status was available had intermittent claudication and 31% had critical limb ischemia), the diagnostic performance of CTA (sensitivity and specificity of 96% and 95%, respectively) was found to be similar to that of contrast-enhanced MRA (sensitivity and specificity of 93% and 94%, respectively) for evaluation of disease severity of aortotibial arteries.(15) **(EG 1)** A meta-analysis of 32 studies comparing MRA with digital subtraction angiography for lower extremity peripheral arterial disease reported that, for steno-occlusions ranging from 50% to 100%, the pooled sensitivity and specificity of MRA were 94.7% and 95.6%, respectively. MRA correctly classified 95.3%, overstaged 3.1%, and understaged 1.6% of the arterial segments. The authors concluded that MRA remains an important diagnostic alternative to radiation-based digital subtraction angiography and CTA.(16) **(EG 1)** A specialty society guideline states that CTA and MRA of the lower extremity are both recommended imaging modalities to diagnose arterial stenoses in patients with suspected lower extremity peripheral arterial disease.(1) **(EG 2)**

For limb ischemia (critical), evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A review article notes that digital subtraction angiography is the gold standard for evaluation of patients with suspected critical limb ischemia. Endovascular revascularization should be considered for treatment of aortoiliac disease, except in patients with relative contraindications or who are good open surgery candidates.(24)(25) **(EG 2)**

For mass or tumor, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Review articles state that conventional, CT, and MR angiography are useful for evaluation of the vascular supply of musculoskeletal tumors and for preprocedural planning for possible tumor resection or embolization.(26)(27)(28) **(EG 2)** Arterial embolization via conventional angiography helps to devascularize a hypervascular tumor, reduce blood loss, and improve perioperative outcomes.(27)(28) **(EG 2)**

For postoperative or postprocedural evaluation, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline notes that digital subtraction angiography is appropriate in patients with recurrent symptoms following lower extremity angioplasty and when vascular ultrasound findings are nondiagnostic, particularly when a focal lesion amenable to intervention is suspected. In high-acuity settings in which catheter-based intervention may be needed, such as a thrombosed bypass graft, direct referral to catheter angiography may be warranted.(2) **(EG 2)**

For preoperative or preprocedural planning prior to lower extremity surgical or endovascular procedures, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that digital subtraction angiography is recommended for evaluation of patients with lower extremity peripheral arterial disease when revascularization is being considered.(1) **(EG 2)**

For previous vascular surgery or endovascular procedure, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that angiography, both invasively by catheter angiography and noninvasively by CTA or MRA, may be considered for postrevascularization surveillance and for symptom recurrence in patients with peripheral arterial disease and prior revascularization.(1) **(EG 2)** Specialty society appropriateness criteria note that CTA is appropriate in patients with recurrent symptoms following lower extremity angioplasty or lower extremity arterial bypass surgery.(2) **(EG 2)** A review article notes that MRA can be useful for follow-up of surgical bypass in patients with peripheral arterial disease.(32) **(EG 2)**

For trauma to the vasculature of the lower extremity, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Digital subtraction angiography, CTA, and MRA are all effective diagnostic modalities for the evaluation of injury. CTA is increasingly preferred due to its noninvasive nature, high sensitivity and specificity, and ability to visualize damage to soft tissue and bone; however, limitations may include inadequate arterial enhancement, motion artifact, and streak artifact.(34)(35)(38)(39)(40)(41) **(EG 2)** A systematic review of 58 studies investigating the use of CTA in the evaluation of vascular trauma concluded that, due to its high sensitivity and specificity in detecting blunt and penetrating vascular trauma to the extremities, CTA should be considered a first-line imaging modality for patients with no indication for immediate operative intervention.(42) **(EG 2)** A retrospective study of 80 patients with lower extremity gunshot wounds concluded that lower extremity CTA was an effective imaging modality for evaluation and could help limit use of more invasive procedures such as catheter (digital subtraction) angiography.(43) **(EG 2)** A specialty society guideline states that patients with dislocation of the knee as a result of acute trauma should undergo digital subtraction angiography, CTA, or MRA, in addition to radiography and MRI of the knee.(44) **(EG 2)** A specialty society guideline recommends CTA of the lower extremity following blunt force trauma when an arterial injury is suspected.(45) **(EG 2)**

For vascular abnormalities of the lower extremity, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Review articles note that digital subtraction angiography is the gold standard for evaluation of the peripheral vasculature, although noninvasive imaging modalities such as CT angiography and MR angiography can provide comparable results.(6)(47) **(EG 2)** A specialty society guideline and a review article note that, although lower extremity arterial disease is often initially characterized by noninvasive methods such as Doppler ultrasound, CT angiography, and MR angiography, digital subtraction angiography is also sometimes used as an initial imaging strategy, particularly when endovascular intervention is planned.(49)(50) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(51); 42 CFR 422.101(52)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(53); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(54); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(55)

Medicare Coverage Determinations: Medicare Coverage Database(56)

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Footnotes

[A] Patients with suspected lower extremity peripheral arterial disease should undergo measurement of the ankle-brachial index. A normal ankle-brachial index value is 1.0 to 1.4; a value greater than 1.4 indicates noncompressible arteries, a value of 0.91 to 0.99 is considered borderline, and a value less than or equal to 0.90 is abnormal and indicates vascular occlusive disease of the lower extremity. A postexercise measurement should be made in patients if the resting ankle-brachial index is normal and the results would change management.(1)(17)(18) [A in Context Link 1]

Codes

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