Clinical Appropriateness Guidelines: Arterial Ultrasound

Appropriate Use Criteria

Effective Date: March 9, 2019

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Proprietary

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Description and Application of the Guidelines



AlM's Clinical Appropriateness Guidelines (hereinafter "AlM's Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by AlM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AlM's guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up to date clinical principles and best practices. Relevant citations are included in the "References" section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of AIM's Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM applies objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The AIM Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline



Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based
 on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a
 review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the
 greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

General Clinical Guideline



History							
Status	Date	Action					
Revised	03/09/2019	Retitled Pretest Requirements to "Clinical Appropriateness Framework" to summarize the components of a decision to pursue diagnostic testing. To expand applicability beyond diagnostic imaging, retitled Ordering of Multiple Studies to "Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions" and replaced imaging-specific terms with "diagnostic or therapeutic intervention." Repeated Imaging split into two subsections, "repeat diagnostic intervention" and "repeat therapeutic intervention."					
Reviewed	07/11/2018	Last Independent Multispecialty Physician Panel review					
Revised	07/26/2016	Independent Multispecialty Physician Panel revised					
Created	03/30/2005	Original effective date					



Duplex Ultrasound Imaging of the Extracranial Arteries



CPT Codes

Standard Anatomic Coverage

Arteries of both the anterior (carotid) and posterior (vertebrobasilar) extracranial systems.

Imaging Considerations

- This guideline does not supersede the enrollee's health plan medical policy specific to Duplex Imaging of the arteries
 of the upper and lower extremities
- Selection of the optimal diagnostic imaging for evaluation of extracranial arterial disease should be made within
 the context of other available modalities (which include Computed Tomography angiography [CTA], Magnetic
 Resonance angiography [MRA] and contrast angiography) so that the resulting information facilitates patient
 management decisions and does not merely add a new layer of testing
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject
 to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there
 has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval
 reassessment
- In some clinical situations, it may be appropriate to perform transcranial Doppler studies in addition to Duplex imaging. Transcranial Doppler studies are not subject to preauthorization and are therefore not addressed in this document
- For the purposes of this guideline symptoms are defined as follows:
 - Anterior symptoms (carotid vascular territory) include unilateral motor or sensory deficit, speech impairment, or amaurosis fugax
 - Posterior symptoms (vertebrobasilar territory) include vertigo, ataxia, diplopia, dysphagia, dysarthria
 - The terms cerebrovascular attack (CVA) and transient ischemic attack (TIA) do not apply specifically to either anterior or posterior circulation
- For the purposes of this quideline, severity of vascular stenosis is defined as follows:
 - Mild disease: <50% stenosis
 - Moderate disease: 50%-69% stenosis
 - Severe disease: 70%-99% stenosis
 - Total occlusion: 100% stenosis
- For the purposes of this guideline, the term "revascularization" should be taken to mean carotid endarterectomy, or stent implantation

Duplex Imaging for Extracranial Arterial Disease

The following diagnostic indications for Duplex imaging for Extracranial Arterial Disease are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Patients with suspected extracranial arterial disease

(any one of the following)

- New or worsening anterior or posterior neurological symptoms
 - This does not apply to patients with syncope or near-syncope
- Hollenhorst plaque seen on retinal examination
- Evaluation for subclavian or vertebral steal syndrome in patients who develop lightheadedness or impaired vision in the setting of upper extremity exertion
- Evaluation for spontaneous carotid artery dissection in patients with a pulsatile neck mass
 - latrogenic or traumatic dissection is better evaluated with CTA or MRA
- Evaluation for TAVR (TAVI)

Patients with established extracranial arterial disease who have not undergone revascularization

(any one of the following)

- New or worsening anterior or posterior neurological symptoms
 - This guideline does not apply to patients with syncope or near-syncope
- Evaluation of syncope when cardiovascular causes (e.g. Rhythm disturbance, valvular disease) have been excluded
- Evaluation for TAVR (TAVI)
- Surveillance studies every 6 months are appropriate for patients with severe (70-99%) carotid stenosis provided that the patient is a candidate for revascularization
- Annual surveillance studies (after the first year) are appropriate for patients with moderate (50-69%) stenosis
 provided that the patient is a candidate for revascularization

Patients with established extracranial arterial disease who have undergone revascularization (any one of the following)

- A baseline study (usually within 1 month following revascularization) is appropriate
- New or worsening neurological symptoms
- Two imaging studies (usually at about 6 and 12 months) are appropriate within the first year following revascularization
- Annual surveillance studies (after the first year) are appropriate
- Following an abnormal surveillance study revealing severe stenosis additional studies at six month intervals are appropriate provided that the patient is a candidate for repeat revascularization
- Evaluation for TAVR (TAVI)

Reference / Literature Review

- 1. American College of Cardiology Foundation (ACCF); American College of Radiology (ACR); American Institute of Ultrasound in Medicine (AIUM); et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS/SVU 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing: a report of the American College of Cardiology Foundation appropriate use criteria task force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, Society for Vascular Surgery, [corrected] and Society for Vascular Ultrasound. J Am Coll Cardiol. 2012;60(3):242-276.
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the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. *J Am Coll Cardiol.* 2011;57(8):e16-e94.

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Duplex Ultrasound Imaging of the Aorta, Inferior Vena Cava and Iliac Vessels



CPT Codes

93978	Duplex scan of aorta	, inferior vena cava,	iliac vasculature,	or bypass	grafts; complete	study
93979	Duplex scan of aorta	, inferior vena cava,	iliac vasculature,	or bypass	grafts; unilateral	or limited study

Standard Anatomic Coverage

Abdominal aorta, inferior vena cava (IVC), iliac vasculature and bypass grafts involving these vessels.

Imaging Considerations

- This guideline does not supersede the enrollee's health plan medical policy specific to Duplex Imaging of the aorta, IVC, iliac vasculature and associated bypass grafts
- Selection of the optimal diagnostic imaging for evaluation of disease of the abdominal aorta, IVC or iliac vasculature should be made within the context of other available modalities (which include CT angiography (CTA), Magnetic Resonance angiography (MRA) and contrast angiography) so that the resulting information facilitates patient management decisions and does not merely add a new layer of testing
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject
 to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there
 has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval
 reassessment
- When screening for abdominal aortic aneurysm (AAA), a negative study should not be followed by additional interval screening studies
- Screening for AAA is only appropriate in patients who are candidates for (and are willing to undergo) repair procedures
- For the purposes of this guideline the term "repair" when used in discussion of aortoiliac disease should be taken to
 mean any of the following; open surgical repair of AAA, aorto-iliac endograft placement for management of aortoiliac aneurysm, aortic or iliac stent placement, or surgical bypass procedures
- The periodic surveillance guidelines for patients with AAA who have not undergone repair are based on maximum external aortic diameter
- For the purposes of this guideline, symptoms are defined as follows:
 - Claudication is defined as muscle fatigue, cramping, or pain that reproducibly begins during exercise and that promptly resolves with rest
 - Rest pain is similar to the pain of claudication but it occurs at rest in a patient with an established diagnosis of PAD or with physical examination evidence of advanced PAD such as markedly diminished pulses, gangrene or ulceration
 - Atypical symptoms describe limb pains other than rest pain or claudication

Duplex Imaging of the Aorta and Iliac Arteries

The following diagnostic indications for Duplex imaging for of the aorta, IVC and iliac vessels are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Asymptomatic patients with neither signs nor symptoms of disease (screening studies) (any one of the following)

- A single screening study for AAA is appropriate in male patients aged 60-75 years who have a first degree relative with AAA
- A single screening study for AAA is appropriate in male patients aged 60-75 years who are current or former smokers
- A single screening study for AAA is appropriate for female patients aged 60-75 who have a first degree relative with AAA and are current or former smokers

Patients with suspected aorto-iliac disease who have abnormal signs or symptoms

(any one of the following)

- Patient with a pulsatile abdominal mass
- Patient with suspected or established femoral or popliteal artery aneurysm
- Patient with a thoracic aortic aneurysm
- Abnormal abdominal X-ray suggestive of AAA
- Patient with decreased or absent femoral pulse
- Patients with lower extremity claudication
- · Patients with abnormal physiological testing suggesting aorto-iliac disease
- Patient with abdominal or femoral bruit
- Patients with evidence of atheroembolic disease of the lower extremities (ischemic or discolored toes, livedo reticularis etc.)

Patients with established aorto-iliac disease who have not undergone repair

Patients with an established diagnosis of AAA may undergo imaging in any one of the following situations:

- New or worsening symptoms or signs of aorto-iliac disease
- AAA greater than or equal to 4.5 cm may undergo surveillance imaging as frequently as every six (6) months
 - o In patients with aneurysms greater than or equal to 5.5 cm, considerations should be given to repair unless there are factors which significantly increase procedural risk
- AAA greater than or equal to 3.5 cm and less than 4.5 cm may undergo surveillance imaging at six (6) monthly intervals in the first year following diagnosis and annually thereafter
- AAA greater than or equal to 3.0 cm and less than 3.5 cm may undergo surveillance imaging one year after diagnosis and then every three (3) years thereafter
- Iliac aneurysms greater than or equal to 3.0 cm may undergo surveillance imaging as frequently as every six (6) months
 - o In patients with aneurysms greater than or equal to 3.5 cm, considerations should be given to repair unless there are factors which significantly increase procedural risk
- Iliac aneurysm less than 3.0 cm may undergo surveillance imaging annually

Patients with established aorto-iliac disease who have undergone repair

Patients who have undergone aorto-iliac repair (as defined in imaging considerations above) may undergo imaging in any <u>one</u> of the following situations:

- New or worsening symptoms or signs of aorto-iliac disease
- Baseline study after aortic or iliac stent placement
- Baseline study after aortic or iliac endograft
 - Some providers will use CT angiography rather than ultrasound in this situation
- Follow-up surveillance study at 6 monthly intervals after aortic or iliac endograft when endograft leak or increasing residual aneurysm sac size was noted on the preceding study
 - Some providers will use CT angiography rather than ultrasound in this situation
- Follow-up surveillance study at yearly intervals after aortic or iliac endograft when there was no evidence of endograft leak or increasing residual aneurysm sac size on the preceding study
- Baseline study of surgical bypass grafting involving the aorto-iliac vessels
- Follow-up surveillance study at 6-12 months following surgical bypass grafting involving the aorto-iliac vessels
- Annual follow-up surveillance study starting 1 year after surgical bypass grafting involving the aorto-iliac vessels

Duplex Imaging of the IVC and Iliac Veins

The following diagnostic indications for Duplex imaging for of the IVC and iliac veins are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Duplex imaging of the IVC and iliac vessels is appropriate in any one of the following situations:

- Suspected or established IVC or iliac vein thrombus
- Suspected or established IVC or iliac vein mass
- Suspected or established external compression of the IVC or iliac veins
- To establish patency of the IVC in a patient with an IVC filter
- To evaluate tumor extension into the IVC in patients with renal or adrenal tumors
- To assist in evaluation of volume status in patients with unexplained hypotension (not usually performed in the outpatient setting)



Reference/Literature Review

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Duplex Ultrasound Imaging of the Arteries of the Upper Extremities



CPT Codes

Standard Anatomic Coverage

· Arteries of the upper extremities

Imaging Considerations

- This guideline does not supersede the enrollee's health plan medical policy specific to Duplex Imaging of the arteries
 of the upper extremities
- This guideline does not address physiological imaging of the upper extremities (CPT codes 93922-93924) which are covered in a separate guideline document
- Selection of the optimal diagnostic imaging for evaluation of peripheral arterial disease should be made within
 the context of other available modalities (which include Duplex Vascular imaging studies, CT angiography (CTA),
 Magnetic Resonance angiography (MRA) and contrast angiography) so that the resulting information facilitates
 patient management decisions and does not merely add a new layer of testing
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject
 to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there
 has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval
 reassessment
- It is assumed that patients who have cardiovascular disease (established coronary, cerebrovascular disease) and
 patients at high risk of cardiovascular disease (including patients with diabetes mellitus and chronic kidney disease)
 will be treated with optimal medical therapy. Therefore, screening for asymptomatic peripheral artery disease (PAD)
 in these populations is unlikely to change management
- Evidence is lacking that treatment of asymptomatic PAD delays the onset of symptomatic PAD
- In general (exceptions noted below), physiological imaging should be the initial imaging approach to the evaluation
 of PAD. Duplex imaging should be reserved for situations in which physiological studies are inconclusive or when
 physiological studies are abnormal, the patient had failed conservative therapy and the patient is being evaluated for
 revascularization
- It is conventional to report ABI measurements as follows: Noncompressible values defined as greater than 1.40, normal values 1.00 to 1.40, borderline 0.91 to 0.99, and abnormal 0.90 or less
- For the purposes of this guideline symptoms are defined as follows:
 - Claudication is defined as muscle fatigue, cramping, or pain that reproducibly begins during exercise and that promptly resolves with rest
 - Rest pain is similar to the pain of claudication but it occurs at rest in a patient with an established diagnosis of PAD or with physical examination evidence of advanced PAD such as markedly diminished pulses, gangrene or ulceration
 - Atypical symptoms describe limb pains other than rest pain or claudication

Duplex Imaging for Peripheral Arterial Disease of the Upper Extremities

The following diagnostic indications for Duplex imaging for Peripheral Arterial Disease of the Upper Extremities are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Asymptomatic patients with suspected PAD

 Screening for asymptomatic PAD has not been shown to affect outcomes and is therefore not considered medically necessary

Symptomatic patients with suspected PAD (see definition of symptoms under Imaging

Considerations above)

(any one of the following)

- Duplex imaging is appropriate for patients with atypical symptoms who have inconclusive physiological testing
- Duplex imaging is appropriate for patients with claudication who have normal or inconclusive physiological testing
- Patients with resting ischemic pain
- Patients with evidence of atheroembolic disease of the upper extremities (ischemic or discolored fingers, livedo reticularis etc.)

Patients with established PAD

(any one of the following)

- Duplex imaging is appropriate for patients with atypical symptoms who have inconclusive physiological testing
- Duplex imaging is appropriate for patients with claudication who have normal or inconclusive physiological testing
- Patients with resting ischemic pain
- Patients with evidence of atheroembolic disease of the upper extremities (ischemic or discolored fingers, livedo reticularis etc.)
- Patients who have persistent claudication despite a trial of conservative therapy who are being evaluated for revascularization
- A routine baseline study is appropriate for patients who have undergone revascularization (percutaneous or surgical)
- Duplex imaging is appropriate for patients who have undergone revascularization when surveillance (no new or worsening symptoms) physiological testing is inconclusive
- A follow-up surveillance (no new or worsening symptoms) study at 6-12 months following surgical revascularization is appropriate. Note that this guideline is not applicable for surveillance following percutaneous revascularization (angioplasty, stent placement etc.)
- An annual follow-up surveillance (no new or worsening symptoms) study starting 1 year after revascularization is appropriate for patients who have undergone surgical revascularization. Note that this guideline is not applicable for surveillance following percutaneous revascularization (angioplasty, stent placement etc.)

Patients who have had procedures requiring arterial access

Duplex imaging is appropriate for evaluation of vascular access complications when a patient who has had vascular access has any one of the following

- A pulsatile mass
- A bruit or thrill at the vascular access site
- A significant (more than would be expected for the procedure performed) hematoma at the vascular access site
- Severe pain (more than would be expected for the procedure performed) at the vascular access site
- Patients with evidence of atheroembolic disease of the upper extremities (ischemic or discolored fingers, livedo reticularis etc.)

Miscellaneous indications for duplex imaging

(any one of the following)

- Following limb trauma when there is suspicion of vascular injury
- To assess the suitability of upper extremity arteries for use as bypass conduits prior to CABG
- For evaluation of suspected positional arterial obstruction (e.g. thoracic outlet syndrome)

Reference/Literature Review

- 1. American College of Cardiology Foundation (ACCF); American College of Radiology (ACR); American Institute of Ultrasound in Medicine (AIUM); et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS/SVU 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing: a report of the American College of Cardiology Foundation appropriate use criteria task force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, Society for Vascular Surgery, [corrected] and Society for Vascular Ultrasound. J Am Coll Cardiol. 2012;60(3):242-276.
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- 3. Brott TG, Halperin JL, Abbara S, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/ SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. J Am Coll Cardiol. 2011;57(8):e16-e94.
- 4. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation. 2006;113(11):e463-e654.
- 5. Moyer VA; U.S. Preventive Services Task Force. Screening for peripheral artery disease and cardiovascular disease risk assessment with the ankle-brachial index in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2013;159(5):342-348.
- 6. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg.* 2007;33 Suppl 1:S1-S75.
- 7. Rooke TW, Hirsch AT, Misra S, et al. 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2011;58(19):2020-2045.
- Rooke TW, Hirsch AT, Misra S, et al.; American College of Cardiology Foundation Task Force; American Heart
 Association Task Force. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/
 AHA Guideline Recommendations): a report of the American College of Cardiology Foundation/American Heart
 Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013;61(14):1555-1570.

Duplex Ultrasound Imaging of the Arteries of the Lower Extremities



CPT Codes

Standard Anatomic Coverage

Arteries of the lower extremities

Imaging Considerations

- This guideline does not supersede the enrollee's health plan medical policy specific to Duplex Imaging of the arteries
 of the lower extremities
- This guideline does not address physiological imaging of the lower extremities (CPT codes 93922-93924) which are covered in a separate guideline document
- Selection of the optimal diagnostic imaging for evaluation of peripheral arterial disease should be made within
 the context of other available modalities (which include Duplex Vascular imaging studies, CT angiography (CTA),
 Magnetic Resonance angiography (MRA) and contrast angiography) so that the resulting information facilitates
 patient management decisions and does not merely add a new layer of testing
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject
 to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there
 has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval
 reassessment
- It is assumed that patients who have cardiovascular disease (established coronary, cerebrovascular disease) and
 patients at high risk of cardiovascular disease (including patients with diabetes mellitus and chronic kidney disease)
 will be treated with optimal medical therapy. Therefore, screening for asymptomatic peripheral artery disease (PAD)
 in these populations is unlikely to change management
- Evidence is lacking that treatment of asymptomatic PAD delays the onset of symptomatic PAD
- In general (exceptions noted below), physiological imaging should be the initial imaging approach to the evaluation
 of PAD. Duplex imaging should be reserved for situations in which physiological studies are inconclusive or when
 physiological studies are abnormal, the patient had failed conservative therapy and the patient is being evaluated for
 revascularization
- It is conventional to report ABI measurements as follows: Noncompressible/inconclusive values defined as greater than 1.40, normal values 1.00 to 1.40, borderline 0.91 to 0.99, and abnormal 0.90 or less
- For the purposes of this guideline symptoms are defined as follows:
 - Claudication is defined as muscle fatigue, cramping, or pain that reproducibly begins during exercise and that promptly resolves with rest
 - Rest pain is similar to the pain of claudication but it occurs at rest in a patient with an established diagnosis of PAD or with physical examination evidence of advanced PAD such as markedly diminished pulses, gangrene or ulceration
 - Atypical symptoms describe limb pains other than rest pain or claudication

Duplex Imaging for Peripheral Arterial Disease of the Lower Extremities

The following diagnostic indications for Duplex imaging for Peripheral Arterial Disease of the Lower Extremities are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Asymptomatic patients with suspected PAD

 Screening for asymptomatic PAD has not been shown to affect outcomes and is therefore not considered medically necessary

Symptomatic patients with suspected PAD (see definition of symptoms under Imaging

Considerations above)

(any one of the following)

- Duplex imaging is appropriate for patients with atypical symptoms who have inconclusive physiological testing (e.g. ABI >1.40)
- Duplex imaging is appropriate for patients with claudication who have normal, borderline, or inconclusive physiological testing (ABI> 0.90)
- Patients with resting ischemic pain
- Patients with evidence of atheroembolic disease of the lower extremities (ischemic or discolored toes, livedo reticularis etc.)

Patients with established PAD

(any one of the following)

- Duplex imaging is appropriate for patients with atypical symptoms who have inconclusive physiological testing (e.g. ABI >1.40)
- Duplex imaging is appropriate for patients with claudication who have normal, borderline, or inconclusive physiological testing (ABI> 0.90)
- Patients with resting ischemic pain
- Patients with evidence of atheroembolic disease of the lower extremities (ischemic or discolored toes, livedo reticularis etc.)
- Patients who have persistent claudication despite a trial of conservative therapy who are being evaluated for revascularization
- A routine baseline study is appropriate for patients who have undergone revascularization (percutaneous or surgical)
- Duplex imaging is appropriate for patients who have undergone revascularization when surveillance (no new or worsening symptoms) physiological testing is inconclusive (ABI >1.40), borderline (ABI 0.91 – 0.99) or abnormal (ABI< or = 0.90)
- A follow-up surveillance (no new or worsening symptoms) study at 6-12 months following surgical revascularization is appropriate. Note that this guideline is not applicable for surveillance following percutaneous revascularization (angioplasty, stent placement etc.)
- An annual follow-up surveillance (no new or worsening symptoms) study starting 1 year after revascularization is appropriate for patients who have undergone surgical revascularization. Note that this guideline is not applicable for surveillance following percutaneous revascularization (angioplasty, stent placement etc.)

Patients who have had procedures requiring arterial access

Duplex imaging is appropriate for evaluation of vascular access complications when a patient who has had vascular access has any one of the following

- A pulsatile mass
- A bruit or thrill at the vascular access site
- A significant (more than would be expected for the procedure performed) hematoma at the vascular access site
- Severe pain (more than would be expected for the procedure performed) at the vascular access site
- Patients with evidence of atheroembolic disease of the lower extremities (ischemic or discolored toes, livedo reticularis etc.)

Miscellaneous indications for duplex imaging

(any one of the following)

- Following limb trauma when there is suspicion of vascular injury
- For evaluation of suspected positional arterial obstruction

Reference/Literature Review

- 1. American College of Cardiology Foundation (ACCF); American College of Radiology (ACR); American Institute of Ultrasound in Medicine (AIUM); et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS/SVU 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing: a report of the American College of Cardiology Foundation appropriate use criteria task force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, Society for Vascular Surgery, [corrected] and Society for Vascular Ultrasound. J Am Coll Cardiol. 2012;60(3):242-276.
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- 4. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation. 2006;113(11):e463-e654.
- 5. Moyer VA; U.S. Preventive Services Task Force. Screening for peripheral artery disease and cardiovascular disease risk assessment with the ankle-brachial index in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2013;159(5):342-348.
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- 7. Rooke TW, Hirsch AT, Misra S, et al. 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2011;58(19):2020-2045.
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 Association Task Force. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/
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Physiologic Testing for Peripheral Arterial Disease (PAD) of the Upper and Lower Extremities



CPT Codes

93922......Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/ brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels) 93923...... Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (e.g., measurements with postural provocative tests, or measurements with reactive hyperemia) 93924...... Noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (i.e., bidirectional Doppler waveform or volume plethysmography recording and analysis at rest with ankle/ brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking

Standard Anatomic Coverage

Arteries of the upper and lower extremities

time, and time to recovery) complete bilateral study

Imaging Considerations

- This guideline does not supersede the enrollee's health plan medical policy specific to diagnostic Physiologic Testing for Peripheral Arterial Disease (PAD) of the Upper and Lower Extremities
- This guideline does not address Duplex imaging of the upper and lower extremities (CPT codes 93925, 93926 93930, and 93931) which are covered in a separate guideline document
- For the purposes of the current guideline, Physiological Testing is defined as follows: Evaluation of the peripheral
 circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or
 other parameters without utilizing data from direct imaging of the blood vessels
- Selection of the optimal diagnostic imaging for evaluation of peripheral arterial disease should be made within
 the context of other available modalities (which include Duplex Vascular imaging studies, CT angiography (CTA),
 Magnetic Resonance angiography (MRA) and contrast angiography) so that the resulting information facilitates
 patient management decisions and does not merely add a new layer of testing
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject
 to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there
 has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval
 reassessment
- It is assumed that patients who have cardiovascular disease (established coronary, cerebrovascular disease) and
 patients at high risk of cardiovascular disease (including patients with diabetes mellitus and chronic kidney disease)
 will be treated with optimal medical therapy. Therefore, screening for asymptomatic PAD in these populations is
 unlikely to change management
- Evidence is lacking that treatment of asymptomatic PAD delays the onset of symptomatic PAD
- Although abnormal ankle brachial index (ABI) has been linked to increased incidence of cardiovascular events, treatment of asymptomatic patients with abnormal ABI (who would not otherwise merit treatment) has not been shown to improve outcomes

- ABI has been used in combination with other risk tools (e.g. Framingham Risk Score) and in some cases has led to reclassification of risk (either upwards or downwards). Management of such patients per their reclassified risk level has not been shown to improve outcomes
- It is conventional to report ABI measurements as follows: Noncompressible values defined as greater than 1.40, normal values 1.00 to 1.40, borderline 0.91 to 0.99, and abnormal 0.90 or less
- ABI of 0.9 or less establishes the diagnosis of PAD. Further imaging studies are required only when the patient is being evaluated for revascularization
- Normal resting physiologic studies may be followed by exercise studies at the discretion of the provider. Exercise studies are usually not appropriate when the resting study is abnormal

Diagnostic Physiologic Testing for PAD of the Lower Extremities

The following diagnostic indications for Physiologic Testing for Peripheral Arterial Disease of the Lower Extremities are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Asymptomatic patients with suspected PAD

 Screening for asymptomatic PAD has not been shown to affect outcomes and is therefore not considered medically necessary

Symptomatic patients with suspected PAD

(any one of the following)

- Physiological testing is appropriate for patients with new or worsening exertional limb symptoms (claudication)
- Physiological testing is appropriate for resting limb pain thought to be due to ischemia (because of diminished or absent pulses)
- Physiological testing is appropriate for patients with non-healing ulcers or gangrene of the lower extremities
- Physiological testing is appropriate for patients with infection of the leg or foot with no palpable pulses
- Physiological testing is appropriate for patients with suspected acute limb ischemia (suggested by sudden onset of pain associated with pulselessness, pallor, loss of motor or sensory function)

Patients with established PAD who have not undergone revascularization

(any one of the following)

- Bilateral ABI should be measured in all patients with newly diagnosed PAD to establish a baseline
- Physiological testing is appropriate for patients with new or worsening exertional limb symptoms (claudication)
- Physiological testing is appropriate for patients with non-healing leg ulcers or gangrene
- Physiological testing is appropriate for patients with infection of the leg or foot with no palpable pulses
- Segmental pressure measurements are appropriate in patients with established PAD to establish the level of disease when intervention is anticipated

Patients with established PAD who have undergone revascularization

(any one of the following)

- Physiological testing is appropriate for patients with new or worsening exertional limb symptoms (claudication)
- Physiological testing is appropriate for patients with leg ulcers or gangrene
- Physiological testing is appropriate for patients with infection of the leg or foot with no palpable pulses
- A post procedure baseline surveillance (no new or worsening symptoms) study is appropriate (usually performed within 6 months of the revascularization procedure)
- A follow-up surveillance (no new or worsening symptoms) study at 6-12 months following surgical revascularization is appropriate. Note that this guideline is not applicable for surveillance following catheter based revascularization (angioplasty, stent placement etc.)
- An annual follow-up surveillance study (no new or worsening symptoms) starting 1 year after revascularization is appropriate
- Segmental pressure measurements are appropriate in patients with established PAD to establish the level of disease when intervention is anticipated

Diagnostic Physiologic Testing for PAD of the Upper Extremities

The following diagnostic indications for Physiologic Testing for Peripheral Arterial Disease of the Upper Extremities are accompanied by pre-test considerations as well as supporting clinical data and prerequisite information:

Asymptomatic patients with suspected PAD

 Screening for asymptomatic PAD has not been shown to affect outcomes and is therefore not considered medically necessary

Symptomatic patients with suspected PAD

(any one of the following)

- Physiological testing is appropriate for new or worsening exertional arm or hand symptoms (claudication)
- Physiological testing is appropriate for unilateral cold painful hand
- Physiological testing is appropriate for finger discoloration or ulcer
- Physiological testing is appropriate for suspected positional arterial obstruction
- Physiological testing is appropriate for arm or hand trauma and a suspicion of vascular injury
- Physiological testing is appropriate prior to planned harvest of the radial artery (e.g. for CABG).
- Physiological testing is appropriate in the presence of pulsatile mass or hand ischemia after upper extremity vascular access
- Physiological testing is appropriate in the presence of bruit after upper extremity access for intervention

Patients with established PAD who have not undergone revascularization

(any one of the following)

- Physiological testing is appropriate for new or worsening exertional arm or hand symptoms (claudication)
- Physiological testing is appropriate for unilateral cold painful hand
- Physiological testing is appropriate for finger discoloration or ulcer
- Physiological testing is appropriate for arm or hand trauma and a suspicion of vascular injury
- Physiological testing is appropriate prior to planned harvest of the radial artery (e.g. for CABG)
- Physiological testing is appropriate in the presence of pulsatile mass or hand ischemia after upper extremity vascular access
- Physiological testing is appropriate in the presence of bruit, thrill, hematoma or severe pain after upper extremity vascular access.
- Segmental pressure measurements are appropriate in patients with established PAD to establish the level of disease when intervention is anticipated

Patients with established PAD who have undergone revascularization

(any one of the following)

- Physiological testing is appropriate for new or worsening exertional arm or hand symptoms (claudication)
- Physiological testing is appropriate for patients with arm or hand ulcers or gangrene
- Physiological testing is appropriate for patients with infection of the arm or hand with no palpable pulses
- Following trauma to the revascularized limb with suspected vascular injury
- A post procedure baseline surveillance (no new or worsening symptoms) study is appropriate (usually performed within 6 months of the revascularization procedure)
- A follow-up surveillance (no new or worsening symptoms) study at 6-12 months following surgical revascularization
 using a vein bypass graft is appropriate. Note that this guideline is not applicable for surveillance following either
 catheter based revascularization (angioplasty, stent placement etc.) or surgical bypass using a prosthetic graft
- An annual follow-up surveillance study (no new or worsening symptoms) starting 1 year after revascularization is appropriate following surgical revascularization using a vein bypass graft or a prosthetic bypass is appropriate

Note This guideline is not applicable for surveillance following catheter based revascularization (angioplasty, stent placement etc.)

Reference/Literature Review

- American College of Cardiology Foundation (ACCF); American College of Radiology (ACR); American Institute of Ultrasound in Medicine (AIUM); et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS/SVU 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing: a report of the American College of Cardiology Foundation appropriate use criteria task force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, Society for Vascular Surgery, [corrected] and Society for Vascular Ultrasound. J Am Coll Cardiol. 2012;60(3):242-276.
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- 4. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation. 2006;113(11):e463-e654.
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