



UM-CDG-025 Noninvasive Vascular Studies

Approved By:
Director, Health Services

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10/22/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address noninvasive vascular studies that utilize ultrasonic Doppler and physiologic principles to assess irregularities in blood flow in arterial and venous systems. The display may be a two-dimensional image with spectral analysis or color flow or a plethysmographic recording. For this coverage determination guideline, noninvasive vascular studies include duplex scans, physiologic studies, and plethysmography.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Duplex Scan: ultrasonic scan procedure with display of both two-dimensional structure and motion with time and Doppler ultrasonic signal documentation with spectrum analysis and/or color flow velocity mapping or imaging

Physiologic Studies: functional measurement procedures that include Doppler ultrasound studies, blood pressure measurements, transcutaneous oxygen tension measurement, or plethysmography.

Plethysmography: involves the measurement and recording by one of several methods of changes in the size of a body part as modified by the circulation of blood in that part.

Transcranial Doppler: pulsed Doppler ultrasound used to interrogate the intracranial vasculature of the Circle of Willis.

POLICY

SECUR Health Plan considers noninvasive vascular diagnostic studies as medically necessary when the ordering physician has reasonable expectation that their outcomes will potentially impact the clinical management of a member. Services are deemed medically necessary when the following conditions are met:

1. Significant signs/symptoms of arterial or venous disease are present, and/or
2. Information is necessary for appropriate medical and/or surgical management, and/or
3. Testing is not redundant of any other diagnostic procedures needed.

The accuracy of non-invasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Consequently, the physician performing and/or interpreting the study must be capable of demonstrating documented training and experience and maintain any applicable documentation. A vascular diagnostic study may be personally performed by a physician or a technologist.

The GAO Report to Congressional Committees entitled Medicare Ultrasound Procedures. Consideration of Payment Reforms and Technician Qualifications Requirements states that “Findings from several peer-reviewed studies, the Medicare Payment Advisory Commission, and ultrasound-related professional organizations support requiring that sonographers either have credentials or operate in facilities that are accredited, where specific quality standards apply. In some localities and practice settings, CMS or its contractors have required that sonographers either be credentialed or work in an accredited facility.” (GAO-07-734)

For areas under CGS Administrators, LLC jurisdiction the requirements became effective for all providers 30 April 2011:

1. All noninvasive vascular diagnostic studies must be performed under at least one of the following settings:
 - a) Performed by a physician who is competent in diagnostic vascular studies or under the general supervision of physicians who have demonstrated minimum entry level competency by being credentialed in vascular technology, or
 - b) Performed by a technician who is certified in vascular technology, or
 - c) Performed in facilities with laboratories accredited in vascular technology.

Under 42 CFR Section 410.33, Independent Diagnostic Testing Facilities, includes credentialing requirements that supersede those above:

The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. See 42 CFR Section 410-33 (2) (b).

Nonphysician personnel: Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met. See 42 CFR Section 410-33 (2)(c).

A referral must be on record for each non-invasive study performed. A referral for one type of study does not qualify as a referral for all tests.

Noninvasive vascular studies are considered medically necessary only if the outcome will potentially impact the clinical course of the patient. For example, if a member is (or is not) proceeding on to other diagnostic and/or therapeutic procedures regardless of the outcome of non-invasive studies, and non-invasive vascular procedures will not provide any unique diagnostic information that would impact patient management, then the non-invasive procedures are not medically necessary. If it is obvious from the findings of the history and physical examination that the patient is going to proceed to angiography, then non-invasive vascular studies are not medically necessary.

Noninvasive vascular studies include patient care required to perform the studies, supervision of the studies, and interpretation of study results with hard copy output or imaging. Digital storage of imaging is acceptable.

The performance of simultaneous arterial and venous studies during the same encounter should be rare. Supporting documentation should support the medical necessity for both studies.

Cerebrovascular Arterial Studies

SECUR Health Plan considers cerebrovascular arterial study testing methods that include (real-time) duplex scans and Doppler ultrasound waveform with spectral analysis as medically necessary if one or more of the following

signs and symptoms are present:

- Asymptomatic or symptomatic cervical bruits;
- Amaurosis fugax;
- Focal cerebral or ocular transient ischemic attacks (including but not limited to):
 - localizing symptoms, e.g., sensory loss; and/or
 - weakness of one side of the face; and/or
 - slurred speech; and/or
 - weakness of a limb;
- Syncope that is strongly suggestive of vertebrobasilar or bilateral carotid artery disease in etiology, as suggested by medical history;
- Recent history of a previous neurologic or cerebrovascular event;
- Before major cardiac and vascular surgery when a bruit is noted or there is a history of previous neurologic or cerebrovascular event;
- After carotid endarterectomy (outside the global period), or follow-up of previously documented stenoses;
- Pulsatile neck mass;
- Evaluation of blunt or penetrating neck trauma;
- Ocular microembolism (optic nerve/retinal arterial-Hollenhorst plaques/ocular)

Testing methods that have not been found to be useful based on authoritative technological assessments or that are included as part of the physical examination are considered not medically necessary. Additionally, studies will be considered as not medically necessary if performed for the following signs and symptoms:

- Drop attack or syncope are rare indications usually seen with vertebrobasilar or bilateral carotid artery disease.
- Dizziness is not a typical indication unless associated with other localizing signs or symptoms. However, episodic dizziness with symptom characteristics typical of transient ischemic attacks may indicate medical necessity, especially when other more common sources, e.g., postural hypotension or transiently decreased cardiac output as demonstrated by cardiac event monitoring, have been previously excluded; and/or
- Headaches (including migraines)

Transcranial Doppler (TCD) Studies

Transcranial Doppler (TCD) studies of the intracranial arteries and transcranial duplex imaging of extracranial arteries are approved methods of testing. The presence, location, and extent of disease can be evaluated by utilizing directional pulsed Doppler to estimate flow velocities and assess intracranial vessel hemodynamics and physiology.

SECUR Health Plan considers TCD studies medically necessary for the following:

- Detection and evaluation of the hemodynamic effects of severe stenosis or occlusion of the extracranial (greater than or equal to 60% diameter reduction) and major basal intracranial arteries (greater than or equal to 50% diameter reduction)
- Detection and serial evaluation of cerebral vasospasm complicating subarachnoid hemorrhage
- Evaluation of intracranial hemodynamic abnormalities in patients with suspected brain death
- Intraoperative and perioperative monitoring of intracranial flow velocity and hemodynamic patterns during carotid endarterectomy, (although the professional component could only be reimbursed if it is provided during the operative procedure by a physician that is not a member of the operating team)
- Evaluation of cerebral embolization, and/or
- Assessing hemodynamic effects, patterns, and extent of collateral circulation in patients with known regions of severe stenosis or occlusion when necessary to care for the patient, and

- Assessing stroke risk in children aged two to sixteen with homozygous sickle cell disease, and
- As an alternative to an echocardiogram to detect residual right to left shunting after repair/closure of an intracardiac or intrapulmonary shunt.

Multiple cerebrovascular procedures may be allowed during the same encounter given the physician/provider can demonstrate medical necessity as documented in the patient's medical record. For example, physiologic studies and a duplex scan are allowed on the same date of service given the provider can document medical necessity, e.g., greater than or equal to 50% stenosis on duplex scan or significant symptoms as demonstrated by the indications for the study.

TCD is not indicated for the following and will be considered as not medically necessary:

- Evaluation of brain tumors
- Assessment of familial and degenerative disease of the cerebrum, brainstem, cerebellum, basal ganglia and motor neurons
- Evaluation of infectious and inflammatory conditions
- Psychiatric disorders
- Epilepsy.

Transcranial Doppler (TCD) is considered investigational and not medically necessary for the following indications:

- Assessing patients with migraine
- Monitoring during cardiopulmonary bypass and other cerebrovascular and cardiovascular interventions, and surgical procedures (except during carotid endarterectomy, as noted above)
- Evaluation of patients with dilated vasculopathies such as fusiform aneurysms
- Assessing autoregulation, physiologic, and pharmacological responses of cerebral arteries
- Evaluating children with various vasculopathies, such as moyamoya disease and neurofibromatosis

Peripheral Arterial Examinations

SECUR Health Plan considers peripheral arterial study testing methods include duplex scans, Doppler waveform or spectral analysis, volume, impedance, or strain gauge plethysmography, and transcutaneous oxygen tension measurement as medically necessary.

Non-invasive peripheral arterial examinations, performed to establish the level and/or degree of arterial occlusive disease, are medically necessary if:

1. Significant signs and/or symptoms of possible limb ischemia are present and
2. The member is a candidate for invasive/surgical therapeutic interventions. Acute ischemia is characterized by the sudden onset of severe pain, coldness, numbness, and pallor of the extremity. Chronic ischemia can be manifested by intermittent claudication, pain at rest, diminished pulse, ulceration, and gangrene.

A routine history and physical examination, which includes ankle/brachial indices (ABIs), can readily document the presence or absence of ischemic disease in most cases. It is not medically necessary to proceed beyond the physical examination for minor signs and symptoms such as hair loss, absence of a single pulse, relative coolness of a foot, shiny thin skin, or lack of toenail growth unless related signs and/or symptoms are present which are severe enough to require possible invasive intervention.

An ABI is not a reimbursable procedure by itself. Rather, ABI may be reimbursed when derived from a more comprehensive procedure which includes a permanent chart copy of the measured pressures and waveforms in the

examined vessels. An ABI should be abnormal and must be accompanied by another appropriate indication before proceeding to more sophisticated or complete studies, except in members with severe diabetes or uremia resulting in medial calcification as demonstrated by artifactually elevated ankle blood pressure.

SECUR Health Plan considers peripheral artery studies medically necessary if the following signs and symptoms are present:

- Claudication of such severity that it interferes significantly with the patient's occupation or lifestyle, or claudication with inability to stress the patient
- Rest pain (typically including the forefoot), usually associated with absent pulses, which becomes increasingly severe with elevation and diminishes with placement of the leg in a dependent position
- Tissue loss defined as gangrene or pre-gangrenous changes of the extremity, or ischemic ulceration of the extremity occurring in the absence of pulses
- Aneurysmal disease
- Evidence of thromboembolic events
- Blunt or penetrating trauma (including complications of diagnostic and/or therapeutic procedures)
- Follow-up of grafts or other vascular intervention

Pre-surgical conduit assessment of the upper extremity/radial artery(ies) may be performed prior to use in coronary artery bypass grafting (CABG) or as other arterial conduits.

Peripheral artery studies are not considered medically necessary if only the following signs and symptoms are present:

- Continuous burning of the feet (considered to be a neurologic symptom)
- Leg pain, nonspecific and pain in limb, as single diagnoses are too general to warrant further investigation unless they can be related to other signs and symptoms
- Edema rarely occurs with arterial occlusive disease unless it is in the immediate postoperative period, in association with another inflammatory process or in association with rest pain
- Absence of pulses in minor arteries, e.g., dorsalis pedis or posterior tibial, in the absence of symptoms. The absence of pulses is not an indication to proceed beyond the physical examination unless it is related to other signs and/or symptoms.

In general, non-invasive studies of the arterial system are to be utilized when invasive correction is contemplated or severity of findings dictate non-invasive study follow-up, but not for following non-invasive medical treatment regimens. The latter may be followed with physical findings and/or progression or relief of signs and/or symptoms. Screening of the asymptomatic patient is not considered medically necessary by SECUR Health Plan.

Peripheral Venous Examinations

Indications for venous examinations are separated into three major categories: deep vein thrombosis (DVT), chronic venous insufficiency, and vein mapping. SECUR Health Plan considers the studies as medically necessary only if the member is a candidate for anticoagulation, thrombolysis or invasive therapeutic procedure(s).

Since the signs and symptoms of arterial occlusive disease and venous disease are so divergent, the performance of simultaneous arterial and venous studies during the same encounter should be rare. Documentation clearly supporting the medical necessity of both procedures performed during the same encounter must be provided in the supporting documentation.

Deep Vein Thrombosis (DVT)

The signs and/or symptoms of DVT are relatively non-specific and due to the risk associated with pulmonary embolism (PE), objective testing is considered medically necessary in members who are candidates for

anticoagulation or invasive therapeutic procedures for the following:

- Clinical signs and/or symptoms of DVT including, but not limited to, edema, tenderness, inflammation, and/or erythema
- Clinical signs and/or symptoms of pulmonary embolus (PE) including, but not limited to, hemoptysis, chest pain, and/or dyspnea
- Unexplained lower extremity edema status, post major surgical procedures, trauma, other or progressive illness/condition
- Unexplained lower extremity pain, excluding pain of skeletal origin

These studies are rarely considered medically necessary for the following:

- Bilateral limb edema in the presence of signs and/or symptoms of congestive heart failure, exogenous obesity and/or arthritis; and/or
- Follow-up of phlebitis unless signs/symptoms suggest possible extension of thrombus.

Chronic Venous Insufficiency

Chronic venous insufficiency may be divided into three categories: primary varicose veins, recurrent DVT, and post-thrombotic (post-phlebotic) syndrome. Peripheral venous studies may be indicated for the evaluation of:

- Venous function in patients with ulceration suspected to be secondary to venous insufficiency when documenting venous valvular incompetence prior to invasive therapeutic intervention
- Varicose veins by themselves do not indicate medical necessity, but medical necessity may be indicated when they are accompanied by significant pain or stasis dermatitis
- Superficial thrombophlebitis involving the proximal thigh (to investigate whether there was thrombus at the saphenofemoral junction that would demand either anticoagulation or surgical ligation)

Vein Mapping

Mapping the saphenous veins prior to scheduled revascularization procedures is considered medically necessary by SECUR Health Plan when it is expected that an autologous vein will be used, but only if there is uncertainty regarding the availability of a suitable vein for bypass.

Vein mapping is not always necessary as a routine preoperative study but is medically reasonable when the member's clinical evaluation indicates one of the following:

- Previous partial harvest of the vein
- Previous thrombophlebitis or DVT in the leg
- Severe varicose veins
- Previous history of vein stripping, ligation, or sclerotherapy
- Obesity to the degree it interferes with clinical determination

Other examples must clearly be supported by the supporting documentation.

Vein mapping may be performed prior to creating a dialysis fistula.

Visceral Vascular Studies

This is indicated in the evaluation and/or management of vascular disease involving vessels of the abdominal, pelvic, scrotal contents, and/or retroperitoneal organs.

Duplex scanning in the evaluation of an abdominal aortic aneurysm is of limited value unless there is a pulsatile abdominal mass and signs and symptoms of peripheral vascular disease are present. Follow-up of an abdominal aneurysm on a periodic basis using abdominal ultrasound rather than visceral vascular studies to determine growth and potential need for intervention is considered medically necessary by SECUR Health Plan.

Vascular studies are not the initial diagnostic modality for the evaluation of abdominal pain/tenderness. There must be a high index of suspicion that the pain is caused by a vascular disorder, such as mesentery ischemia.

Noninvasive vascular studies are considered medically necessary only if the outcome will potentially impact the clinical course of the member. For example, if a member is going to proceed on to other diagnostic and/or therapeutic procedures regardless of the outcome of noninvasive studies, noninvasive vascular procedures are usually not be considered medically necessary. If it is obvious from the findings of the history and physical examination that the member is going to proceed to angiography, then noninvasive vascular studies will not be considered medically necessary.

Hemodialysis Access Examination

SECUR Health Plan will consider vascular studies on symptomatic end stage renal disease (ESRD) members, when Doppler flow studies are used to provide diagnostic information to determine the appropriate medical intervention as medically necessary. SECUR Health Plan considers a Doppler flow study medically necessary when the member's dialysis access site manifests signs or symptoms associated with vascular compromise, and when the results of this test are necessary to determine the clinical course of treatment.

Signs and symptoms in members with ESRD of impending access site failure include:

- Elevated venous pressure > 200mm Hg on a 200 cc/min. pump
- Elevated recirculation of time of 12% or greater
- Low urea reduction rate < 60%
- An access with a palpable "water hammer" pulse on examination (which implies venous outflow obstruction)

Vessel Mapping of Vessels for Hemodialysis Access

Vessel mapping of vessels for hemodialysis access is considered medically necessary when it is performed preoperatively prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow.

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28. Local Coverage Determination (LCD) L34045, Non-Invasive Vascular Studies

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34045#:~:text=Digital%20storage%20of%20imaging%20is%20acceptable.&text=The%20performance%20of%20simultaneous%20arterial,as%20non%2Dcovered%20screening%20services.&text=Covered%20cerebrovascular%20arterial%20study%20testing,signs%20and%20symptoms%20are%20present:>

29. Local Coverage Determination (LCD) L33667, Duplex Scan of Lower Extremity Arteries

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33667#:~:text=An%20ABI%20is%20not%20a,asymptomatic%20patient%20is%20not%20covered.>