Local Coverage Determination (LCD): Noninvasive Peripheral Arterial Studies (L34219)

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**Contractor Information**

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**LCD Information**

**Document Information**

**LCD ID**
L34219

**LCD Title**
Noninvasive Peripheral Arterial Studies

**Proposed LCD in Comment Period**
N/A

**Original Effective Date**
For services performed on or after 10/01/2015

**Revision Effective Date**
For services performed on or after 10/01/2019

**Revision Ending Date**
N/A

**Retirement Date**
N/A
CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

The Code of Federal Regulations (CFR), 42 CFR §410.32. Specifies that all diagnostic tests “must be ordered by the physician who is treating the beneficiary.”

The Code of Federal Regulations (CFR), 42 CFR §411.15(k)(1). States any services that are not reasonable and
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Noninvasive peripheral arterial studies are useful in detecting extremity arterial compromise, functional severity and hemodynamic significance of atherosclerosis. These procedures help to differentiate claudication from pain of non-vascular etiologies. Lower extremity noninvasive testing is also a valuable tool in monitoring graft complications including occlusions, early flow compromise secondary to technical problems, or chronic reoccurrence of anastomotic or distal disease and aneurysmal diseases of the artery. Information regarding collateral circulation can also be gained.

"Vascular studies include patient care required to perform the studies, supervision of the studies and interpretation of study results with copies for patient records of hard copy output with analysis of all data, including bidirectional vascular flow or imaging when provided."

"The use of a simple hand-held or other Doppler device that does not produce hard copy output or that produces a record that does not permit analysis of bidirectional vascular flow, is considered to be part of the physical examination of the vascular system and is not separately reported." (End of Quote) (CPT 2007, p 398)

The two basic modalities of evaluation are:

1. The indirect methods (e.g. Ankle/Brachial Index (ABI), segmental limb pressures, transcutaneous oxygen tension measurement (TcPO2), CW bi-dimensional Doppler and plethysmographic waveforms) that provide information regarding functional severity of disease.
2. The direct method of evaluation which is color-duplex imaging (CDI), the duplex scan that provides more specific anatomic and physiologic information.

Ankle/Brachial Index

The most common test is the Ankle-Brachial Index (ABI). This test measures the blood pressure at the ankle and elbow, and is performed using a Doppler stethoscope. While inflating cuffs placed on arms and legs, the technician positions the Doppler at a 45-degree angle to three arteries: the dorsalis pedis, posterior tibia, and brachial of the right and left sides.

Single Level Pressure and Physiologic Waveform

Blood pressure and physiologic waveform (Doppler velocity signal or plethysmography tracing) recordings are obtained bilaterally at a single level (usually the ankle).

Segmental Pressure and Physiologic Waveform

Blood pressures at various limb levels are measured to identify areas of regional hypotension. Physiologic waveforms (Doppler velocity signals or plethysmography tracings) are recorded at the same level to localize the level of disease.
Transcutaneous Oxygen Tension Measurement (TcPO2)
The quantity of oxygen available for diffusion to the skin depends on the quantity delivered by the influx of blood and what is extracted to meet metabolic demands. TcPO2 (Oxygen Tension) levels provide an index of the adequacy of tissue perfusion. Measurement may be made from any region of interest, usually the dorsum of the foot or upper calf. Whereas many claudicants have resting values in the normal range, measurements made from the feet of patients with limb-threatening ischemia are usually less than 20 mm Hg and frequently approach zero. This test is used in assessing the healing potential of wounds.

Stress Testing
Exercise testing provides a medium for evaluating the functional significance of arterial occlusive disease. Upon completion of a maximum appropriate stress testing, arterial signals and blood pressures are reassessed at the ankle level. A patient with arterial occlusive disease will respond to exercise with a decrease in the ankle blood pressure. The magnitude of the decrease and time to return to baseline establish the severity and functional significance of arterial obstruction. Stress testing is useful in differentiating the pain of arterial insufficiency from that of other conditions such as arthritis and neuropathies. It also will identify those patients whose symptoms of fatigue are due to coronary or pulmonary disease rather than arterial insufficiency.

Color-Flow Doppler Duplex Scanning
Duplex scan describes an ultrasonic scanning procedure for characterizing the pattern and direction of blood flow in arteries or veins with the production of real-time images integrating B-mode two-dimensional vascular structure, Doppler spectral analysis, and color flow Doppler imaging.

Color-flow scanning adds Doppler information encoded as color to the conventional duplex scan to survey the arteries throughout their course. This test is used in those patients being evaluated for an invasive interventional procedure (laser, angioplasty or surgery). It can identify stenosis or occlusion, estimate the percentage of diameter reduction and determine the length of the lesion. Color-flow Doppler can be used to enhance conventional data acquisition.

Noninvasive peripheral arterial examinations performed to establish the level and/or degree of arterial occlusive disease are reasonable and necessary if significant signs and/or symptoms of possible limb ischemia are present and the patient is a candidate for invasive therapeutic procedures.

Indications for peripheral arterial evaluations:

1. Claudication of less than one block or such severity that interferes significantly with the patient's occupation or lifestyle
2. Rest pains (typically including the forefoot), usually associated with diminished or absent pulses, which become increasingly severe with elevation and diminishes with placement of the leg in a dependent position
3. Tissue loss defined as gangrene or pre-gangrenous changes of the extremity or ischemic ulceration of the extremity occurring with diminished or absent pulses.
4. Aneurysmal disease
5. Evidence of thromboembolic events
6. Blunt or penetrating trauma (including complications of diagnostic and/or therapeutic procedures)
7. Lower extremities surgical procedure where vascular disease is clinically suspected
8. For the patient with chronic renal failure and for whom an A/V fistula is planned
9. For radial artery evaluation in a patient scheduled for CABG

Follow-up studies for post-operative conditions:
1. In the immediate post-operative period, patients may be studied if reestablished pulses are lost, become equivocal, or if the patient develops related signs and/or symptoms of ischemia with impending repeat intervention.
2. With regards to autogenous lower extremity vein bypass surgeries, a study can be performed at three-month intervals during the first year, and at six-month intervals thereafter.
3. Follow-up studies more frequent than every 6 months are not reasonable and necessary post-angioplasty in the absence of signs and symptoms of ischemia. Synthetic grafts may be studied if the patient develops signs and/or symptoms of occlusive disease.

A routine history and physical examination, which includes Ankle/Brachial Indices (ABIs), can readily document the presence or absence of ischemic disease in a majority of cases. It is not reasonable and necessary to proceed beyond the physical examination for minor signs and symptoms unless related signs and/or symptoms are present which are severe enough to require possible invasive intervention.

Examples of signs and symptoms that do not indicate reasonableness and necessity:

1. Continuous burning of the feet is considered to be a neurologic symptom.
2. "Leg pain, nonspecific" and "Pain in Limb" as a single diagnosis is too general to warrant further investigation unless they can be related to other signs and symptoms.
3. 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.
4. Absence of relatively minor pulses (i.e., 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.
5. Minor symptoms such as hair loss, relative coolness of a foot, shiny thin skin.
6. Screening of an asymptomatic patient is not covered by Medicare.

ABIs, as separate procedures, are not reimbursable. An abnormal ABI (i.e., <0.9 must be accompanied by another appropriate indication before proceeding to more sophisticated or complete studies, except in patients with severe elevated ankle blood pressure.

If an arteriogram is planned, an abnormal ABI should be sufficient to determine its necessity. In some instances, ABI may prove inadequate because of a stovepipe vessel with ischemic signs and symptoms; a digital pressure study could be done. A few patients that have borderline ABIs would qualify for exercise studies to determine if there was a significant drop in pressure after exercise and an increase in symptoms. These qualify for further segmental studies.

In planning for foot and/or ankle surgery, a Transcutaneous Oximetry (TcPO2) or special waveform analysis should be considered adequate for determination of possible healing problems and extensive noninvasive vascular studies would not be required. This statement remains true for any surgery of the distal lower extremity in patients where healing is a concern. It is expected that the frequency will be no greater than twice in any 60-day period. Repetition of the test is only necessary when there is a need to modify treatment. Documentation to indicate reasonableness and necessity must be kept and made available to Medicare upon request.

Procedures rendered not meeting the criteria stated in the Indications and Limitations of Coverage and/or Medical Necessity section of this policy will be denied as not reasonable and necessary.

Methods not acceptable for reimbursement:

1. Mechanical oscillometry
2. Inductance plethysmography
3. Capacitance plethysmography
4. Photoelectric plethysmography
5. Thermography

Duplex scan for post-interventional follow-up which is typically limited in scope and unilateral in nature should use the unilateral or "limited study" codes. Consequently, the "complete" duplex scan codes should seldom be used except in patients who had bilateral interventions.

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. Therefore, documentation clearly supporting reasonableness and necessity of both procedures performed during the same encounter must be available for post-payment audit.

Duplex scanning and physiologic studies are reimbursed during the same encounter if the physiologic studies are abnormal and/or to evaluate vascular trauma, thromboembolic events or aneurysmal disease.

**Hemodialysis Access Examination**

Limited coverage has been established for duplex scanning of hemodialysis access sites in patients with end-stage renal disease (ESRD). These procedures are medically necessary only in the presence of signs or symptoms of possible failure of the access site and when the results may impact the clinical course of the patient. Furthermore, when services are provided by the ESRD physician of record, services are considered renal-related and are therefore part of the physician's monthly capitated fee and are not separately reportable. Services performed by a Medicare-approved ESRD facility are covered services under the composite rate of the facility and therefore are not separately reimbursable.

For dialysis to take place, there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access, and when occlusions occur, either declot the access or refer the patient for appropriate treatment. Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

ESRD facilities are monitoring access through noninvasive vascular studies such as duplex and Doppler flow scans and billing separately for these procedures. Noninvasive vascular studies are not covered as a separately billable service if used to monitor a patient's vascular access site. Medicare pays for the technical component of the procedure in the composite payment rate.

An ESRD facility must furnish all necessary services, equipment, and supplies associated with a dialysis treatment, either directly or under arrangements that make the facility financially responsible for the service. If an ESRD facility or a renal physician decides to monitor the patient's access site with a noninvasive vascular study and does not have the equipment to perform the procedure, the facility or physician may arrange for the service to be furnished by another source. The alternative source, such as an independent diagnostic testing facility must look to the ESRD facility for payment. No separate payment for noninvasive vascular studies for monitoring the access site of an ESRD patient, whether coded as the access site or peripheral site, is permitted to any entity.

Where there are signs and symptoms of vascular access problems, Doppler flow studies may be used as a means to obtain diagnostic information to permit medical intervention to address the problem. Doppler flow studies may be considered medically necessary in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient.

When a dialysis patient exhibits signs and symptoms of compromise to the vascular access site, Doppler flow studies may provide diagnostic information that will determine the appropriate medical intervention. Medicare considers a Doppler flow study medically necessary when the beneficiary'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.

Appropriate indications for duplex scan of hemodialysis access sites include:

- Complication (complication NOS, occlusion NOS, embolism, fibrosis, hemorrhage, pain, stenosis, thrombosis) due to renal dialysis device, implant, and graft
- Clear documentation in the dialysis record of signs of chronic (i.e., three successive dialysis sessions) abnormal function

Examples supporting the medical necessity of Doppler flow studies include:

- Elevated dynamic venous pressure greater than 200mmHg when measured during dialysis with the blood pump set on a 200cc/min
- Access recirculation of 12 percent or greater
- An otherwise unexplained urea reduction rate of less than 60 percent
- An access with a palpable "water hammer" pulse on examination (which implies venous outflow obstruction)

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both.

An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates reduced flow (blood flow rate less than 800cc/min or a decreased flow of 25 percent or greater from previous study) and the physician requires an arteriogram to further define the extent of the problem. The patient's medical record must provide documentation supporting the need for more than one imaging study.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

**Summary of Evidence**

N/A

**Analysis of Evidence**

(Rationale for Determination)

N/A

**General Information**
Associated Information

Documentation Requirements

The provider must ensure that documentation showing reasonableness and necessity of the procedures is kept on file and made available to this A/B MAC on request.

The accuracy of noninvasive vascular diagnostic studies depends on the knowledge, skills and experience of the technologist and physician performing and interpreting the studies. It is recommended that noninvasive vascular studies either be rendered in a physician’s office by/or under the direct supervision of persons credentialed in the specific type of procedure being performed or performed in laboratories accredited in the specific type of evaluation. Noninvasive vascular studies done in an IDTF facility or vascular laboratory are subject to the rules and regulations governing the facility.

This A/B MAC is not a credentialing body; therefore, this LCD will recommend certification, but not recommend certifying bodies.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Sources of Information

9. Medicare consultants and Contractor Medical Directors

Updated Sources:

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NOTE: Some of the websites used to create this policy may no longer be available.

Bibliography

N/A

Revision History Information

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<td>10/01/2019</td>
<td>R5</td>
<td>10/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. LCD was converted to the &quot;no-codes&quot; format.</td>
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Effective 10/1/2017, LCD is revised per the annual ICD-10-CM code update to:

Add ICD-10-CM codes: L97115; L97116; L97118; L97119; L97125; L97126; L97128; L97129; L97205; L97206; L97208; L97209; L97215; L97216; L97218; L97219; L97305; L97306; L97308; L97309; L97315; L97316; L97318; L97319; L97325; L97326; L97.328; L97.329; L97416; L97418; L97419; L97425; L97426; L97428; L97429; L97816; L97818; L97819; L98415; L98416; L98418; L98419; L98425; L98426; L98428; L98429

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**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)

A57223 - Billing and Coding: Noninvasive Peripheral Arterial Studies

**Related National Coverage Documents**

N/A

**Public Version(s)**

Updated on 09/19/2019 with effective dates 10/01/2019 - N/A

Updated on 08/30/2017 with effective dates 10/01/2017 - 09/30/2019

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- Peripheral
- Arterial
- Studies