Non-Invasive Peripheral Arterial Studies (DRAFT POLICY)

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Effective: 3/1/2008
Status: Draft Final
Revision Date: 11/30/2007

LCD Title

Non-Invasive Peripheral Arterial Studies - 4U-20AB

Contractor's Determination Number

4U-20AB (L26747)

Contractor Name

TrailBlazer Health Enterprises, LLC

Contractor Number

- 04001.
- 04002.

Contractor Type

- MAC – Part A.
- MAC – Part B.

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

- *Medicare Benefit Policy Manual* – Pub. 100-02.
- *Medicare National Coverage Determinations Manual* – Pub. 100-03.
- Correct Coding Initiative – *Medicare Contractor Beneficiary and Provider Communications Manual* – Pub. 100-09, Chapter 5.
- Social Security Act (Title XVIII) Standard References, Sections:
  - 1862 (a)(1)(A) Medically Reasonable & Necessary.
  - 1862 (a)(1)(D) Investigational or Experimental.
  - 1862 (a)(7) Screening (Routine Physical Checkups).
  - 1833 (e) Incomplete Claim.

Primary Geographic Jurisdiction

- CO – 04101.
- NM – 04201.
- OK – 04301.
- TX – 04401.
  - Indian Health Service.
  - End Stage Renal Disease (ESRD) facilities.
  - Skilled Nursing Facilities (SNFs).
  - Rural Health Clinics (RHCs).
- CO – 04102.
- NM – 04202.
- OK – 04302.
- TX – 04402.
  - Indian Health Service.

Secondary Geographic Jurisdiction

N/A

Oversight Region

- Region VI.

Original Determination Effective Date

03/01/2008

03/21/2008

06/13/2008

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Vascular studies include supervision and interpretation of the studies and its results. **A hard copy or soft copy convertible to a hard copy provides a permanent record of the study performed and must be of a quality that meets accepted medical standards.** These studies also include the patient care required to perform them. The two basic modalities of evaluation are:

- **Indirect**

Indirect methods (e.g., ABI, segmental limb pressures, Transcutaneous Oxygen Tension Measurement ($TcPO_2$), Continuous Wave (CW) bi-dimensional Doppler and plethysmographic waveforms) that provide information regarding functional severity of disease.

- **Direct**

The direct method of evaluation is Color-Duplex Imaging (CDI). The duplex scan provides more specific anatomic and physiologic information.

Ankle/Brachial Index (ABI)

This is the most common test. It is performed using a Doppler (ultrasound stethoscope) and is as painless as having blood pressure checked. While inflating cuffs placed on arms and legs, the technician positions the Doppler at a 45-degree angle to three arteries: 1) dorsalis pedis; 2) posterior tibia; and 3) 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 are recorded at the same level to localize the level of disease to the inflow/outflow or runoff vessels.

Transcutaneous Oxygen Tension Measurement ($TcPO_2$)

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. $TcPO_2$ levels provide an index of tissue perfusion adequacy. 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 normal range, measurements made from the feet of patients with limb-threatening ischemia are usually less than 20 mmHg 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 test, 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

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.

Non-invasive peripheral arterial examinations are performed to establish the level and/or degree of arterial occlusive disease. These studies are medically necessary **if at least one of the following criteria** is present and documented in the patient's medical record:

- Significant signs and/or symptoms of limb ischemia are present and the patient is a candidate for invasive therapeutic procedures.
- Claudication of such severity that it interferes significantly with the patient's occupation or lifestyle.
- Rest pain (typically including the forefoot), which should be associated with absent pulses and 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.
- Aneurysmal disease.
- Evidence of thromboembolic events.
- Blunt or penetrating trauma (including complications of diagnostic and/or therapeutic procedures).
- Preoperative examination in patients with clinically suspected vascular disease who will undergo a lower extremities surgical procedure for which healing will be compromised without vascular intervention. In planning for foot and/or ankle surgery, a TcPO2 or special waveform analysis should be considered adequate for determination of possible healing problems and extensive non-invasive 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. Duplex scanning studies are not usually considered necessary to determine the level of amputation of lower extremity. This remains a clinical decision based upon the physical exam and judgment within the operating theater and measurement of relevant segmental pressures. (Dual diagnosis required; see below.)
- **Following vascular intervention** in the immediate postoperative period if re-established pulses are lost, become equivocal, or if the patient develops related signs and/or symptoms of ischemia with impending repeat intervention. Duplex post-interventional follow-up studies are typically limited in scope and are generally unilateral in nature.

- Transcutaneous oxygen tension measurements are acceptable to evaluate healing potential in non-healing or difficult-to-heal wounds.

Non-invasive peripheral arterial examinations are not considered reasonable and necessary in the following circumstances:

- Vague symptoms such as the following:
- Continuous burning of the feet is considered a neurological symptom.
- "Leg pain, non-specific" and "pain in limb" as a single diagnosis are too general to warrant further investigation unless they can be related to other signs and symptoms.
- Minor symptoms such as hair loss, relative coolness of a foot and shiny, thin skin.
- Edema as a solitary presenting complaint (i.e., edema that does not occur in the context of significant pre-test probability of finding peripheral vascular occlusion).
- Decreased or absent pedal pulses (e.g., dorsalis pedis or posterior tibial) in the absence of symptoms.

Duplex scanning and physiologic studies will be reimbursed during the same encounter if the physiologic studies are abnormal and/or to evaluate vascular trauma, thromboembolic events, aneurysmal disease or graft patency. Doppler scans and physiologic studies for graft patency of arteriovenous shunts created for dialysis are covered under Medicare in the monthly capitation and therefore will not be reimbursed separately. Medicare will allow a bilateral duplex scan only when the non-invasive physiological studies demonstrate bilateral disease.

ABIs are not separately reimbursable. An abnormal ABI (e.g., <0.9 at rest) must be accompanied by another appropriate indication before proceeding to more sophisticated or complete studies, except in patients with severe elevated ankle blood pressure. **A careful history and physical examination, which includes 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 and severe enough to require possible invasive intervention.** 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 stove-pipe vessel with ischemic signs and

symptoms; a digital pressure study could be performed. Patients who fall into borderline ABIs qualify for exercise studies to determine if there is a significant drop in pressure after exercise and an increase in symptoms. These qualify for further segmental studies.

The use of contrast media, i.e., microbubbles, with non-invasive peripheral arterial studies is considered investigational and is not covered.

All non-invasive vascular diagnostic studies, when performed by a technologist, must be performed by a technologist who has demonstrated competency in ultrasound by receiving one of the following credentials in vascular ultrasound technology:

- Registered Vascular Specialist (RVS) provided by Cardiovascular Credentialing International (CCI).
- Registered Vascular Technologist (RVT) provided by The American Registry of Diagnostic Medical Sonographers (ARDMS).
- Vascular Sonographer (VS) provided by The American Registry of Radiologic Technologists, Sonography (ARRT) (S).

Alternatively, studies must be performed in a facility or vascular laboratory accredited by one of the following nationally recognized accreditation organizations*. If a vascular laboratory or facility is accredited, the technologists performing non-invasive peripheral venous studies in that laboratory are considered to have demonstrated competency in vascular ultrasound:

- American College of Radiology (ACR) Vascular Ultrasound Accreditation Program.
- Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL).

Additionally, transcutaneous oxygen measurement may be performed by people possessing the following credentials obtained from the National Board of Diving and Hyperbaric Medicine Technology (NBDHMT):

- Certified Hyperbaric Technologist (CHT).
- Certified Hyperbaric Registered Nurses (CHRN).

For areas already within TrailBlazer jurisdiction, these credentialing requirements remain unchanged. Otherwise, the effective date for the credentialing requirement is 12/31/2009.

Note: Type of Bill and Revenue Codes DO NOT apply to Part B.

Coverage Topics

Diagnostic Tests and X-rays

Type of Bill Codes

12X, 13X, 18X, 21X, 22X, 23X, 71X, 83X, 85X

Revenue Codes

Note: TrailBlazer has identified the Type of Bill (TOB) and Revenue Center (RC) codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all the TOB and/or RC codes listed. CPT/HCPCS codes are required to be billed with specific TOB and RC codes. Providers are encouraged to refer to the CMS *Internet-Only Manual* (IOM) Pub. 100-04, *Claims Processing Manual,* for further guidance.

092X

CPT / HCPCS Codes

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short CPT descriptors in policies published on the Web.

93922©	Extremity study
93923©	Extremity study
93924©	Extremity study
93925©	Lower extremity study
93926©	Lower extremity study
93930©	Upper extremity study
93931©	Upper extremity study

ICD-9-CM Codes that Support Medical Necessity

The CPT/HCPCS codes included in this policy will be subjected to "procedure to diagnosis" editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will

automatically deny the service as not medically necessary.

Medicare is establishing the following limited coverage for **HCPCS/CPT codes 93922, 93923, 93924, 93925, 93926, 93930 and 93931**:

Covered for:

250.70–250.73	Diabetes with peripheral circulatory disorders
353.0	Thoracic outlet syndrome
410.00–410.02**	Acute myocardial infarction of anterolateral wall
410.10–410.12**	Acute myocardial infarction of other anterolateral wall
410.20–410.22**	Acute myocardial infarction of inferolateral wall
410.30–410.32**	Acute myocardial infarction of inferoposterior wall
410.40–410.42**	Acute myocardial infarction of other inferior wall
410.50–410.52**	Acute myocardial infarction of other lateral wall
410.60–410.62**	Acute myocardial infarction, true posterior wall infarction
410.70–410.72**	Acute myocardial infarction, subendocardial infarction
410.80–410.82**	Acute myocardial infarction, other specified sites
411.0–411.1**	Other acute and subacute forms of ischemic heart disease
411.81**	Acute coronary occlusion without myocardial infarction
411.89**	Other acute and subacute forms of ischemic heart disease other
412**	Old myocardial infarction
413.0–413.1**	Angina pectoris
413.9**	Other and unspecified angina pectoris
414.00–414.07**	Coronary atherosclerosis
414.10–414.12**	Aneurysm and dissection of heart
414.19**	Other aneurysm of heart
414.8**	Other specified forms of chronic ischemic heart disease
435.2	Subclavian steal syndrome
440.0	Atherosclerosis of aorta
440.20–440.24	Atherosclerosis of the extremities
440.30–440.32	Atherosclerosis of bypass graft of extremities
440.4	Chronic total occlusion of artery of the extremities
441.00–441.03	Dissection of aorta
441.1–441.7	Aortic aneurysm and dissection
442.0	Other aneurysm of artery of upper extremity

442.2–442.3	Other aneurysm
442.82	Aneurysm of subclavian artery
443.0–443.1	Other peripheral vascular disease
443.21–443.24	Other arterial dissection
443.29	Dissection of other artery
443.81–443.82	Other specified peripheral vascular diseases
443.89	Other specified peripheral vascular diseases
443.9	Peripheral vascular disease, unspecified
444.0–444.1	Arterial embolism and thrombosis
444.21–444.22	Arterial embolism and thrombosis, of arteries of the extremities
444.81	Arterial embolism and thrombosis of iliac artery
444.89	Arterial embolism and thrombosis of other specified artery
444.9	Arterial embolism and thrombosis of unspecified artery
445.01–445.02	Artherothrombolic microembolism
445.81	Artherothrombolic microembolism, of other sites, kidney
445.89	Artherothrombolic microembolism, of other site
446.5	Giant cell arteritis
446.7	Takayasu's disease
447.0–447.2	Other disorders of arteries and arterioles
447.5–447.6	Other disorders of arteries and arterioles
447.8–447.9	Other disorders of arteries and arterioles
449	Septic arterial embolism
585.3–585.6	Chronic kidney disease (CKD)
707.10–707.15	Ulcer of lower limbs, except decubitus
707.19	Ulcer of other part of lower limb
707.8	Chronic ulcer of other specified sites
710.1	Systemic sclerosis (scleroderma)
719.45	Pain in joint involving pelvic region and thigh
729.5*	Pain in limb *** Note:** Use 729.5 to report only limb pain that is clinically suggestive of ischemia as per the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.
729.71–729.72*	Nontraumatic compartment syndrome
747.60	Anomaly of peripheral vascular system, unspecified site
747.63–747.64	Other anomalies of peripheral vascular system
785.4	Gangrene
789.30–789.37	Abdominal or pelvic swelling mass or lump

894.0–894.2	Multiple and unspecified open wound of lower limb
903.00–903.02	Injury to blood vessels of upper extremity, axillary vessel(s)
903.1–903.5	Injury to blood vessels of upper extremity
903.8–903.9	Injury to blood vessels of upper extremity
904.0–904.3	Injury to blood vessels of lower extremity and unspecified sites
904.40–904.42	Injury to popliteal blood vessels
904.50–904.54	Injury to tibial blood vessels
904.6–904.9	Injury to blood vessels of lower extremity and unspecified sites
996.1	Mechanical complication of other vascular device, implant, and graft
996.62	Infection and inflammatory reaction due to other vascular device implant and graft
996.70–996.78	Other complications of internal (biological) (synthetic) prosthetic device, implant and graft
996.80–996.87	Complications of transplanted organ
996.90–996.96	Complications of reattached extremity or body part
997.2	Peripheral vascular complications not elsewhere classified
998.11–998.13	Hemorrhage or hematoma or seroma complicating a procedure
998.2	Accidental puncture or laceration during a procedure
998.31–998.32	Disruption of operation wound
V43.4	Blood vessel replaced by other means
V45.81–V45.82	Other postprocedure status
V58.49	Other specified aftercare following surgery
V58.73	Aftercare following surgery of the circulatory system not elsewhere classified
V67.09	Follow-up examination, following other surgery

Medicare is establishing the following limited coverage **dual diagnosis** requirement for **CPT / HCPCS codes 93922, 93923, 93924, 93925, 93926, 93930 and 93931 when used in** preoperative examination of patients with clinically suspected vascular disease who will undergo a lower extremities surgical procedure for which healing will be compromised without vascular intervention. The **primary** ICD-9-CM diagnosis code must be one of the following:

V72.81	Pre-operative cardiovascular examination
V72.83	Other specified pre-operative examination

The **second** ICD-9-CM diagnosis code must be one of the double

asterisked (**) diagnoses from the list above.

Note: Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims.

Diagnoses that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

All diagnoses not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Documentation Requirements

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request.

Appendices

N/A

Utilization Guidelines

- Following lower extremity bypass interventions, Medicare would not expect to see services that exceed the following:
  - Following bypass surgery, at three-month intervals during the first year, six-month intervals during the second year and annually thereafter when clinically indicated.
  - Following angioplasty with or without stent placement at three months, six months and one year when clinically indicated.
- Transcutaneous oxygen tension measurements are acceptable to evaluate healing potential in non-healing or difficult-to-heal wounds at a frequency of no greater than twice in any 60-day period.

Sources of Information and Basis for Decision

United States Government Accountability Office, Medicare Ultrasound Procedures, Consideration of payment reforms and technician qualification requirements. June 2007.

J4 (CO, NM, OK, TX) MAC Consolidation

TrailBlazer Health Enterprises, LLC adopted, with inclusion of additional diagnoses, the TrailBlazer LCD, "Non-Invasive Peripheral Arterial Studies," for the Jurisdiction 4 (J4) MAC transition.

Full disclosure of the sources of information is found with original contractor LCD.

Other Contractor Local Coverage Determinations

"Non-Invasive Peripheral Arterial Studies," Trailblazer Health Enterprises, LLC LCD, (00400) L18373, (00900) L18375.

"Noninvasive Peripheral Arterial Studies," Noridian Administrative Services, LLC LCD, (CO) L16478, L23741.

Start Date of Notice Period

12/20/2007

Revision History

Number	Date	Explanation
N/A	06/13/2008	LCD effective in TX Part A and Part B and Part A CO and NM 06/13/2008
N/A	03/21/2008	LCD effective in CO Part B 03/21/2008
N/A	03/01/2008	LCD effective in NM Part B and OK Part A and Part B 03/01/2008
	12/20/2007	Consolidated LCD posted for notice effective: 12/20/2007

This content pertains to...
Programs: Part A,Part B
Topics: Not Topic Specific
Subtopics: Not Subtopic Specific

PART A - OKLAHOMA

PART B - OKLAHOMA

PART B - COLORADO

PART B - NEW MEXICO

PART A - TEXAS/NEW MEXICO/COLORADO

PART B - TEXAS

INDIAN HEALTH

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ELECTRONIC DATA INTERCHANGE

LOCAL COVERAGE DETERMINATIONS

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Version: 1.3.2.0