Non-Invasive Peripheral Arterial Vascular Studies

Medicare Advantage Medical Policy No.: MNG-028

The Health Plan reserves the right to amend this policy and procedure at any time. Exceptions to this policy and procedure will be made on a case-by-case basis at the total discretion of the Health Plan.

Effective Date: August 22, 2024

Instructions for use

This policy serves to provide guidance in determining coverage based on medical necessity. It also gives a list of resources used to create these guidelines. Medical necessity determinations will be made in accordance with generally accepted standards of medical practice, taking into account credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of the physicians practicing in relevant clinical areas, and other relevant factors, as they relate to the member's clinical circumstances.

Medicare Advantage Members

Coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria will be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of the coverage criteria and is to be used by all plans and lines of business unless Federal or State law, contract language, including member or provider contracts, take precedence over the policy.

Basic Requirements for Clinical Appropriateness:

1. Before diagnostic or therapeutic intervention, a clinician must confirm the diagnosis or establish the likelihood based on a history and physical exam and, when appropriate, a review of laboratory studies, previous diagnostic testing and response to any prior interventions, specifically relevant to the clinical situation.
2. An alternative treatment or other appropriate intervention should not offer any greater benefit based on standards of medical practice and/or current literature.
3. The potential benefit to the patient should outweigh the risk of the diagnostic or therapeutic intervention.
4. A reasonable likelihood of the intervention changing management and/or leading to an improved outcome for the patient must exist, based on the clinical evaluation, current literature and standards of medical practice.

If these requirements are not apparent in the request for authorization, including the clinical documentation provided, 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 and/or repeated diagnostic or therapeutic interventions in the same anatomic area may be denied, unless individual circumstances support the medical necessity of performing interventions simultaneously or repeatedly. This should be apparent in clinical documentation or in peer-to-peer conversations.

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When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider non-invasive peripheral arterial vascular studies to be eligible for coverage.**

When Services are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers non-invasive peripheral arterial vascular studies when the coverage criteria are not met and for all other indications to be investigational.*

Coverage Indications, Limitations, and/or Medical Necessity

Background/Overview

NON-INVASIVE PERIPHERAL ARTERIAL VASCULAR STUDIES utilize ultrasonic Doppler and physiologic studies to assess the irregularities in blood flow in arterial systems. These noninvasive peripheral arterial vascular studies include the patient care required to perform the studies, supervision of the studies, and interpretation of study results, with copies for patient records of test results and analysis of all data, including bi-directional vascular flow or imaging when provided.

Diagnostic tests must be ordered by the physician who is treating the beneficiary and the results used in the management of the beneficiary's specific medical problem. Services are deemed medically necessary when all of the following conditions are met:

1. Signs/symptoms of ischemia or altered blood flow are present;
2. The information is necessary for appropriate medical and/or surgical management;
3. The test is not redundant of other diagnostic procedures that must be performed. Although, in some circumstances, non-invasive vascular tests are complimentary, such as MRA and duplex,

where the latter may confirm an indeterminate finding or demonstrate the physiologic significance of an anatomic stenosis (especially in the lower extremity arterial system).

Definitions:

Duplex Scans

Duplex combines Doppler and conventional ultrasound, allowing the structure of blood vessels, how the blood is flowing through the vessels and whether there is any obstruction in the vessels to be seen. Color Doppler produces a picture of the blood vessel, and a computer converts the Doppler sounds into colors overlaid on the image, representing information about the speed and direction of blood flow. Using spectral Doppler analysis, the duplex scan images provide anatomic and hemodynamic information, identifying the presence of any stenosis or plaque in the arteries. Duplex scans are in real-time.

Physiologic Studies

Functional measurement procedures including ankle/brachial index measurement (ABI), blood pressure and physiologic waveforms, Doppler ultrasound, segmental pressure measurements, blood pressure measurements, transcutaneous oxygen tension measurements, exercise testing, and/or plethysmography. These studies do not involve imaging.

The most common is the ABI test, which compares the blood pressure measured at the ankle with the blood pressure measured at the arm (brachial) using a Doppler stethoscope and blood pressure cuff.

Doppler Ultrasound uses reflected sound waves called physiologic waveforms to evaluate the blood as it flows through an artery. The waveforms bounce off blood cells in a motion that causes a change in the pitch of the sound, called the Doppler effect. These can be measured at a single level, or at segmental (various) limb levels. If there is no blood flow, the pitch does not change.

Exercise testing can be used to analyze the functional significance of vascular disease by reassessing the blood pressure with the Doppler stethoscope after completion of an appropriate amount of stress testing.

Plethysmography is a measurement of the volume of an organ or limb section, or flow rate, in response to the inflation and deflation of a BP cuff.

Transcutaneous oxygen tension measurement may be done in any area of interest, usually the foot or calf. It measures the influx of blood that provides oxygen for diffusion to the skin.

Peripheral Arterial Examinations

In general, noninvasive studies of the arterial system are to be utilized when invasive correction is contemplated, or severity of findings dictates noninvasive study follow up. The latter may also be followed with physical findings and/or progression or relief of signs and/or symptoms. It can be useful in pre-operative evaluation of patients with known arteriosclerotic diseases who will be undergoing surgeries which put them at high risk for vascular complications (i.e. CABG, cranial surgeries etc.). It can be used for surveillance to ensure graft patency post-operatively.

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

- Signs and/or symptoms of possible limb ischemia are present; and

- The patient can be medically managed or is a candidate for percutaneous, surgical, diagnostic or therapeutic procedures.

Acute ischemia is characterized by the sudden onset of severe pain, coldness, numbness, and pallor of the extremity. Chronic ischemia or critical limb ischemia can have intermittent claudication, pain at rest, diminished pulse, ulceration and gangrene.

Indications

1. Signs and symptoms of reduced peripheral blood flow that result in tissue loss, gangrene or pre-gangrenous changes. Duplex scans are not always needed but may be helpful in defining the regions for arteriography (angiograms), thus limiting the contrast load to the patient.
2. Suspected arterial occlusive disease with symptoms including claudication, rest pain, ischemic tissue loss, aneurysm, and/or arterial embolization. Claudication is defined as pain occurring within 1 block or less of walking and/or of such severity that it interferes significantly with the patient's occupation or lifestyle. Rest pain of vascular disease (typically including the forefoot), is usually associated with absent pulses, which becomes increasingly severe with elevation and diminishes with placement of the leg in a dependent position.
3. Evaluation of grafts or other vascular intervention when signs and symptoms of ischemia, rejection, and/or vascular disease are present.
4. The monitoring of sites of previous surgical interventions, including sites of previous bypass surgery with either synthetic or autologous vein grafts.
5. The monitoring of sites of various percutaneous interventions, including angioplasty, thrombolysis/thrombectomy, atherectomy or stent placement.
6. Follow-up for progression of previously identified disease, such as documented stenosis in an artery that has not undergone intervention, aneurysms, atherosclerosis or other occlusive diseases.
7. The evaluation of suspected vascular and perivascular abnormalities, including masses, aneurysms, pseudoaneurysms, arterial dissections, vascular injuries, arteriovenous fistulae, thromboses, emboli, various communications between arteries and veins or vascular malformations.
8. Mapping of arteries prior to surgical interventions.
9. Clarifying or confirming the presence of significant arterial abnormalities identified by other imaging modalities.
10. Evaluation of arterial integrity in the setting of blunt or penetrating trauma with suspicion of vascular injury (including complications of diagnostic and/or therapeutic procedures).
11. Evaluation of patients suspected of thoracic outlet syndrome, with symptoms of positional numbness, pain, tingling or a cold hand.
12. Allen’s test to establish patency of palmar arch.

Limitations

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

1. Continuous burning of the feet as it is considered to be a neurologic symptom.
2. Nonspecific leg pain and pain in a limb as a single diagnosis is too general to warrant further investigation, unless they are related to other signs and symptoms.
3. Peripheral edema will only be covered with arterial occlusive disease in the immediate postoperative period, in association with another inflammatory process, or in association with rest pain.
4. Absence of peripheral pulses, e.g., dorsalis pedis or posterior tibial, is not an indication to proceed beyond the physical examination unless the absent pulses can be related to other signs and/or symptoms.
5. Screening of the asymptomatic patient is not covered.
6. Ankle-brachial index alone or when part of the physical examination, and not as part of the limited or complete bilateral physiologic studies, is not separately covered.
7. The use of a simple hand-held Doppler device that does not produce hard copy 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 reimbursable.

Non-covered peripheral arterial study testing methods include thermography, mechanical oscillometry, inductance or capacitance plethysmography, photoelectric plethysmography, differential plethysmography and light reflective rheography.

Credentialing and Accreditation Standards

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. A vascular diagnostic study may be personally performed by a physician, a certified technologist, or in a certified vascular testing lab.

Services will be considered medically reasonable and necessary only if performed by appropriately trained providers.

1. All non-invasive vascular diagnostic studies must be performed meeting at least one of the following:
    a. performed by a licensed qualified physician, or
    b. performed by a technician who is certified in vascular technology, or
    c. performed in facilities with laboratories accredited in vascular technology
2. A licensed qualified physician for these services is defined as:
    a. Having trained and acquired expertise within the framework of an accredited residency or fellowship program in the applicable specialty/subspecialty in ultrasound (US) or

must reflect equivalent education, training, and expertise endorsed by an academic institution in ultrasound or by applicable specialty/subspecialty society in ultrasound, or

b. Has the Registered Vascular Technologist (RVT), Registered Physician Vascular Interpretation (RPVI), or American Society of Neuroimaging (ASN): Neuroimaging Subspecialty Certification; and

c. Is able to provide evidence of proficiency in the performance and interpretation of each type of diagnostic procedure performed.

3. Nonphysician personnel performing tests must demonstrate basic qualifications to perform tests and have training and proficiency as evidenced by licensure or certification by an appropriate State health or education department. In the absence of a State licensing board, non-physician personnel must be certified by an appropriate national credentialing body. Appropriate personnel certification includes the American Registry of Diagnostic Medical Sonographers (ARDMS) or Registered Vascular Technologist (RVT) credential; or Cardiovascular Credentialing International's Registered Vascular Specialist (RVS).

4. Laboratories must be certified by one of the following:

   a. Intersocietal Accreditation Commission (IAC),

   b. American College of Radiology (ACR),

   c. Joint Commission (Vascular lab certification would need to be noted under the main certification either under inpatient or ambulatory care depending on where the test is being performed), or

   d. DNV-GL (specific for hospitals only)

   According to which certifying body listed above is selected, that accrediting body's standards must be followed.

5. Transcutaneous oxygen tension measurement should be performed by personnel possessing the following credentials obtained from the National Board of Diving and Hyperbaric Medicine Technology (NBDHMT): Certified Hyperbaric Technologist (CHT), or Certified Hyperbaric Registered Nurse (CHRN).

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation

Adequate documentation is essential for high-quality patient care and to demonstrate the reasonableness and medical necessity of the study(ies). Documentation must support the criteria as described in the Coverage Indications, Limitations, and/or Medical Necessity section of this LCD. There should be a permanent record of the studies performed and the interpretation. The documentation

should include a description of the studies performed and any contrast media and/or radiopharmaceuticals used. Any known significant patient reaction or complications should be recorded. Comparison with prior relevant studies needs to be addressed in the documentation along with both normal and abnormal findings. Variations from normal should be documented along with measurements. The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical questions, this should be explained in the documentation. Retention of the ultrasound examination images and final interpretation should be consistent both with clinical need and with relevant legal and local health care facility requirements.

If the provider of the study is other than the ordering/referring physician/nonphysician practitioner, that provider must maintain a copy of the test results and interpretation, along with copies of the ordering/referring physician/nonphysician practitioner's order for the studies. This order is required to provide adequate diagnostic information to the performing provider. The physician/nonphysician practitioner must state the clinical indication/medical necessity for the study in his/her order for the test. The provider is responsible for ensuring the medical necessity of procedures and maintaining the medical record, which must be available to Medicare upon request. Results of all testing must be shared with the referring physician. Non-invasive vascular studies are medically reasonable and medically necessary only if the outcomes will be utilized in the clinical management of the patient.

Utilization Guidelines

Each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each study reported to be clearly documented in the patient's medical record.

Frequency of follow-up studies will be carefully monitored for medical necessity and it is the responsibility of the physician/provider to maintain documentation of medical necessity in the patient's medical record.

Generally, it is expected that noninvasive vascular studies would not be performed more than once in a year, excluding inpatient hospital (21) and emergency room (23) places of services.

Only one preoperative scan is considered reasonable and necessary for bypass surgery. If a more current preoperative scan is indicated for a patient with multiple comorbidities having difficulty being stabilized for surgery or a change in condition, the medical record would need to support the medical necessity of the second scan.

In the immediate post-operative period, patients may be studied if re-established pulses are lost, become equivocal, or if the patient develops related signs and/or symptoms of ischemia with impending repeat intervention.

The frequency of medically necessary follow-up noninvasive vascular studies post-angioplasty is dictated by the vascular distribution treated.

Pre-surgical conduit mapping of the radial artery(ies) should only be accompanied by vein-mapping studies when the arterial studies demonstrate a non-acceptable conduit or an insufficient conduit is available for multiple bypass procedures.

Duplex scanning and physiologic studies may be reimbursed during the same encounter if the physiologic studies are abnormal and/or to evaluate vascular trauma, thromboembolic events or aneurysmal disease. The documentation must support the medical necessity.

Assessment of the Ankle brachial indices (ABI) only is considered part of the physical examination and is not covered according to Title XVIII of the Social Security Act section 1862 (a) (7) which excludes routine physical examinations and services from Medicare coverage.

Preventive and/or screening services unless covered in Statute are not covered by Medicare.

Sources of Information

1. ACR. (2012, Amended 2014). ACR-AIUM-SIR-SRU Practice parameter for the performance of physiologic evaluation of extremity arteries. American College of Radiology Practice Parameter. Resolution 39. pp. 1-7.
2. ACR. (Revised 2014). ACR-AIUM-SRU Practice parameter for the performance of peripheral arterial ultrasound using color and spectral Doppler. American College of Radiology Practice Parameter. Resolution 26. pp.1-11.
3. ACR. (Revised 2014). ACR Practice parameter for communication of diagnostic imaging findings. American College of Radiology Practice Parameter. Resolution 11. pp. 1-9.
4. ACR. (2011, Amended 2014). ACR-SPR-SRU Practice parameter for performing and interpreting diagnostic ultrasound examinations. American College of Radiology. Resolution 39. pp. 1-6.
5. ACR. (Revised 2011). ACR Technical standard for diagnostic medical physics performance monitoring of real time ultrasound equipment. American College of Radiology Practice Parameter. Resolution 3. pp.1-7.
6. ACR. (2010, Sep 9). Ultrasound accreditation program requirements. American College of Radiology. pp.1-10.
7. Intersocietal Accreditation Commission. (2013, Jun 15). IAC Standards and Guidelines for Vascular Testing Accreditation. Pages 1-67.
8. Intersocietal Accreditation Commission. (2010, Apr). ICAVL Standards for accreditation in noninvasive vascular testing. Parts I through VII. Pages 1-73.

References:

1. Aboyans V, Criqui MH, Abraham P, et al. Measurement and interpretation of the ankle-brachial index. Circulation. 2012;126(24):2890-2909. doi:10.1161/cir.0b013e318276fbcb.
2. Gerhard-Herman M, Gardin JM, Jaff M, Mohler E, Roman M, Naqvi TZ. Guidelines for noninvasive Vascular LABORATORY Testing: A report from the American Society of echocardiography and the Society of Vascular medicine and biology. Journal of the American Society of Echocardiography. 2006;19(8):955-972. doi:10.1016/j.echo.2006.04.019.
3. Mohler ER, Gornik HL, Gerhard-Herman M, Misra S, Olin JW, Zierler RE. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral Vascular ultrasound and Physiological testing Part I: Arterial ultrasound and Physiological testing. Journal of the American College of Cardiology. 2012;60(3):242-276. doi:10.1016/j.jacc.2012.02.009.

Policy History

Chief Medical Officer Review: 08/22/2024

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Utilization Management Committee Review: 08/22/2024

Coding

The five-character codes included in this medical policy are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93922, 93923, 93924, 93925, 93926, 93930, 93931
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

    1. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    2. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.