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Comments and Responses Regarding Draft Local Coverage Determination Non-Invasive Vascular Studies

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Non-Invasive Vascular Studies LCD. The official notice period for the final LCD begins on October 1 2008, and the final determination will become effective on November 15, 2008.

Comment: A Kentucky Carrier Advisory Committee (CAC) member and the Kentucky Chapter of the American College of Physicians requested the criteria listed under "Credentialing and Accreditation Standards" for all non-invasive vascular studies become recommendations rather than requirements. In addition, they and the American College of Physicians asked that the criteria not be implemented for non-imaging physiological vascular studies. Concern was expressed that the requirements could interfere with access to non-invasive vascular studies (NIVS) performed in small rural communities

Response: All documents received including peer-reviewed literature referenced in the policy were reviewed. A radiologist and hospital personnel from small communities wrote that they were concerned about the ability to recruit and maintain registered vascular technicians. However, it was noted that the hospital had previously had two registered technicians. One criterion listed in the draft policy is, "(1) performed by a physician who is competent in diagnostic vascular studies ..." No information was provided regarding the presence or absence of such physicians. However, one would anticipate that there would be physicians who would have such competence.

Although there was criticism of the cited references, no literature was provided to refute the value of credentialing/accreditation. The Government Accounting Office (GAO) report¹ noted Medicare carriers in 24 states and the District of Columbia had established LCDs requiring, and an additional 17 states recommending, sonographer certification or laboratory accreditation for NIVS. Review of the states with the requirement demonstrated several states with large rural areas. Only nine states were noted not to have a credentialing or accreditation requirement.

Non-invasive physiological studies (CPT codes 93875, 93922, 93923, 93924, and 93965) are considered and included as "Noninvasive Vascular Diagnostic Studies" in the CPT manual. We agree that the references to date of which we are aware have not studied the role credentialing may play in the quality of non-invasive physiological studies. However, it is rational to consider that training and demonstration of competence should positively influence the quality of the study result.

The credentialing and accreditation requirements as described in the draft LCD are already in place for New York Part B providers except those in Queens County. The requirements will be retained in the final policy and take effect in other National Government Services jurisdictions two years from the effective date of the policy, November 15, 2010.

Comment: Two Kentucky CAC members who perform or supervise vascular studies and perform vascular surgery strongly supported the credentialing/accreditation standards being adopted as requirements rather than recommendations. They noted discussion had occurred in the CAC meetings beginning in 2000. Concern was expressed about the potential adverse outcomes that could result from inappropriately performed or interpreted studies.

Response: Please see above.

Comment: A large number of comments were submitted by one physician. Comments were restricted to the narrative portions of the policy and did not address "ICD-9 Codes that Support Medical Necessity."

Response: The following non-editorial changes were accepted.

- "Registered Physician Vascular Interpretation (RPVI)" was added to the list of appropriate personnel certifications.
- Ocular pneumoplethysmography (OPG-Gee) was deleted from the description of covered cerebrovascular arterial testing methods. The technique is considered outmoded.
- "Of less than one block" was deleted in "Claudication of less than one block or such severity that it interferes significantly with the patient's occupation or lifestyle,....."
- "Or other vascular interventions" was added to the bullet, "Follow-up of grafts" listed under conditions in which "Peripheral artery studies may be considered medically necessary if the following signs and symptoms are present:"
- "Only" was added to the first sentence under "Peripheral Arterial Examinations (93922 – 93931)," "Limitations." The sentence now reads, "Peripheral artery studies may **not** be considered medically necessary if only the following signs and symptoms are present:"
- "Other predisposing illness/condition" was added to the list of reasons objective testing is allowed for deep vein thrombosis in patients who are candidates for anticoagulation or invasive therapeutic procedures.
- "Primary" was deleted in the term, "primary varicose veins."
- Under "Chronic Venous Insufficiency," "stasis dermatitis" was added to the second bullet which now reads, "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; and/or"
- "Obesity to the degree it interferes with clinical determination" was added as a bullet under reasonable considerations for pre-operative vein mapping study.
- Under "Utilization Guidelines," "If patient develops symptoms of carotid disease, repeat duplex scans are allowed without regard to the above schedule" was added.
- Under "Utilization Guidelines," the statement addressing follow-up post-angioplasty was changed to read, "The frequency of medically necessary follow-up studies post-angioplasty is dictated by the vascular distribution treated."

The following non-editorial comments were not accepted.

- Delete, under “General Limitations,” “It is rarely necessary to perform cerebrovascular and upper extremity studies on the same day. Documentation supporting the need for both studies should be available for review.” The sentences are valid and will remain.
- “Intraoperative evaluation of reconstructions” was not added to “Indications” for “Extracranial Arterial Studies (93875 – 93882).” Intraoperative vascular studies by the surgeon are not separately reimbursed.
- “Drop attack or syncope are rare indications usually seen with vertebrobasilar or bilateral carotid artery disease” was not deleted under “Limitations” for “Extracranial Arterial Studies (93875 – 93882).” In the same section, “especially when other more common sources...” was not deleted.
- Under “Transcranial Doppler (TCD) Studies (93886 – 93893),” “Limitations,” the following second sentence was not deleted.

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 is able to 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.
- Under “Peripheral Arterial Examinations (93922 – 93931),” “Indications,” the following was not deleted.

An ABI should be abnormal, e.g., <0.9 at rest, and must be accompanied by another appropriate indication before proceeding to more sophisticated or complete studies, except in patients with severe diabetes or uremia resulting in medial calcification as demonstrated by artifactually elevated ankle blood pressure.
- Under “Peripheral Arterial Examinations (93922 – 93931),” “Limitations,” “but not for following non-invasive medical treatment regimens” was not deleted. The sentence was modified to read, “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 noninvasive medical treatment regimens.”
- The second sentence below was not removed under “Limitations” for Visceral Vascular Studies.

Noninvasive vascular studies are medically necessary only if the outcome will potentially impact the clinical course of the patient. For example, if a patient 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 medically necessary. That is, if it is obvious from the findings of the history and physical examination that the patient is going to proceed to angiography, then noninvasive vascular studies may not be medically necessary.
- The statement, “However, contrast fistulograms provide much more complete evaluations of fistulas” was not added to “Hemodialysis Access Examination (93990),” “Limitations.”
- The first paragraph under “Vessel mapping of Vessels for Hemodialysis Access (93990/G0365),” “Limitations” was not removed. The paragraph restates information in the CMS policy manual (100-02, Chapter 11, Section 20.1).

Comment: A list of ICD-9-CM codes were sent with a request to add to the “ICD-9 Codes that Support Medical Necessity.” No grouping of the diagnoses for the various types of procedures was provided.

Response: The submitter was contacted and told the diagnoses would need to be organized by procedure groupings for the diagnosis codes to be considered. The list was not resubmitted.

ⁱ United States Government Accountability Office. GAO report to congressional committees. GAO-07-734. Medicare ultrasound procedures. Consideration of payment reforms and technician qualifications requirements. June 2007.