Local Coverage Determination (LCD):
Treatment of varicose veins of the lower extremity
(L33762)

Contractor Information

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LCD Information

Document Information

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LCD Title
Treatment of varicose veins of the lower extremity

Proposed LCD in Comment Period
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Source Proposed LCD
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Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub 100-08, Program Integrity Manual, Chapter 13, Section 5.1

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Indications of Coverage and/or Medical Necessity

Varicose veins are a manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension. Varicose veins are superficially located, dilated, tortuous, veins of the lower extremities. They are usually caused by insufficiency, or valvular reflux, of the valvular apparatus (primary disease), or as a result of previous thrombosis or trauma (secondary disease). These dilated superficial veins of the lower limbs are considered pathologic when they are 5 mm or greater in diameter or sometimes 3 mm or greater in diameter (depending on the indication as outlined further in the LCD) when measured in the upright position and have greater than 500 milliseconds of reflux by duplex scan. CVD can cause clinically significant pain and result in a decrease in quality of life and even disability which may necessitate treatment which would be considered reasonable and necessary. CVD is progressive, and over time may progress to secondary skin changes (edema, lipodermatosclerosis, and ulceration), which is referred to as chronic venous insufficiency (CVI). CVD and CVI can be further complicated by superficial thrombophlebitis and variceal hemorrhage.

The superficial venous system has one-way valves that prevent backflow of blood (reflux) when normal and allow movement of blood toward the heart. The axial superficial veins communicate with the deep venous system at different locations. The point where the great saphenous vein (GSV) joins the common femoral vein, saphenofemoral junction (SFJ), is located proximally at the groin. The point where the small saphenous vein (SSV) joins the popliteal vein, saphenopopliteal junction (SPJ), is typically located behind the knee. Reflux involves the main axial superficial veins: GSV and SSV saphenous veins and their tributaries. Clinically significant reflux can also be found in accessory great saphenous veins (i.e., anterior or posterior) which parallel the GSV in the saphenous compartment, the SSV, circumflex veins which course oblique to the GSV, or perforating veins (veins that connect the superficial to the deep veins). There are numerous perforator veins found throughout the leg from the thigh to the ankle that traverse the muscular fascia of the lower extremity and, under normal circumstances, drain from the superficial veins toward the deep (intramuscular) veins. Variations in the anatomy of the deep and superficial venous systems are common.

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences—edema and skin changes—should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A duplex ultrasound scan of the deep and superficial venous systems must support the examination findings.

The treatment of C1 disease (spider telangiectasia and their feeding reticular veins) is considered cosmetic, and therefore, not reasonable and necessary for the purposes of Medicare coverage.

For patients with C2 disease and VCSS score <6, the plan of care must include at least a 90 day course of compression therapy further defined below. (C2 patients with VCSS <6, who failed at least a 90 day course of compression therapy, would start a new 90 day episode of care, and proposed interventions should be addressed in the plan of care.)
For patients with C2 disease and VCSS score >6, or patients with C3-C6 disease, proposed interventions for a 90 day episode of care should be addressed in the treatment plan.

**Classification for chronic venous disorders (CVD and CVI)—**

The CEAP classification for chronic venous disorders was developed by an international committee that classifies venous disease according to the clinical severity (C), etiology (E), anatomy (A), and pathophysiology (P) to improve the accuracy of the diagnosis. The CEAP classification includes the following elements:

**Clinical Classification and Description:**

C 0- No visible or palpable signs of venous disease

C 1- Telangiectasies or reticular veins less than 3 mm

C 2- Simple varicose veins (3 mm or larger)

C 3- Ankle edema of venous origin (not foot edema)

C 4a- Skin pigmentation or eczema

C 4b- Lipodermatosclerosis or atrophie blanche

C 5- Healed venous ulcer

C 6- Open venous ulcer

S- Symptomatic, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction

A- Asymptomatic

**Etiologic Classification:**

Ec- Congenital

Ep- Primary

Es- Secondary (postthrombotic)

En- No venous cause identified

**Anatomic classification:**

As- Superficial veins

Ap- Perforator veins

Ad- Deep veins

An- No venous location identified

**Pathophysiologic classification:**

Pr- Reflux

Po- Obstruction

Pr,o- Reflux and obstruction
Pn- No venous pathophysiology identifiable

CEAP is a static classification; however, disease can be reclassified at any time. Classification starts with the patient’s initial visit but can be better defined longitudinally after further investigations. A final classification may not be complete until after treatment. Eklöf et al. therefore recommend that any CEAP classification be followed by the date, for example, C4bS, Ep, As, Pr (2003-08-21).

**Instructions for using the revised Venous Clinical Severity Score—**

“For each leg, please check 1 box for each item (symptom and sign) that is listed below.”

**Pain or other discomfort** (i.e., aching, heaviness, fatigue, soreness, burning)
The clinician describes the 4 categories of leg pain or discomfort that are outlined below to the patient and asks the patient to choose, separately for each leg, the category that best describes the pain or discomfort the patient experiences.

**None** = 0: None

**Mild** = 1: Occasional pain or discomfort that does not restrict daily activities

**Moderate** = 2: Daily pain or discomfort that interferes with, but does not prevent, regular daily activities

**Severe** = 3: Daily pain or discomfort that limits most regular daily activities

**Varicose Veins**
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the patient’s superficial veins. The standing position is used for varicose vein assessment. Veins must be ≥3 mm in diameter to qualify as “varicose veins.”

**None** = 0: None

**Mild** = 1: Few, scattered, varicosities that are confined to branch veins or clusters. Includes “corona phlebectatica” (ankle flare), defined as >5 blue telangiectases at the inner or sometimes the outer edge of the foot

**Moderate** = 2: Multiple varicosities that are confined to the calf or the thigh

**Severe** = 3: Multiple varicosities that involve both the calf and the thigh

**Venous Edema**
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the patient’s pattern of leg edema. The clinician’s examination may be supplemented by asking the patient about the extent of leg edema that is experienced.

**None** = 0: None

**Mild** = 1: Edema that is limited to the foot and ankle

**Moderate** = 2: Edema that extends above the ankle but below the knee

**Severe** = 3: Edema that extends to the knee or above

**Skin Pigmentation**
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the patient’s skin pigmentation. Pigmentation refers to color changes of venous origin and not secondary to other chronic diseases (i.e., vasculitis purpura).

**None** = 0: None, or focal pigmentation that is confined to the skin over varicose veins

**Mild** = 1: Pigmentation that is limited to the perimalleolar area
Moderate = 2: Diffuse pigmentation that involves the lower third of the calf
Severe = 3: Diffuse pigmentation that involves more than the lower third of the calf

Inflammation
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the patient’s skin inflammation. Inflammation refers to erythema, cellulitis, venous eczema, or dermatitis, rather than just recent pigmentation.

None = 0: None
Mild = 1: Inflammation that is limited to the perimalleolar area
Moderate = 2: Inflammation that involves the lower third of the calf
Severe = 3: Inflammation that involves more than the lower third of the calf

Induration
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the patient’s skin induration. Induration refers to skin and subcutaneous changes such as chronic edema with fibrosis, hypodermitis, white atrophy, and lipodermatosclerosis.

None = 0: None
Mild = 1: Induration that is limited to the perimalleolar area
Moderate = 2: Induration that involves the lower third of the calf
Severe = 3: Induration that involves more than the lower third of the calf

Active Ulcer Number
The clinician examines the patient’s legs and, separately for each leg, chooses the category that best describes the number of active ulcers.

None = 0: None
Mild = 1: 1 Ulcer
Moderate = 2: 2 Ulcers
Severe = 3: ≥3 Ulcers

Active Ulcer Duration
If there is at least 1 active ulcer, the clinician describes the 4 categories of ulcer duration that are outlined below to the patient and asks the patient to choose, separately for each leg, the category that best describes the duration of the longest unhealed ulcer.

None = 0: No active ulcers
Mild = 1: Ulceration present for <3 mo
Moderate = 2: Ulceration present for 3-12 mo
Severe = 3: Ulceration present for >12 mo

Active Ulcer Size
If there is at least 1 active ulcer, the clinician examines the patient’s legs, and separately for each leg, chooses
the category that best describes the size of the largest active ulcer.

**None** = 0: No active ulcer

**Mild** = 1: Ulcer <2 cm in diameter

**Moderate** = 2: Ulcer 2-6 cm in diameter

**Severe** = 3: Ulcer >6 cm in diameter

**Use of Compression Therapy**
Choose the level of compliance with medical compression therapy

**None** = 0: Not used

**Mild** = 1: Intermittent use

**Moderate** = 2: Wears stockings most days

**Severe** = 3: Full compliance: stockings

**Varicose vein terminology relevant to this policy:**

*Varicose veins* are visible distended superficial veins > 3mm with venous incompetence. Not all require treatment, and some treatment is cosmetic and not a Medicare benefit. *Spider veins* are intradermal venules of <1 mm, also known as telangiectasia or thread veins. *Reticular veins* are subdermal veins of 1-3 mm in diameter. *Superficial veins* include truncal (GSV/SSV) and accessory/tributary veins in the subcutaneous tissue. *Perforator veins* are the veins that link the superficial and deep veins. *Deep veins* are located deep to the muscular fascia, such as the common femoral vein.

**Conservative management:**
The venous circulation may be altered sufficiently to cause symptoms such as pain, aching, burning, tingling, cramps, feelings of heaviness or throbbing, itching skin, and accelerated leg fatigue. Leg pain may be associated with edema, superficial thrombophlebitis, stasis dermatitis, or venous ulcers. Conservative therapy refers to the nonsurgical management of varicose veins which includes leg elevation, weight management for the overweight and obese, and the use of graduated compression stockings or wraps. Leg elevation helps venous return and decreases venous hypertension; in contrast, standing for long periods or sitting with legs dependent for long periods, can aggravate the symptoms and signs of venous insufficiency. Conservative therapy for uncomplicated cases may be sufficient for symptom relief and early signs of venous insufficiency. However, compression therapy does not cure the underlying venous pathology of valvular reflux or venous valvular insufficiency; and for patients with significant concomitant arterial disease, its use may be limited or contraindicated.

The rationale for compression therapy is to decrease venous hypertension and assist the calf pump. Compression therapy is an important adjunct for patients with advanced signs of venous insufficiency especially those with edema, skin changes, and venous stasis ulcers (C3-C6). For some people with symptomatic varicose veins (C2), wearing graduated compression stockings may relieve many of their symptoms.

For C2 patients with VCSS <6, documentation of the failure of compression therapy (graduated compression stockings (15-20 mmHg)) is required for consideration of ablations, as outlined below. A plan of care is required for all patients receiving treatment per the indications of this LCD.

**Plan of Care:**
For the purposes of this LCD, any reference to plan of care signifies a 90 day episode of care that begins with the first date of service of procedures outlined in this policy. Procedures will only be considered covered (reasonable and necessary) if the patient meets the criteria for the procedure as outlined in this LCD, and the intervention is addressed and supported in the plan of care. The plan of care is based on the treating physician’s assessment with CEAP and VCSS classification including the date(s) of exam and diagnostic evaluation. The minimum evaluation that must be documented includes history, physical exam, and a formal venous duplex ultrasound scan. The indications for venous duplex ultrasound scan in patients with symptomatic varicose veins and the components of a satisfactory report are outlined later in this LCD. (For other indications of duplex scan, see the LCD for Non-Invasive Evaluation of Extremity Veins.)
Supplemental plethysmography, contrast venography, venous pressure measurements, IVUS, CT venography, MR venography may be relevant to the plan of care in patients with severe or unusual presentations of venous disease in which there is possible concurrent involvement of pelvic veins or arterial-venous malformations or fistulae. Indications for these more extensive procedures should be documented in the plan of care.

The initial plan of care is expected to address all sites of clinically significant axial or non-axial reflux along with a description of the specific procedure(s) to be used in a 90 day episode of care consistent with the CEAP and VCSS classification and supporting clinical and diagnostic data. Again, for patients with C2 disease and a VCSS score <6, the initial plan of care must include at least a failure of a 90 day course of compression therapy before a new 90 day episode of care.

The timing of an intervention(s) must be outlined versus the timing of routine post-op (post procedure) follow-up (for example, procedure(s) on day 1 and reevaluation in 3 months versus procedure(s) on day 1 and 7 and reevaluation in 3 months). Therefore, any planned thermal ablation, and/or sclerotherapy (liquid or foam), and/or phlebectomy must be addressed in the plan of care – and must be supported in a complete operative procedure note. Thermal ablation includes the necessary ultrasound imaging for any additional procedures done with the thermal ablation. Thermal ablation of the GSV, SSV, or other veins of the same leg on different days (utilizing two base codes on separate days vs. a base code with an add-on code) must be clearly supported in the plan of care as to why this is necessary. Incompetent perforator vein intervention should be clearly supported based on CEAP classification and other patient specific clinical information. Such claims may be subject to prepayment medical review.

**Surgical ligation and stripping:**

The traditional treatment of varicose veins in the lower legs includes a surgical procedure called high ligation and saphenous vein stripping (HL/S), which had been the gold standard of treatment; and its primary goal is removal of refluxing veins and improvement of symptoms. HL/S is typically a three-step process: first, controlling reflux by proximal ligating of an incompetent vein; then, stripping a vein segment (usually the GSV or SSV) or removing of an incompetent long axial vein segment (usually the saphenous vein) from circulation through incisions in the groin and lower in the leg. The third step is removing tributaries via stab phlebectomies or sclerotherapy, either at the time of ligation or subsequent to the ligation. Phlebectomy of the distal branch varicosities in the lower leg without elimination of proximal axial venous insufficiency is not reasonable and necessary without a clear explanation in the plan of care.

**Thermal ablation:**

Thermal ablation of superficial and perforating veins can by performed with endovenous radiofrequency ablation (RFA) or endovenous laser ablation (EVLA). These techniques are minimally invasive alternatives to HL/S and can be performed in an office/outpatient setting using local anesthesia and typically require no or minimal sedation. The thermal ablation code descriptors include all imaging guidance and monitoring. It is only a treatment option for sufficiently straight superficial vein segments that will allow passage of the device. RFA and EVLA have the same purpose, that is, to damage the endothelium of the vein resulting in fibrosis and occlusion of a vein segment to eliminate reflux. There is sufficient evidence of the effectiveness of thermal ablation procedures for the primary treatment of the GSV and/or SSV, and incompetent accessory saphenous veins.

Medicare will consider RFA and EVLA for the treatment of symptomatic GSV, SSV, or accessory saphenous veins medically reasonable and necessary for the following conditions:

For C2 patients, the plan of care must include a duplex scan report demonstrating saphenous vein reflux (at least 500 ms) and a GSV diameter of at least 5 mm and SSV diameter of at least 3 mm. The signs and symptoms (e.g., persistent pain, swelling, itching, burning) must significantly interfere with activities of daily living or quality of life and exceed a VCSS score of 6 or have a VCSS <6 with documentation of the failure of compression therapy.

There is insufficient evidence to support the effectiveness of thermal ablation procedures for perforator veins.

For C3-C6, the plan of care should also include a duplex ultrasound scan report demonstrating saphenous vein reflux (at least 500 ms) and a GSV diameter of at least 5 mm and SSV diameter of at least 3 mm. Documentation must include signs such as skin thickening and discoloration, superficial phlebitis, edema, variceal hemorrhage, and ulceration. If perforator vein treatment is a consideration, the plan of care must also include evidence of perforator venous insufficiency (outward flow of at least 500 ms) measured by recent duplex ultrasonography report, perforator vein size of 3.5 mm or greater, and documentation in office notes and recent
duplex ultrasound study that the perforating vein lies beneath or contiguous to a healed or active venous stasis ulcer (unless the deep veins are obstructed).

**Phlebectomy:**
Stab phlebectomy also referred to as stab avulsion, phlebectomy, ambulatory stab phlebectomy, or microphlebectomy is a surgical treatment involving the removal of varicose veins through small “stab” 1-2 mm incisions in the skin overlying the vein. The vein is hooked and brought to the surface at each incision site to release it from the surrounding tissues and to sever any connections to other veins. Transilluminated powered phlebectomy (TriVex) should be billed as a phlebectomy and can be covered if it meets indications as outlined for phlebectomy.

Phlebectomy is an adjunctive procedure and may be covered for patients with symptomatic varicose tributary veins for those with C2 and VCSS >6, or C2 and VCSS <6 with documentation of the failure of compression therapy, or patients with C3-C6 disease, ideally at the same time or following surgical or thermal ablation treatment of the saphenous veins, as outlined in the plan of care that addresses the episode of care. If treatment does not meet the Medicare reasonable and necessary threshold for coverage, claims billed for this procedure will be denied.

**Subfascial endoscopic perforator surgery:**
Subfascial endoscopic perforator surgery (SEPS) is a treatment option of incompetent perforator veins in patients with advanced chronic venous insufficiency (e.g., venous ulcer, active or healed) when conservative management has failed. The overall goal of SEPS in treating chronic venous ulcers is to interrupt the incompetent perforating veins in order to decrease reflux and pressure in areas above the ankle. SEPS for the treatment of C1-C4 is not covered. The Clinical Practice Guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) has determined that current studies do not support treatment of perforator veins in patients with simple varicose veins. Pathologic perforating veins include those with outward flow of >500 ms, with a diameter of >3.5 mm, located beneath or contiguous to a healed or open venous ulcer (CEAP class C5-C6).

**Sclerotherapy:**
Sclerotherapy is another minimally invasive treatment modality. Sclerotherapy is the injection of a chemical (FDA-approved sclerosing agent) into a varicose or incompetent vein to achieve endoluminal fibrosis and obstruction. Sclerotherapy (liquid or foam) is performed for signs and symptoms of refluxing veins and can be used as an adjunct to surgical or ablative therapy (radiofrequency or laser). Evidence supports sclerotherapy limited to the treatment of residual or recurrent varicose tributary veins following control of reflux in the GSV/SSV either by surgical ligation or endovenous thermal ablation. Sclerotherapy for cosmetic purposes is not considered medically reasonable and necessary. Procedures that correct an anatomical abnormality without improving or restoring physiologic function are considered cosmetic procedures.

Medicare will consider sclerotherapy as an adjunctive procedure and covered for patients with symptomatic varicose tributary veins for those with C2 and VCSS >6, or C2 and VCSS <6 with documentation of the failure of compression therapy, or patients with C3-C6 disease and ideally at the same time or following surgical or thermal ablation treatment of the saphenous veins, as outlined in the plan of care that addresses the episode of care. If endothermal ablation is unsuitable, image-guided foam sclerotherapy for tributary vein can be a consideration if clinically significant reflux is documented and addressed in the plan of care. Sclerotherapy injections for the treatment of telangiectasias and reticular veins less than 3 mm in diameter are considered cosmetic and noncovered.

There is no unique code for image-guided foam sclerotherapy. Currently, if performed by a qualified physician (MD/DO) who has had appropriate training in image guidance, CPT code 36470/36471 (sclerotherapy) and CPT code 76942 (ultrasound guidance for needle placement) should be utilized for such procedures. The scope of this LCD does not include solutions used to perform chemical ablation sclerotherapy. It is the responsibility of the provider to comply with all applicable State and Federal laws related to the human use of agents. Device/sclerosant combination procedures for residual or recurrent varicose tributary veins (coded as CPT code 37799— Unlisted procedure, vascular surgery) that generate an injectable foam may be considered for coverage for the indications of sclerotherapy.

**Limitations of Coverage and/or Medical Necessity**
CPT code 37241 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) is not applicable (incorrect coding) for saphenous ablation and is not covered.

CPT code 76942 has limited coverage by qualified physicians for image-guided foam sclerotherapy, as outlined in this policy.

Thermal ablation includes the necessary ultrasound imaging for any additional procedures done with the thermal ablation.

CPT add-on code 76937 (ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting) is not a covered service for outpatient varicose vein procedures.

Local anesthesia and minimal to no sedation is the standard of care. Monitored Anesthesia Care (MAC) or moderate (conscious) sedation needs clear support in the medical record based on patient clinical presentation/characteristics and may be subject to prepayment review.

Photothermal sclerosis (also referred to as an intense pulsed light source, e.g., the PhotoDerm VascuLight, VeinLase), transdermal laser treatment, and mechanochemical ablation (MOCA) (Clarivein) (CPT codes 36473 and 36474) do not meet the Medicare reasonable and necessary threshold for coverage. Providers are required to code to specificity. If no such procedure of service exists, then report the service using the appropriate unlisted procedure code. Unlisted procedure, vascular surgery code 37799 should be reported until the specific CPT codes are established. Claims billed for these procedures will be denied.

If it is determined on review that the varicose veins were asymptomatic, the claim will be denied as a non-covered (cosmetic) procedure. Isolated injections for the treatment of telangiectasias and reticular veins less than 3mm in diameter are considered cosmetic and do not meet the Medicare reasonable and necessary threshold for coverage. Claims billed for these procedures will be denied.

Device/sclerosant combination procedures without a unique CPT code are described by CPT code 37799. The sclerosant is included in the procedure. Coverage is limited to the ‘sclerotherapy’ indications.

Training and qualifications:

The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (accessible at http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf) outlines that “reasonable and necessary” services are "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. The Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic Association (AOA), and the American Association of Colleges of Osteopathic Medicine (AACOM) have agreed to a single accreditation system for graduate medical education (GME) residency programs in the U.S.

A qualified physician for this service/procedure is defined as follows: A) Physician is properly enrolled in Medicare. B) Training and expertise must have been acquired within the framework of an accredited residency (general or vascular surgery, radiology, cardiology) and/or fellowship program in the applicable specialty/subspecialty in the United States or must reflect equivalent education, training, and expertise endorsed by an academic institution in the United States or by the applicable specialty/subspecialty society in the United States.

Nonphysician practitioners (NPP) have a defined scope of practice per state licensure. Use of ultrasound for chronic venous disease (CVD) diagnosis or therapy guidance is not covered. A NPP under the supervision of qualified physician for the intra service aspects of sclerotherapy (standard or foam) and/or phlebectomy must be able to demonstrate education and training in the intervention.

The accuracy of non-invasive diagnostic studies depends on the knowledge, skill and experience of the technologist and the physician performing the interpretation of the study. Consequently, the technologist and the physician must maintain proof of training and experience. All non-invasive vascular diagnostic studies must be: (1) performed by a qualified physician or (2) performed under the general supervision of a qualified physician or technologist who has demonstrated minimum entry level competency by being credentialed in vascular technology, and/or (3) performed in a laboratory accredited in vascular technology.
Examples of certification in vascular technology for non-physician personnel include:

- Registered Vascular Technologist (RVT) credential
- Registered Vascular Specialist (RVS) credential

These credentials must be provided by nationally recognized credentialing organizations such as:

- The American Registry of Diagnostic Medical Sonographers (ARDMS) which provides RDMS, RVT, and Registered Physician in Vascular Interpretation (RPVI) credentials
- The Cardiovascular Credentialing International (CCI) which provides RVS credential

Appropriate, nationally recognized laboratory accreditation bodies include:

- Intersocietal Accreditation Commission (IAC), formerly Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL)
- American College of Radiology (ACR)

**General Supervision means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.**

*Note that ultrasound technologists and therapists do not qualify to surgically treat varicose veins.*

**Duplex scanning:**

Medicare will consider non-invasive evaluation of extremity veins to be medically necessary for the evaluation of a patient with symptomatic varicose veins that interferes with activities of daily living or diminishes quality of life; and symptoms are suspected to be secondary to venous insufficiency including skin thickening, superficial phlebitis, edema, varicose hemorrhage, lipodermatosclerosis, stasis dermatitis, or stasis ulceration; and testing is performed to confirm this diagnosis by documenting venous insufficiency and valvular incompetence prior to an invasive therapeutic intervention, which meets criteria for medical necessity.

Duplex scanning will be considered medically necessary when used to initially determine the extent and mapping of the varicose veins and identify the location of incompetence. Evaluation of reflux or obstruction in the deep and superficial veins with duplex scanning should be performed with the patient upright for most of the exam. For a complete examination, all deep veins of the leg are examined, including the common femoral, femoral, deep femoral, popliteal, peroneal, soleal, gastrocnemial, anterior, and posterior tibial veins. The superficial veins are then evaluated including the GSV, the SSV, the accessory saphenous veins, perforating veins, and tributary veins. Six components that should be included in a complete duplex scanning examination for CVD are (1) visibility, (2) compressibility, (3) venous flow, including measurement of the duration of reflux, (4) augmentation, (5) phasicity, and (6) vein size. The cutoff value of 500 ms is for the saphenous, tibial, deep femoral, and perforating vein incompetence, and 1 second for femoral and popliteal vein incompetence. The SVS/AVF Guideline Committee definition of “pathologic” perforating veins includes those with outward flow of >500 ms, with a diameter of >3.5 mm, located beneath a healed or open venous ulcer (CEAP class C5-C6). An acceptable exam should also report if there is evidence of chronic deep venous occlusion or significant obstruction or evidence of acute deep venous thrombosis. The report should provide documentation that a duplex Doppler was performed consisting of two-dimensional (2D) real time imaging (to provide details of the speed and direction of the blood flow). A duplex Doppler ultrasound uses ultrasound and integrates the 2D real-time, color Doppler, and spectral analysis to provide anatomic and hemodynamic information.

It is the expectation that one complete bilateral duplex scan will precede the development of the plan of care. One unilateral (or bilateral if both extremities are treated) study post treatment (CPT code 76970) may be performed if supported in the plan of care. Additional studies in the absence of new or recurrent symptoms during the 90-day episode of care may result in prepayment medical review. Repeat and any limited studies must meet the criteria of the LCD for Non-invasive Evaluation of Extremity Veins.

CPT add-on code 76937 (ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting) is not a covered service for outpatient varicose vein procedures. CPT code 76942 has limited coverage by qualified physicians for image-guided foam sclerotherapy, as outlined in this policy.

**Summary of Evidence**
Analysis of Evidence (Rationale for Determination)
N/A

Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
083x Ambulatory Surgery Center
085x Critical Access Hospital

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

036X Operating Room Services - General Classification
049X Ambulatory Surgical Care - General Classification
051X Clinic - General Classification
0761 Specialty Services - Treatment Room
0920 Other Diagnostic Services - General Classification
0921 Other Diagnostic Services - Peripheral Vascular Lab
0929 Other Diagnostic Services - Other Diagnostic Service

CPT/HCPCS Codes

Group 1 Paragraph:
CPT codes 36470, 36471, 36482, and 36483 are only covered if the conditions of the sclerotherapy section of the LCD above are met.

Group 1 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36470</td>
<td>INJECTION OF SCLEROSANT; SINGLE INCOMPETENT VEIN (OTHER THAN TELANGIECTASIA)</td>
</tr>
<tr>
<td>36471</td>
<td>INJECTION OF SCLEROSANT; MULTIPLE INCOMPETENT VEINS (OTHER THAN TELANGIECTASIA), SAME LEG</td>
</tr>
<tr>
<td>36475</td>
<td>ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; FIRST VEIN TREATED</td>
</tr>
<tr>
<td>36476</td>
<td>ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; SUBSEQUENT VEIN(S) TREATED IN A SINGLE EXTREMITY, EACH THROUGH SEPARATE ACCESS SITES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
<tr>
<td>36478</td>
<td>ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; FIRST VEIN TREATED</td>
</tr>
<tr>
<td>36479</td>
<td>ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; SUBSEQUENT VEIN(S) TREATED</td>
</tr>
<tr>
<td>CPT Code</td>
<td>Procedure Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>36482</td>
<td>Endovenous Ablation Therapy of Incompetent Vein, Extremity, by Transcatheter Delivery of a Chemical Adhesive (e.g., Cyanoacrylate) Remote from the Access Site, Inclusive of All Imaging Guidance and Monitoring, Percutaneous; First Vein Treated</td>
</tr>
<tr>
<td>36483</td>
<td>Endovenous Ablation Therapy of Incompetent Vein, Extremity, by Transcatheter Delivery of a Chemical Adhesive (e.g., Cyanoacrylate) Remote from the Access Site, Inclusive of All Imaging Guidance and Monitoring, Percutaneous; Subsequent Vein(s) Treated in a Single Extremity, Each Through Separate Access Sites (List Separately in Addition to Code for Primary Procedure)</td>
</tr>
<tr>
<td>37500</td>
<td>Vascular Endoscopy, Surgical, with Ligation of Perforator Veins, Subfascial (SEPS)</td>
</tr>
<tr>
<td>37700</td>
<td>Ligation and Division of Long Saphenous Vein at Saphenofemoral Junction, or Distal Interruptions</td>
</tr>
<tr>
<td>37718</td>
<td>Ligation, Division, and Stripping, Short Saphenous Vein</td>
</tr>
<tr>
<td>37722</td>
<td>Ligation, Division, and Stripping, Long (Greater) Saphenous Veins from Saphenofemoral Junction to Knee or Below</td>
</tr>
<tr>
<td>37735</td>
<td>Ligation and Division and Complete Stripping of Long or Short Saphenous Veins with Radical Excision of Ulcer and Skin Graft and/or Interruption of Communicating Veins of Lower Leg, with Excision of Deep Fascia</td>
</tr>
<tr>
<td>37765</td>
<td>Stab Phlebectomy of Varicose Veins, 1 Extremity; 10-20 Stab Incisions</td>
</tr>
<tr>
<td>37766</td>
<td>Stab Phlebectomy of Varicose Veins, 1 Extremity; More than 20 Incisions</td>
</tr>
<tr>
<td>37780</td>
<td>Ligation and Division of Short Saphenous Vein at Saphenopopliteal Junction (Separate Procedure)</td>
</tr>
<tr>
<td>37785</td>
<td>Ligation, Division, and/or Excision of Varicose Vein Cluster(s), 1 Leg</td>
</tr>
<tr>
<td>37799</td>
<td>Unlisted Procedure, Vascular Surgery</td>
</tr>
<tr>
<td>93970</td>
<td>Duplex Scan of Extremity Veins Including Responses to Compression and Other Maneuvers; Complete Bilateral Study</td>
</tr>
<tr>
<td>93971</td>
<td>Duplex Scan of Extremity Veins Including Responses to Compression and Other Maneuvers; Unilateral or Limited Study</td>
</tr>
</tbody>
</table>

**Group 2 Paragraph:**
The following CPT codes are not reasonable and necessary for coverage:

**Group 2 Codes:**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Procedure Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36465</td>
<td>Injection of Non-Compounded Foam Sclerosant with Ultrasound Compression Maneuvers to Guide Dispersion of the Injectate, Inclusive of All Imaging Guidance and Monitoring; Single Incompetent Extremity Truncal Vein (e.g., Great Saphenous Vein, Accessory Saphenous Vein)</td>
</tr>
<tr>
<td>36466</td>
<td>Injection of Non-Compounded Foam Sclerosant with Ultrasound Compression Maneuvers to Guide Dispersion of the Injectate, Inclusive of All Imaging Guidance and Monitoring; Multiple Incompetent Truncal Veins (e.g., Great Saphenous Vein, Accessory Saphenous Vein), Same Leg</td>
</tr>
<tr>
<td>36473</td>
<td>Endovenous Ablation Therapy of Incompetent Vein, Extremity, Inclusive of All Imaging Guidance and Monitoring, Percutaneous, Mechanocchemical; First Vein Treated</td>
</tr>
<tr>
<td>36474</td>
<td>Endovenous Ablation Therapy of Incompetent Vein, Extremity, Inclusive of All Imaging Guidance and Monitoring, Percutaneous, Mechanocchemical; Subsequent Vein(s) Treated in a Single Extremity, Each Through Separate Access Sites (List Separately in Addition to Code for Primary Procedure)</td>
</tr>
</tbody>
</table>

**ICD-10 Codes that Support Medical Necessity**

**Group 1 Paragraph:**
Group 1 Codes:

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I80.11 - I80.13</td>
<td>Phlebitis and thrombophlebitis of right femoral vein - Phlebitis and thrombophlebitis of femoral vein, bilateral</td>
</tr>
<tr>
<td>I80.221 - I80.223</td>
<td>Phlebitis and thrombophlebitis of right popliteal vein - Phlebitis and thrombophlebitis of popliteal vein, bilateral</td>
</tr>
<tr>
<td>I80.231 - I80.233</td>
<td>Phlebitis and thrombophlebitis of right tibial vein - Phlebitis and thrombophlebitis of tibial vein, bilateral</td>
</tr>
<tr>
<td>I80.291 - I80.293</td>
<td>Phlebitis and thrombophlebitis of other deep vessels of right lower extremity - Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral</td>
</tr>
<tr>
<td>I80.3</td>
<td>Phlebitis and thrombophlebitis of lower extremities, unspecified</td>
</tr>
<tr>
<td>I83.001 - I83.813</td>
<td>Varicose veins of unspecified lower extremity with ulcer of thigh - Varicose veins of bilateral lower extremities with pain</td>
</tr>
<tr>
<td>I83.891 - I83.893</td>
<td>Varicose veins of right lower extremity with other complications - Varicose veins of bilateral lower extremities with other complications</td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous insufficiency (chronic) (peripheral)</td>
</tr>
<tr>
<td>R60.0</td>
<td>Localized edema</td>
</tr>
</tbody>
</table>

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:
The following ICD-10 codes are applicable to procedure code 37241 and are NOT covered:

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>178.0 - 178.9</td>
<td>Hereditary hemorrhagic telangiectasia - Disease of capillaries, unspecified</td>
</tr>
<tr>
<td>I80.11 - I80.13</td>
<td>Phlebitis and thrombophlebitis of right femoral vein - Phlebitis and thrombophlebitis of femoral vein, bilateral</td>
</tr>
<tr>
<td>I80.221 - I80.223</td>
<td>Phlebitis and thrombophlebitis of right popliteal vein - Phlebitis and thrombophlebitis of popliteal vein, bilateral</td>
</tr>
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<td>Phlebitis and thrombophlebitis of other deep vessels of right lower extremity - Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral</td>
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</tr>
<tr>
<td>I83.001 - I83.813</td>
<td>Varicose veins of unspecified lower extremity with ulcer of thigh - Varicose veins of bilateral lower extremities with pain</td>
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<tr>
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<td>Varicose veins of right lower extremity with other complications - Varicose veins of bilateral lower extremities with other complications</td>
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<tr>
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<td>Venous insufficiency (chronic) (peripheral)</td>
</tr>
<tr>
<td>R60.0</td>
<td>Localized edema</td>
</tr>
</tbody>
</table>

ICD-10 Additional Information

General Information

Associated Information
Documentation Requirements

The following must be documented in the patient’s medical record and made available to Medicare upon request:
The initial work up plan/plan of care is based on the treating physician’s assessment and includes the date(s) of exam and diagnostic evaluation. The minimum evaluation that must be documented includes history, physical exam, basic CEAP classification, VCSS score, and venous duplex scan; Once the initial work up plan is completed, the plan of care should outline interventions for 90 days; Thermal ablation of the same leg on different days (utilizing two base codes on separate days vs. a base code with an add-on code) for C2 staging and standard axial treatment of GSV and/or SSV would not be allowed unless the procedure note clearly documents why the procedure had to be split; Failure of at least a 90 day course of compression therapy as described in the Indications section of the LCD must be documented for C2 patients with VCSS <6; Exclusion of other causes of leg pain, ulceration, and edema; Performance of duplex scanning used to confirm the presence, location, and size of incompetent veins; Imaging including 2D and spectral analysis comprising the venous duplex scan; All other requirements of medical necessity outlined in the Coverage Guidance section, under the heading "Coverage Indications, Limitations and/or Medical Necessity" of this LCD.

Utilization Guidelines

Claims data analysis demonstrating persistent outlier code utilization (frequent use of the base code for thermal ablation [CPT code 36475 for RFA or 36478 for EVLA]) in a single episode of care may be subject to prepayment review.

Providers are required to code to specificity. If there is not a specific code, use the unlisted code.

Sources of Information

First Coast Service Options, Inc. reference LCD number(s) – L29031, L29298, L29403


Lane, T., Bootun, R., Dharmarajah, B., (2016). A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins – Final results of the Venefit versus Clarivein for varicose veins trial, *Phlebology, 0*(0), 1-10.


Novitas Solutions, Inc. Local Coverage Determination (LCD): Treatment of varicose veins in lower extremities. (L32678)


Bibliography

N/A

Revision History Information

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tr>
<td>04/17/2018</td>
<td>R11</td>
<td>05/22/2018: The link from the following article in the Sources of Information section of the LCD has been removed due to a technical error: Caggiati, A, Bergan, JJ, Gloviczki, P, et al. (2002). Nomenclature of the veins of the lower limbs: An international interdisciplinary consensus statement. Journal of Vascular Surgery, 36, 416-22.</td>
<td>• Typographical Error</td>
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<tr>
<td>04/17/2018</td>
<td>R9</td>
<td>Revision Number: 4&lt;br&gt;Publication: May 2018 Connection&lt;br&gt;LCR A/B2018-039&lt;br&gt;Explanation of Revision: Based on an annual review of this LCD, the “Coverage Indications, Limitations, and/or Medical Necessity” section of the LCD was revised under “Sclerotherapy” to provide clarification. Also, the “CPT/HCPCS Codes” section of the LCD under “Group 1 Paragraph” was revised to provide clarification for CPT codes 36470, 36471, 36482, and 36483. In addition, the “Sources of Information” section of the LCD was updated to include multiple published sources from reconsideration requests for CPT codes 36473 and 36474 (endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical). The content of the LCD has not been changed in response to the reconsideration requests. The effective date of this revision is based on date of service. 04/17/2018: 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.</td>
<td>• Other (Revisions based on annual review completed on 03/28/2018.)</td>
</tr>
<tr>
<td>Revision History Date</td>
<td>Revision History Number</td>
<td>Revision History Explanation</td>
<td>Reason(s) for Change</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------</td>
<td>-----------------------------</td>
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</tr>
<tr>
<td>01/01/2018</td>
<td>R8</td>
<td>Revision Number: 3 Publication: December 2017 Connection LCR A/B2018-001 Explanation of Revision: Annual 2018 HCPCS update. CPT codes 36465 and 36466 were added to the “CPT/HCPCS Codes - Group 2 Codes” section of this LCD, which are not medically reasonable and necessary. Also, CPT codes 36482 and 36483 were added to the “CPT/HCPCS Codes - Group 1 Codes” section of the LCD. In addition, descriptors were revised for CPT codes 36470 and 36471. The effective date of this revision is based on date of service. 01/01/2018: 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.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td>01/01/2017</td>
<td>R7</td>
<td>Revision Number: 2 Publication: September 2017 Connection LCR A/B2017-038 Explanation of Revision: Based on CR 10153 (Annual 2018 ICD-10-CM Update) the LCD was revised. Descriptor revised for ICD-10-CM diagnosis code I83.891. The effective date of this revision is based on date of service. 10/01/2017: 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.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td>01/01/2017</td>
<td>R6</td>
<td>Revision Number: 1 Publication: December 2016 Connection LCR A/B2017-001 Explanation of Revision: Annual 2017 HCPCS Update. CPT/HCPCS codes 36473 and 36474 were added in the “Limitations” section of this LCD to describe mechanochemical ablation, which is not medically reasonable and necessary. The “CPT/HCPCS Codes” section of the this LCD was revised to add a “Group 2 Paragraph” and “Group 2 Codes” section for the following codes that are considered not reasonable and necessary for coverage: 36473 and 36474. Additionally, this LCD was revised to reflect descriptor changes for the following CPT codes: 36476 and 36479. The effective date of this revision is based on date of service.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R5</td>
<td>03/31/2016 - Documentation Requirement section, 4th bullet corrected (90 course), corrected to: 90 day course.</td>
<td>• Other</td>
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<tr>
<td>10/01/2015</td>
<td>R4</td>
<td>8/11/2015 - - The language and/or ICD-10-CM</td>
<td>• Provider</td>
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<td>Revision History Number</td>
<td>Revision History Explanation</td>
<td>Reason(s) for Change</td>
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<tr>
<td>10/01/2015</td>
<td>R3</td>
<td>diagnoses were updated to be consistent with the current ICD-9-CM LCD’s language and coding.</td>
<td>Education/Guidance</td>
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<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>Additional contract numbers designated/associated</td>
<td>Other</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>LCD transitioned to JN contractor number.</td>
<td></td>
</tr>
</tbody>
</table>

**Associated Documents**

**Attachments**
N/A

**Related Local Coverage Documents**
Article(s)
A55884 - Response to Comments: Treatment of varicose veins of the lower extremity, L33762

**Related National Coverage Documents**
N/A

**Keywords**
N/A