



Medicare Part C Medical Coverage Policy

Varicose Vein Treatment

Origination Date: June 1, 1993
Review Date: February 21, 2018
Next Review: February, 2020

DESCRIPTION OF PROCEDURE OR SERVICE

Varicose veins of the lower extremities occur in sixty percent of the adult population. Conservative measures often yield satisfactory results in treatment of varicose veins. Treatments for varicose veins include:

1. **Varicose vein excision and ligation** involves tying off the affected vein and removing the varicosity. Removal of symptomatic, malfunctioning, superficial veins restores the venous circulation to a more normal state and provides relief of symptoms of venous hypertension.
2. **Sclerosing injections, or sclerotherapy of varicose veins is performed generally for signs and symptoms of diseased vessels, as an adjunct to surgical therapy or for cosmetics.** Sclerotherapy treatment destroys the lining of the affected vein by injecting an irritant solution (either a detergent, osmotic solution, or a chemical irritant), ultimately resulting in the complete obliteration of the vessel. Too little destruction leads to thrombosis without fibrosis and ultimate recanalization. Too much destruction leads to vascular dehiscence. The success of the treatment depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosing solution, and post procedure compression. Sclerotherapy may be performed in conjunction with vein stripping or ligation (either simultaneously or delayed).
3. **Endovenous Radiofrequency Ablation (ERFA)** has been developed as an alternative to vein ligation and stripping. The procedure is designed to damage the intimal wall of the vein, resulting in fibrosis and subsequent obliteration of the lumen of a segment of the vessel thus eliminating reflux. The procedure is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within 1-2 cm of the sapheno-femoral junction. High frequency radiowaves (200-300 kHz) are delivered through the catheter electrode and cause direct heating of the vessel wall, causing the vein to collapse. The catheter is slowly withdrawn, closing the vein.

POLICY STATEMENT

Coverage will be provided for varicose vein treatment when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations, if the criteria are met. Coverage decisions for members will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; **and**
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

- 1) Preauthorization by the Plan is required;
- 2) The interventional treatment of varicose veins (only with techniques outlined in this policy and only under the conditions described below) may be medically necessary if the member remains symptomatic after a 6-8 week trial of conservative therapy. Components of conservative therapy include, but are not limited to:
 - A. Weight reduction **OR**
 - B. A daily exercise plan **OR**
 - C. Periodic leg elevation, **AND**
 - D. The use of graduated compression stockings

****Note: In the presence of advanced skin changes, ulceration or bleeding, the need for a conservative therapy period may be waived. In cases where such complications are present, the medical record must include detailed documentation of the nature and extent of the complications. In these scenarios, the medical record or documentation that supports the consideration to waive conservative therapy must be sent to the Medical Director for review.**

- E. The member is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record:
 - 1) Stasis ulcer of the lower leg
 - 2) Significant pain and/or significant edema that interferes with activities of daily living
 - 3) bleeding associated with the diseased vessels of the lower extremities
 - 4) recurrent episodes of superficial phlebitis
 - 5) stasis dermatitis, or
 - 6) Refractory dependent edema

****Note: The conservative therapy must be documented in the medical record. Conservative treatment may slow down progression of disease or may**

demonstrate (if symptoms reduced) that treating the disease may eliminate the symptoms.

- 3) Duplex studies of the venous system are performed that fully defines the anatomy, size, and tortuosity of the great and small saphenous vein, superficial venous segments and perforators. Studies must demonstrate the following criteria:
 - a. Absence of deep venous thrombosis **and**
 - b. Saphenous (small or great) valvular incompetence/reflux that correlates with the patient's symptoms and is CEAP Class C2 or greater.
- 4) Indications for Endovenous Radiofrequency Ablation (ERFA) or laser ablation (CPT codes 36475, 36476, 36478, 36479) include:
 - a. Patient's anatomy amenable to laser or radiofrequency catheter.
 - b. Non-aneurismal saphenous vein(s).
 - c. Absence of thrombosis or vein tortuosity, that would impair catheter advancement.
 - d. Laser ablation of veins with a vein diameter less than or equal to 20 mm, or
 - e. Absence of significant peripheral artery disease.
- 5) In addition, the following conditions apply to specific individual procedures:
 - A. Injection/Compression Sclerotherapy
 1. No saphenofemoral insufficiency, incompetence, or occlusion of the deep venous system, and
 2. Vessel diameter should be at least 3-5 millimeters in size. It is NOT considered an appropriate option for large, extensive or truncal varicosities of 5 millimeters or greater in diameter, and
 3. Foam sclerotherapy of the saphenous vein at its junction with the deep venous system has been proposed as an alternative to ligation or saphenectomy, but its efficacy lacks significant scientific evidence to support its widespread use.
 - B. Microfoam Sclerotherapy
 1. Use up to 5 ml per injection and no more than 15 ml per session
 2. Treatment sessions should be separated by a minimum of 5 days.
 3. Not for use in patients with known allergy to polidocanol, acute thromboembolic disease or in patients who are pregnant
 4. Physicians administering Varithena® must be experienced with venous procedures, possess a detailed working knowledge of the use of duplex ultrasound in venous disease, and be trained in the administration of Varithena®.
 - C. Surgical Ligation or Stripping
 1. May be covered as part of a combination procedure with sclerotherapy.
 2. Number of veins and their locations should be documented.

- D. Ambulatory or Stab Phlebectomy
 - 1. Use of 2mm stab incisions to remove vein via crochet type hook.
 - 2. May be covered only when the patient displays symptoms and functional problems attributable only to the secondary, smaller vessels.
 - E. Subfascial Endoscopic Perforator Surgery (SEPS)
 - 1. Must have symptoms of perforator incompetence.
 - 2. The superficial saphenous veins have been previously eliminated; AND
 - 3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND
 - 4. The venous insufficiency is not secondary to deep venous thromboembolism
- 6) The treatment of spider veins/telangiectasis (36468) will be considered medically necessary only if there is persistent and significant bleeding.
- 7) Stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary services are met and documentation in the chart supports the medical necessity.

WHEN COVERAGE WILL NOT BE APPROVED

- A. When the above coverage criteria have not been met.
- B. Noncompressive sclerotherapy is not covered by Medicare.
- C. Any type of treatment (sclerotherapy, ligation with or without stripping, ERFA, or laser system ablation) of varicose veins for cosmetic reasons is not medically necessary and not covered.
- D. The treatment of asymptomatic veins with endovenous ablation or sclerotherapy is not considered medically reasonable and necessary.
- E. The treatment of spider veins or superficial telangiectasis by any technique is considered cosmetic, and therefore not covered, except as described in item #6 under Indications For Coverage above..
- F. Laser treatment of superficial varicosities or spider veins is considered cosmetic and is not covered.
- G. Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not covered by Medicare.
- H. Ultrasound-monitored or duplex-guided techniques for sclerotherapy will not be covered when used in conjunction with injection sclerotherapy techniques.
- I. Reinjection following recanalization or failure of a vein closure without recurrent signs or symptoms;
- J. Any interventional treatment that uses equipment not approved for such purposes by the FDA.

LIMITATIONS

The Plan will cover these procedures only when performed with FDA approved devices and when these approved devices are used only for their specific FDA approved indications.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: 36465, 36466, 36468, 36470, 36471, 36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37500, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785, 93965, 93970, 93971

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

Doppler ultrasound is often used to map the anatomy of the venous system prior to the procedure and also during the procedure to guide treatment and monitor effectiveness of therapy. Coverage will include one ultrasound prior to the procedure and intraoperative ultrasonic guidance when medically necessary to improve outcomes and minimize complications.

A duplex ultrasound is also covered when performed within 1 week of EFRA to check for any evidence of thrombus extension from the saphenofemoral junction into the deep system.

Photographs may be requested by the medical director if the clinical received is inconclusive.

CEAP is method used to layer patients according to the severity of their venous disease. CEAP stands for **Clinical Etiologic Anatomic Pathophysiologic**. Based on these categories there are now 6 classifications that will allow treatment to be rendered appropriately based on the progression of the venous disease.

References:

1. Medicare Local Coverage Determination LCD L33454: Varicose Veins of the Lower Extremities. Effective Date 10/1/2015. Revision Effective Date 1/1/17. Accessed via internet site www.cms.gov: Viewed on 2/15/17.
2. Medicare Local Coverage Determination: Treatment of Varicose Veins of the Lower Extremities (L34536 Wisconsin Part A); Effective date: 10/1/2015. Accessed Via Internet site www.cms.gov; Viewed on 2/15/17.
3. Capitol Vein and Laser Centers Accessed Via Internet site <http://www.mycvl.com/physician-resources/ceap/> and viewed on 7/11/16.

Policy Implementation/Update Information:

Revision Date: June 26, 2000; August 20, 2003; June 9, 2004; June 28, 2006

Revision Date: August 2012-Criteria updated to reflect CMS LCDs.

Revision Date: October 16, 2013; Clarified criteria for staff (Criteria 2); Updated codes and references.

Revision Date: Annual Review; revised item #6 added item #7 to Indications For Coverage, added item A and revised item D to When Coverage Will Not Be Approved per LCD, updated code section.

Revision Date: July 20, 2016: CMS Update notification of LCD L33454. Description of Procedure or Service Section: #3 Endoluminal Changed to Endovenous. Indications for Coverage Section: #3.b "Greater saphenous vein" changed to "Saphenous (small or great)" and added "and is CEAP Class C2 or greater." #4 "Endoluminal" changed to "Endovenous"#7 Spelling correction of "phlebectomy"Special Notes: Added definition of CEAP Classification Method.

Revision Date: February 15, 2017: CMS Update LCD L33454. Indications for Coverage Section updated to mirror updates to LCD. (#2, #4, #5, and #7). When Coverage will Not be Approved also updated to mirror LCD.

Revision Date: February 21, 2018; Added OR to Subpoints A. and B. for #2 under Indications for Coverage.

Approval Dates:

Medical Coverage Policy Committee: February 21, 2018

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator