



Medicare Part C Medical Coverage Policy

Varicose Vein Treatment

Origination Date: June 1, 1993

Review Date: April 17, 2019

Next Review: April, 2021

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. Endovenous radiofrequency ablation is Food and Drug Administration (FDA)-approved for treatment of the great saphenous vein, perforators and tributary veins. Endovenous laser ablation is FDA-approved for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein. Radiofrequency/laser ablation is covered for treatment of the small saphenous or great saphenous veins and selected tributaries to improve symptoms attributable to saphenous vein reflux. Treatment of perforator and tributary veins with Radiofrequency/laser ablation may be reasonable and necessary when there is documented reflux after the saphenous system has been treated.

- 4. Mechanochemical Endovenous ablation (MOCA)** may be considered medically necessary for treatment of patients who meet the medical necessity criteria listed for varicose vein treatment. Mechanochemical endovenous ablation (MOCA) is FDA-approved and uses a rotating wire in conjunction with an infused sclerosing agent to damage the wall of the vein. The most common site of treatment is the greater saphenous vein. The procedure includes any imaging guidance and monitoring. Tumescence anesthesia is not required.

CEAP is method used to classify 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.

The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. The following is the Clinical portion of the CEAP:

- C0 No visible or palpable signs of venous disease
- C1 Telangiectasies or reticular veins
- C2 Varicose veins
- C3 Edema
- C4a Pigmentation and eczema
- C4b Lipodermatosclerosis and atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer
- S Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
- A Asymptomatic

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 determinations;
- 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) **Conservative Therapy**
Components of conservative therapy must be documented in the medical record and should include, but are not limited to:
 - A. Oral venoactive drugs (including but not limited to horse chestnut seed extract and micronized purified flavonoid fraction); some of which are not covered by Medicare **OR**
 - B. Weight reduction **OR**
 - C. A daily exercise plan **OR**
 - D. Periodic leg elevation, **AND**
 - E. The use of graduated compression stockings
- 3) **Saphenous Veins (Greater, Small or Accessory)**
Endovenous thermal ablation (laser and radiofrequency), mechanical/chemical (MOCA) ablation of the saphenous veins (only with techniques outlined below and only under the conditions described wherein) will be considered reasonable and necessary when any of the following signs or symptoms **AND CEAP class C2 of saphenous vein** (greater, small or accessory) reflux (>500 msec) are documented in the medical record:
 - A. Ulceration secondary to venous stasis **OR**
 - B. Significant pain and/or significant edema associated with saphenous reflux that interferes with activities of daily living **OR**
 - C. bleeding associated with the ruptured superficial varicosity **OR**
 - D. recurrent episodes of superficial phlebitis **OR**
 - E. stasis dermatitis, **OR**
 - F. Refractory dependent edema
- 4) **Perforator Veins**
Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met:
 - 1) There is demonstrated perforator reflux; **AND**
 - 2) The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries) 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 disease is not secondary to acute deep venous thromboembolism.

- 5) Duplex studies of the venous system are performed that fully define the anatomy, size, and tortuosity of the great and small saphenous vein, superficial venous segments and perforators.
- 6) In addition, the following conditions apply to specific individual procedures:
- A. Injection/Compression Sclerotherapy
 1. Vessel diameter should be at least 3-6 millimeters in size.
 - B. Ambulatory or Stab Phlebectomy
 1. May be covered only when the patient displays symptoms and functional problems attributable only to the secondary, smaller vessels.
Note: 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.
 - C. Subfascial Endoscopic Perforator Surgery (SEPS) (CPT 37500)
 1. Must have symptoms of perforator incompetence **AND**
 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
- 7) The treatment of spider veins/telangiectasis (36468) will be considered medically necessary only if there is persistent and significant bleeding.

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 #5 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. Reinjection following recanalization or failure of a vein closure without recurrent signs or symptoms;
- I. Any interventional treatment that uses equipment not approved for such purposes by the FDA.
- J. Pregnancy
- K. If member has a diagnosis of Klippel-Trenaunay Syndrome or other congenital venous abnormalities
- L. If member has an advanced generalized systemic disease that limits quality-of-life improvements expected following venous intervention

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 one (1) week of EFRA (preferably within 72 hours) 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.

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 4/17/19.
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 4/17/19.
3. Capitol Vein and Laser Centers Accessed Via Internet site <http://www.mycvl.com/physician-resources/ceap/> and viewed on 4/17/19.
4. BCBSNC Medical Coverage Policy: Varicose Veins of the Lower Extremities, Treatment for; 11/2017; Medical and Scientific Evidence; viewed online at <http://www.bcbsnc.com/content/services/medical-policy/index.htm>; viewed on 4/17/19.

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.

Revision Date: November 20, 2018; **Indications for Coverage:** Moved Note about Conservative therapy under #2. Moved #4 under what was #5 and made it #4. Added CPT code for SEPS to #4 Subpoint F. Moved Stab Phlebectomy Note to #4 subpoint E.

Definition section of policy, Added "Mechanochemical Ablation utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3,500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without the need for the tumescent anesthesia used in radiofrequency (RF) ablation or endovenous laser ablation (EVLT)." Added to **Special Notes:** "The standard of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system The following is the Clinical portion of the CEAP: C0 No visible or palpable signs of venous disease C1 Telangiectasies or reticular veins C2 Varicose veins C3 Edema C4a Pigmentation and eczema C4b Lipodermatosclerosis and atrophie blanche C5 Healed venous ulcer C6 Active venous ulcer S Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction A Asymptomatic"; Changed "layer" to "classify", and Updated **References** by adding #4.

Revision Date: April 17, 2019: CMS Update to LCD. Removed multiple criteria within the LCD to make compliant with future effective LCD. Reorganized to mirror LCD subheadings. Description Section: Edited Definitions to match new LCD definitions. Moved CEAP Classification to the top for determination of symptoms. Indications for Coverage: Removed "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." Added: 2) New Subheading "Conservative Therapy" "Components of conservative therapy must be documented in the medical record and should include, but are not limited to: A. Oral venoactive drugs (including but not limited to horse chestnut seed extract and micronized purified flavonoid fraction); some of which are not covered by Medicare" Removed**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.**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. Removed: "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: Stasis ulcer of the lower leg Significant pain and/or significant edema that interferes with activities of daily living bleeding associated with the diseased vessels of the lower extremities recurrent episodes of superficial phlebitis stasis dermatitis, or Refractory dependent edema" Reformatted as: "1) Saphenous Veins (Greater, Small or Accessory) Endovenous thermal ablation (laser and radiofrequency), mechanical/chemical (MOCA) ablation of the saphenous veins (only with techniques outlined below and only under the conditions described wherein) will be considered reasonable and necessary when any of the following signs or symptoms AND CEAP class C2 of saphenous vein (greater, small or accessory) reflux (>500 msec) are documented in the medical record: Ulceration secondary to venous stasis OR Significant pain and/or significant edema associated with saphenous reflux that interferes with activities of daily living OR bleeding associated with the ruptured superficial varicosity OR recurrent episodes of superficial phlebitis OR stasis dermatitis, OR Refractory dependent edema. Added New Subheading to mirror LCD: "Perforator Veins Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met: There is demonstrated perforator reflux; AND The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries)

have been previously eliminated; AND Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND The venous disease is not secondary to acute deep venous thromboembolism.”

Approval Dates:

Medical Coverage Policy Committee: April 17, 2019

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