



## Medicare Part C Medical Coverage Policy

### Varicose Vein Treatment

**Origination Date:** June 1, 1993  
**Review Date:** September 21, 2023  
**Next Review:** September 2024

***\*\*\*This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. \*\*\****

#### **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. Surgical: Ligation, Stripping, Phlebectomy:** Saphenous vein ligation and division is the detachment of the saphenous vein (GSV, SSV, AGSV) through an incision at the groin at its confluence with the saphenofemoral junction and common femoral vein. It is the traditional treatment and is called high ligation and saphenous vein stripping. The primary goal is removal of the refluxing veins at the saphenofemoral junction. Phlebectomy, also known as stab phlebectomy, ambulatory phlebectomy, or microphlebectomy, involves the removal of secondary smaller veins as the removal of the varicose veins are through a small 1-2 mm incision in the skin overlying the vein.
- 2. Sclerotherapy** is a minimally invasive percutaneous technique using chemical irritants, that is, liquid and foam sclerotherapy techniques, to close unwanted veins. Sclerotherapy for treatment of varicose veins or reflux is followed by compression therapy of the affected lower limb using either elastic or conventional bandaging.
  - a) **Liquid Sclerosant:** Liquid sclerotherapy can be used to treat telangiectasias, reticular veins, small varicose veins (3-6 mm), residual or recurrent veins following endovenous ablation or surgery, and perforator veins.<sup>4</sup> Some examples of sclerotherapy agents are polidocanol, hypertonic saline, sodium tetradecyl sulfate, and glycerin.
  - b) **Foam Sclerosant: Ultrasound-Guided Foam Sclerotherapy (UGFS):** Foam sclerotherapy is a procedure that is performed under ultrasound guidance and is a nonthermal therapy. The different types of foam are physician-compounded foam (PCF) and non-compounded foam (NCF). Foam preparations are used for treatment of symptomatic varicose

veins  $\geq 3$  mm. The heavier foam is needed to displace the increased volume of blood in these larger veins, which increases the contact time of the sclerosant with the vein wall, enhancing the sclerosant effect. Ultrasound-Guided Foam Sclerotherapy (UGFS) is used for the treatment of reflux of the superficial axial veins (great saphenous vein (GSV), small saphenous vein (SSV), accessory saphenous vein (ASV)), reflux of perforator veins, and venous malformations. It is recognized that foam sclerotherapy is not FDA-approved. However, UGFS has been in use in the United States for more than 20 years and is a standard of care for many venous disorders with an excellent safety profile.

### 3. Thermal Abrasion:

- a) **Radiofrequency Ablation (RFA), Endovenous Radiofrequency Ablation (ERFA);** Radiofrequency ablation (RFA) is a minimally invasive percutaneous technique using radiofrequency energy and ultrasound guidance to puncture the vein and position a catheter to ablate incompetent veins. The device is used primarily to treat insufficiency of the axial veins (i.e. great, small, anterior accessory great saphenous veins), but perforator veins can also be treated with a specialized radiofrequency stylet. The indications for RFA are the same as for other venous ablation techniques.<sup>6</sup> Members with persistent symptoms and signs of superficial venous disease and documented axial venous reflux (i.e. retrograde flow  $>500$  ms for superficial or perforator veins) are candidates for treatment. The procedure may be performed in an outpatient setting.
  - b) **Endovenous Laser Ablation (EVLA), Endovenous Laser Ablation Therapy (EVLt);** is a percutaneous technique that uses laser energy to ablate incompetent superficial veins. The axial veins are the primary target for this therapy and include the GSV, SSV, and AAGSVs. A relative contraindication to thermal ablation (EVLA and RFA) is severe tortuosity of a vein segment in which passage of the device may not be possible. Minimally invasive therapies, including RFA and EVLA, provide similar or improved clinical outcomes compared with GSV ligation and stripping.
4. **Chemical Adhesive (Cyanoacrylate embolization):** This nonthermal ablation technique uses a glue delivered into the saphenous vein using a catheter for access that induces a foreign body reaction leading to inflammation and fibrotic occlusion of the vessel. It is used for the treatment of incompetent saphenous veins (GSV, SSV, AAGSV).
5. **Mechanochemical Endovenous ablation (MOCA)** This nonthermal technique uses both mechanical damage to the vein endothelium with a rotating wire and simultaneous chemical injury with installation of a liquid sclerosant to lead to

scarring and fibrosis. The most common site of treatment is the GSV. It is used for the treatment of incompetent saphenous veins (GSV, SSV, AAGSV).

6. **CEAP** is a method used to classify patients according to the severity of their venous disease. CEAP stands for **C**linical **E**tiologic **A**natomic **P**athophysiologic. 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
- C2r Recurrent varicose veins
- C3 Edema
- C4 Changes in skin and subcutaneous tissue secondary to chronic venous disease
- C4a Pigmentation and eczema
- C4b Lipodermatosclerosis and atrophie blanche
- C5 Healed venous ulcer
- C6 Active venous ulcer
- C6r Recurrent 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 Management (Noninvasive procedures) :**
  - A. The member has components of conservative therapy discussed and individualized to meet their needs and are documented in the medical record. Discussion should include but is not limited to:
    1. Weight reduction **OR**
    2. Exercise plan and prescribed physical activity (walking, treadmill, cycling) **OR**
    3. Periodic leg elevation **OR**
    4. Compressive therapy with the use of surgical grade compression stockings (minimum 20-30 mmHg)
  - B. When members meet any one of the following criteria, conservative therapy may be waved:
    1. C4-C6 disease (skin changes assigned to venous disease, healed venous leg ulceration, and active venous leg ulceration)
    2. Hemorrhage
    3. Recurrent superficial thrombophlebitis
3. **Non-Invasive Venous Studies:** Pre-operative venous studies are considered reasonable and necessary prior to varicose vein treatment when initially performed by an accredited vascular technician. The study will fully define the anatomy, size, and tortuosity of the great and lesser saphenous vein, superficial venous segments, and perforators and will determine the extent of venous valvular incompetence. A pre-procedure duplex scan used in conjunction with other non-invasive physiologic testing to determine the extent and configuration of the varicosities will also be covered. It is expected that these studies will be performed by the physician planning to provide the therapy or by a registered vascular technologist (RVT). Intraoperative ultrasonic guidance will also be covered in situations when it is deemed medically necessary. A post procedural study is allowed to be performed within a 6-month period.
4. **Invasive Treatment** of varicose veins (only with the techniques outlined in this policy and under the conditions described) will be considered reasonable and necessary when documentation in the medical record includes a history, physical examination, CEAP clinical classification, and a venous duplex scan documenting reflux (>500 msec), Treatment is covered for each of the following procedures:

- A. **Liquid sclerotherapy** will be considered reasonable and necessary to treat telangiectasias, reticular veins, small varicose veins (3-6 mm), residual or recurrent veins following endovenous ablation or surgery, and perforator veins. Treatment of telangiectasias and reticular veins (C1) (<3 mm) is considered reasonable and necessary with documentation of spontaneous and/or traumatic venous hemorrhage, **OR** for dilated intradermal veins in the elderly judged to be a substantial risk for hemorrhage with minimal trauma, **OR** near an active or healed ulcer if judged to contribute to local venous hypertension.
- B. **Saphenous Veins (GSV, SSV, AAGSV) management, with UGFS, endovenous thermal ablation (radiofrequency or laser), chemical adhesive (cyanoacrylate embolization), MOCA, and surgery (surgical ligation and stripping)** is considered reasonable and necessary with documentation in the medical record of CEAP class C2-C6 disease, reflux (>500 msec), and **ANY** of the following signs or symptoms:
- ulceration secondary to venous stasis;
  - significant pain or significant edema associated with saphenous reflux that interferes with activities of daily living (ADLs);
  - bleeding associated with ruptured superficial varicosity;
  - recurrent episodes of superficial phlebitis;
  - stasis dermatitis;
  - refractory dependent edema
- C. **Incompetent perforator veins (IPVs)** are the most common cause of recurrent varicose veins after treatment. Minimally invasive treatments have replaced traditional surgical treatments for IPVs. UGFS and endovenous thermal ablation with either radiofrequency or laser energy sources will be considered reasonable and necessary with the following conditions:
- Demonstrated perforator reflux >500 msec; **AND**
  - No saphenous reflux (greater, small, or accessory) and/or symptomatic varicose tributaries; **AND**
  - An active venous ulcer; **AND**
  - The IPV is at least 3.5 mm in diameter; **AND**
  - The perforator is in the vicinity of the ulcer.

#### **WHEN COVERAGE WILL NOT BE APPROVED**

- When the above coverage criteria have not been met.
- CEAP clinical classification C0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable and necessary
- CEAP clinical classification C1 (telangiectasias or reticular veins) is considered cosmetic and not reasonable and necessary with the exception of documentation of spontaneous and or traumatic venous hemorrhage;
- Severe distal arterial occlusive disease
- Acute DVT or superficial vein thrombosis

- F. Allergy to the sclerosant
- G. Pregnancy
- H. Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
- I. 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, 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.

### **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](http://www.cms.gov); Retired on 03/10/2020..
2. Medicare Local Coverage Determination LCD L39121 Treatment of Varicose Veins of the Lower Extremities; Effective 4/3/2022. Accessed via internet site [www.cms.gov](http://www.cms.gov). Viewed on 08/17/2023.
3. Medicare Local Coverage Article A58876 Billing and Coding: Treatment of Varicose Veins of the Lower Extremities. Effective date: 04/03/2022. Accessed via [www.cms.gov](http://www.cms.gov) on 08/17/2023.
4. 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.go](http://www.cms.go); Viewed on 08/17/2023.

5. Medicare Local Coverage Article A56914 Billing and Coding: Treatment of Varicose Veins of the Lower Extremities. Effective date:08/29/2019. Accessed via [www.cms.gov](http://www.cms.gov) on 08/17/2023.
6. Capitol Vein and Laser Centers Accessed Via Internet site <http://www.mycvl.com/physician-resources/ceap/>. Old reference.
7. BCBSNC Corporate Medical Coverage Policy: Varicose Veins of the Lower Extremities, Treatment for; 11/2017; Medical and Scientific Evidence; viewed online at [https://www.bluecrossnc.com/content/dam/bcbnsnc/pdf/providers/policies-guidelines-codes/policies/commercial/surgery/varicose\\_veins\\_of\\_the\\_lower\\_extremities\\_treatment\\_for.pdf](https://www.bluecrossnc.com/content/dam/bcbnsnc/pdf/providers/policies-guidelines-codes/policies/commercial/surgery/varicose_veins_of_the_lower_extremities_treatment_for.pdf); viewed on 08/17/2023.

### 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 (EVLV)." 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."

Revision Date: 8/21/19: Updated When Coverage Will not be approved: E. From #5 to #7.

Revision Date: 2/12/2020: Staff Clarification; Update to verbiage of Indications for Coverage 6. A. to read "Injection/Compression Sclerotherapy 1.For local small to medium symptomatic varices measuring 3-6 mm in size" for consistency with LCD.

Revision Date: 10/21/2020: Annual Review; CMS Update; LCD L33454 now retired. Restructured entire policy to now match format and content in LCD L34536.

Revision date: 5/18/2022: CMS Update; NEW LCD L39121. Entire Policy Revised to align with new format of new Palmetto LCD L39121.

Revision Date: September 21, 2023: Annual Review; No CMS Update. Verbiage added to reflect LCD. Additional references added.

**Approval Dates:**

Medical Coverage Policy Committee:

September 21, 2023

Policy Owner: Beth Sell BSN, RN, CCM, CPC-A  
Medical Policy Coordinator