Treatment of Varicose Veins/Venous Insufficiency

Policy # 00034
Original Effective Date: 08/26/2002
Current Effective Date: 02/01/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

SAPHENOUS VEINS

Great or Small Saphenous Veins

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider treatment of the great or small saphenous veins by surgery (ligation and stripping), endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy or cyanoacrylate adhesive for symptomatic varicose veins/venous insufficiency to be **eligible for coverage**** when the following criteria have been met:

Patient Selection Criteria
Coverage eligibility will be met when all of the following criteria are met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater; AND
- There is documentation of one or more of the following indications:
    - Ulceration secondary to venous stasis; or
    - Recurrent superficial thrombophlebitis; or

- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; or
- Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, and conservative management including compression therapy for at least three months has not improved the symptoms.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of treatment for great or small saphenous veins by surgery, endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive that does not meet the criteria described above to be **not medically necessary**.**

Accessory Saphenous Veins

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider treatment of accessory saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive for symptomatic varicose veins/venous insufficiency to be **eligible for coverage**** when the following criteria have been met:

Patient Selection Criteria

Coverage eligibility will be met when all of the following criteria are met:

- Incompetence of the accessory saphenous vein is isolated, OR the great or small saphenous veins had been previously eliminated (at least 3 months)~~:~~ AND
- There is demonstrated accessory saphenous reflux; AND
- There is documentation of one or more of the following indications:
  - Ulceration secondary to venous stasis; or

- Recurrent superficial thrombophlebitis; or
- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; or
- Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least three months has not improved the symptoms.

Concurrent treatment of the accessory saphenous veins along with the great or small saphenous veins may be considered **eligible for coverage**** when above criteria is met for each vein and there is documentation of anatomy showing that the accessory saphenous vein discharged directly into the common femoral vein.

When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers treatment of accessory saphenous veins by surgery or endovenous radiofrequency or laser ablation, microfoam sclerotherapy, or cyanoacrylate adhesive that does not meet the criteria described above is **not medically necessary.****

Symptomatic Varicose Tributaries

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the following treatments to be **eligible for coverage**** as a component of the treatment of symptomatic *varicose tributaries* when performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins (none of these techniques has been shown to be superior to another) when vein size is 2.5 mm or greater in diameter measured by recent ultrasound:

- Stab avulsion
- Hook phlebectomy

- Sclerotherapy
- Transilluminated powered phlebectomy

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers treatment of symptomatic *varicose tributaries* when performed either at the same time or following prior treatment of saphenous veins using any other techniques than noted above to be **investigational.***

Perforator Veins

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation, or ultrasound-guided microfoam sclerotherapy of incompetent perforator veins as a treatment of leg ulcers associated with chronic venous insufficiency may be considered to be **eligible for coverage**** 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 three months; AND
- The venous insufficiency is not secondary to deep venous thromboembolism.

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When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is considered to be **not medically necessary.****

Telangiectasia

Based on review on available data, the Company considers treatment of telangiectasia such as spider veins, angiomata, and hemangiomata cosmetic and is **not a covered benefit.**

Other Veins

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers techniques for conditions not specifically listed above and when coverage criteria are not met to be **investigational*** including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy, of greater, small, or accessory saphenous veins
- Sclerotherapy of perforator veins when criteria are not met
- Sclerotherapy or phlebectomy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins
- Endovenous radiofrequency or laser ablation of tributary veins
- Endovenous cryoablation of any vein
- Mechanochemical ablation of any vein (e.g. MOCA, ClariVein™ Catheter)‡

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When Services Are Not Covered

Based on review of available data, the Company considers sclerotherapy and phlebectomies for treatment of tributary veins < 2.5 mm in diameter to be **not covered**.

Note:
Although sclerotherapy and phlebectomy can be used to treat visible veins less than 2.5 mm in size, these small veins do not cause symptoms and their treatment is considered cosmetic and therefore excluded from coverage.

Policy Guidelines

Endovenous ablation is contraindicated in patients with acute deep vein thrombosis due to the risk of developing new thrombosis. Deep venous system includes popliteal and femoral veins.
The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. Table PG1 provides is the Clinical portion of the CEAP.

Table PG1. Clinical Portion of the CEAP Classification System

Class	Definition
C_0	No visible or palpable signs of venous disease
C_1	Telangiectasies or reticular veins
C_2	Varicose veins
C_{2r}	Recurrent varicose veins
C_3	Edema
C_4	Changes in skin and subcutaneous tissue secondary to CVD
C_{4a}	Pigmentation and eczema
C_{4b}	Lipodermatosclerosis or atrophie blanche
C_{4C}	Corona phlebectatica
C_5	Healed

C_6	Active venous ulcer
C_{6r}	Recurrent active venous ulcer
S	Symptomatic
A	Asymptomatic

Adapted from: https://www.jvsvenous.org/article/S2213-333X(20)30063-9/pdf
CEAP: Clinical, Etiologic, Anatomic, Pathophysiologic classification system; CVD, chronic venous disease. Each clinical class subcharacterized by a subscript indicates the presence (symptomatic, s) or absence (asymptomatic, a) of symptoms attributable to venous disease.

It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. When ultrasound guidance is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

Background/Overview

Venous Reflux/Venous Insufficiency

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory, or duplicate, veins that travel in parallel with the great and small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins with visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification of venous disease considers the clinical, etiologic, anatomic, and pathologic characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment of Saphenous Veins and Tributaries
Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux has traditionally included the following:

- Identification by preoperative Doppler ultrasonography of the valvular incompetence
- Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
- Removal of the superficial vein from circulation, eg, by stripping of the great and/or small saphenous veins.
- Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. These include forms of sclerotherapy, cyanocrylate adhesive, and thermal ablation using cryotherapy, high-frequency radio waves (200 to 300 kHz), or laser energy.

Thermal Ablation
Radiofrequency ablation (RFA) is performed using a specially designed catheter inserted through a small incision in the distal medial thigh to within 1 to 2 cm of the saphenofemoral junction. The catheter is slowly withdrawn, closing the vein. Laser ablation is performed similarly. A laser fiber is introduced into the great saphenous vein under ultrasound guidance. The laser is then activated and slowly removed, along the course of the saphenous vein. Cryoablation uses extreme cold. The objective of endovenous techniques is to injure the vessel, causing retraction and subsequent fibrotic occlusion of the vein. Technical developments since thermal ablation procedures were initially introduced include the use of perivenous tumescent anesthesia, which allows successful treatment of veins larger than 12 mm in diameter and helps to protect adjacent tissue from thermal damage during treatment of the small saphenous vein.

Sclerotherapy
The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately occluding the vessel. Treatment success depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations. Technical

improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). Physician-compounded foam is produced at the time of treatment. A commercially available microfoam sclerosant with a proprietary gas mix is available and is proposed to provide a smaller and more consistent bubble size than what is produced with physician-compounded sclerosant foam.

Endovenous Mechanochemical Ablation
Endovenous mechanochemical ablation uses 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 3500 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 with endovenous thermal ablation techniques (RFA, endovenous laser ablation).

Cyanoacrylate Adhesive
A cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material on contact with body fluids or tissue). The adhesive is gradually injected along the length of the vein in conjunction with ultrasound and manual compression. The acute coaptation halts blood flow through the vein until the implanted adhesive becomes fibrotically encapsulated and establishes chronic occlusion of the treated vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and surgical incisions or other skin wounds.

Transilluminated Powered Phlebectomy
Transilluminated powered phlebectomy is an alternative to stab avulsion and hook phlebectomy. This procedure uses 2 instruments: an illuminator, which also provides irrigation, and a resector, which has an oscillating tip and suction pump. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of varicosity. The resector is then inserted under the skin

from the opposite direction, and the oscillating tip is placed directly beneath the illuminated veins to fragment and loosen the veins from the supporting tissue. Irrigation from the illuminator is used to clear the vein fragments and blood through aspiration and additional drainage holes. The illuminator and resector tips may then be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or hook phlebectomy. It has been proposed that transilluminated powered phlebectomy might decrease surgical time, decrease complications such as bruising, and lead to a faster recovery than established procedures.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2015, the VenaSeal™‡ Closure System (Sapheon, part of Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (P140018) process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation. The VenaSeal Closure System seals the vein using a cyanoacrylate adhesive agent. FDA product code: PJQ.

In 2013, Varithena®‡ (formerly Varisolve), a sclerosant microfoam made with a proprietary gas mix, was approved by the FDA under a new drug application (205-098) for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.

The following devices were cleared for marketing by the FDA through the 510(k) process for endovenous treatment of superficial vein reflux:

In 1999, the VNUS Closure®‡ System, a radiofrequency device, was cleared by the FDA through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." In 2005, the VNUS RFS®‡ and RFS*Flex*®‡ devices were cleared by the FDA for "use in vessel and tissue coagulation including treatment of incompetent (ie, refluxing) perforator and tributary veins." In 2008, the modified VNUS ClosureFast®‡ Intravascular Catheter was cleared by the FDA through the 510(k) process. FDA product code: GEI.

In 2002, the Diomed 810 nm surgical laser and EVLT®‡ (endovenous laser therapy) procedure kit were cleared by the FDA through the 510(k) process ".....for use in the endovascular coagulation

of the great saphenous vein of the thigh in patients with superficial vein reflux." FDA product code: GEX.

In 2005, a modified Erbe Erbokryo cryosurgical unit (Erbe USA) was approved by the FDA for marketing through the 510(k) process. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.

In 2003, the Trivex system (InaVein), a device for transilluminated powered phlebectomy, was cleared by the FDA through the 510(k) process for "ambulatory phlebectomy procedures for the resection and ablation of varicose veins." FDA product code: DNQ.

In 2008, the ClariVein®‡ Infusion Catheter (Merit Medical) was cleared by the FDA through the 510(k) process (K071468) for mechanochemical ablation. The FDA determined that this device was substantially equivalent to the Trellis Infusion System (K013635) and the Slip-Cath Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock, and syringe, and is intended for the infusion of physician-specified agents in the peripheral vasculature. FDA product code: KRA

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgery, thermal ablation, sclerotherapy, mechanochemical ablation (MOCA), cyanoacrylate adhesive (CAC), and cryotherapy. The application of each modality is influenced by the severity of the symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent) treatment.

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Summary of Evidence
Saphenous Veins
For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive endovenous thermal ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at 2- to 5-year follow-up has supported the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. In a Cochrane review, ultrasound-guided foam sclerotherapy was inferior to both ligation and stripping and endovenous laser ablation for technical success up to 5 years and beyond 5 years, but there was no significant difference between treatments for recurrence up to 3 years and at 5 years. For physician-compounded sclerotherapy, there is high variability in success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the U.S. Food and Drug Administration (FDA) are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that once occluded, recurrence rates at 2 years are similar to those of ligation and stripping. Together, this evidence indicates that the more consistent occlusion with the microfoam sclerotherapy preparation will lead to recurrence rates similar to ligation and stripping in the longer term. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation (MOCA), the evidence includes 4 RCTs with 6 months to 2-year results that compared MOCA to thermal ablation, and a prospective cohort with follow-up out to 5 years. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and

treatment-related morbidity. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared with thermal ablation is that MOCA does not require tumescent anesthesia and may result in less pain during the procedure. Results to date have been mixed regarding a reduction in intraprocedural pain compared to thermal ablation procedures. Occlusion rates at 6 months to 2 years from RCTs indicate lower anatomic success rates compared to thermal ablation, but a difference in clinical outcomes at these early time points has not been observed. Experience with other endoluminal ablation procedures suggests that lower anatomic success in the short term is associated with recanalization and clinical recurrence between 2 to 5 years. The possibility of later clinical recurrence is supported by a prospective cohort study with 5-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort study was begun, and clinical progression is frequently observed with venous disease. Because of these limitations , longer follow-up of the more recently conducted RCTs is needed to establish the efficacy and durability of this procedure compared with the criterion standard of thermal ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive (CAC), the evidence includes 2 RCTs and a prospective cohort study. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Evidence includes a multicenter noninferiority trial with follow-up through 36 months, an RCT with follow-up through 24 months, and a prospective cohort with 30-month follow-up. The short-term efficacy of VenaSeal CAC has been shown to be noninferior to RFA at up to 36 months. At 24 and 36 months, the study had greater than 20% loss to follow-up, but loss to follow-up was similar in the 2 groups at the long-term follow-up and is not expected to influence the comparative results. A second RCT (N=525) with the same active CAC ingredient (N-butyl cyanoacrylate) that is currently available outside of the U.S. found no significant differences in vein closure between CAC and thermal ablation controls at 24-month follow-up. The CAC procedure and return to work were shorter and pain scores were lower compared to thermal ablation, although the subjective pain scores may have been influenced by differing expectations in this study. A prospective cohort study reported high closure rates at 30 months. Overall, results indicate that outcomes from CAC are at least as good as thermal ablation techniques, the current standard of care. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Varicose Tributary Veins

For individuals who have varicose tributary veins who receive ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlenectomy (TIPP) is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Perforator Veins

For individuals who have perforator vein reflux who receive ablation (eg, subfascial endoscopic perforator surgery) of perforator veins, the evidence includes RCTs, systematic reviews of RCTs, and a retrospective study. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as an alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating or ablating incompetent perforator veins. Subfascial endoscopic perforator surgery is possibly as effective as the Linton procedure with a reduction in adverse events. Endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared with surgical interventions. The

evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies while this policy was under review in 2015. There was no agreement on the need to treat varicose tributaries to improve functional outcomes in the absence of saphenous vein disease. Input was also mixed on the use of mechanochemical ablation and cyanoacrylate adhesive.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Venous Forum et al

In 2020, in response to published reports of potentially inappropriate application of venous procedures, the American Venous Forum, Society for Vascular Surgery, American Vein and Lymphatic Society, and the Society of Interventional Radiology published appropriate use criteria for the treatment of chronic lower extremity venous disease. Appropriate use criteria were developed using the RAND/UCLA method incorporating best available evidence and expert opinion.

Appropriate use criteria were determined for various scenarios (eg, symptomatic, asymptomatic, CEAP [Clinical, Etiology, Anatomy and Pathophysiology] class, axial reflux, saphenofemoral junction reflux) for the following:

- Saphenous vein ablation

  - Great saphenous vein
  - Small saphenous vein
  - Accessory great saphenous vein
- Nontruncal varicose veins
- Diseased tributaries associated with saphenous ablation
- Perforator veins
- Iliac vein or inferior vena cava stenting as a first line treatment
- Duplex ultrasound
- Timing and reimbursement.

Treatment of saphenous veins for asymptomatic CEAP class 1 and 2, or symptomatic class 1, was considered to be rarely appropriate or never appropriate, and treatment of symptomatic CEAP class 2, 3, and 4 to 6 without reflux was rated as never appropriate. Based on the 2011 Guidelines from the Society for Vascular Surgery and American Venous Forum (see below), treatment of perforator veins for asymptomatic or symptomatic CEAP class 1 and 2 was considered to be rarely appropriate or never appropriate. Perforator vein treatment was rated as appropriate for CEAP classes 4 to 6, and may be appropriate for CEAP class 3. Except for a recommendation to use endovenous procedures for perforator vein ablation, techniques used to treat veins in these scenarios were not evaluated.

Society for Vascular Surgery, American Vein and Lymphatic Society, and American Venous Forum

The Society for Vascular Surgery and the American Venous Forum (2011) published joint clinical practice guidelines. Table 1 provides the recommendations.

Table 1. Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases

Recommendation	Grade[a]	SOR	QOE
Compression therapy for venous ulcerations and varicose veins			
Compression therapy is recommended as the primary treatment to aid healing of venous ulceration	1B	Strong	Moderate

Recommendation	Grade[a]	SOR	QOE
To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended	1A	Strong	High
Use of compression therapy for patients with symptomatic varicose veins is recommended	2C	Weak	Low
Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended	1B	Strong	Moderate
Treatment of the incompetent great saphenous vein			
Endovenous thermal ablation (radiofrequency or laser) is recommended over chemical ablation with foam or high ligation and stripping due to reduced convalescence and less pain and morbidity. Cryostripping is a technique that is new in the United States, and it has not been fully evaluated.	1B	Strong	Moderate
Varicose tributaries			
Phlebectomy or sclerotherapy are recommended to treat varicose tributaries	1B	Strong	Moderate
Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy	2C	Weak	Low
Perforating vein incompetence			
Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended	1B	Strong	Moderate
Treatment of pathologic perforating veins (outward flow of ≥500 ms duration, with a diameter of ≥3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6) is recommended	2B	Weak	Moderate

CEAP: Clinical Etiology Anatomy Pathophysiology; QOE: quality of evidence; SOR: strength of recommendation.

[a] Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.

The Society for Vascular Surgery, the American Vein and Lymphatic Society (AVLS), and the American Venous Forum published a joint clinical practice guideline in 2022 on management of lower extremity varicose veins. The guideline will be published in sections; the first part (published in 2022) focuses on duplex scanning and treatment of superficial truncal reflex. The second part of the guideline has not yet been published. Superficial truncal veins are defined as the great saphenous vein, small saphenous vein, anterior accessory great saphenous vein, and posterior accessory great saphenous vein. A summary of the guideline recommendations is provided in Table 2.

Table 2. Summary of Recommended Treatment of Superficial Truncal Reflex

Recommendation	Grade[a]	SOR	QOE
Symptomatic varicose veins and axial reflux			
Reflux in the great or small saphenous vein - superficial venous intervention preferred over long-term compression stockings	1B	Strong	Moderate
Reflux in the anterior accessory or posterior accessory great saphenous vein - superficial venous intervention preferred over long-term compression stockings	2C	Weak	Low
Reflux in the superficial truncal vein - compression therapy suggested for primary treatment	2C	Weak	Low
Reflux in the great saphenous vein - endovenous ablation preferred over high ligation and stripping[b]	1B	Strong	Moderate
Reflux in the small saphenous vein - endovenous ablation preferred over high ligation and stripping[b]	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - endovenous ablation (with phlebectomy if needed) over ligation and stripping[b]	2C	Weak	Low

Recommendation	Grade[a]	SOR	QOE
Patients who place a high priority on long-term outcomes (quality of life and recurrence) - laser ablation, radiofrequency ablation, or ligation and stripping over ultrasound-guided foam sclerotherapy	2C or 2B	Weak	Moderate or Low
Symptomatic axial reflux			
Reflux in the great saphenous vein - thermal and nonthermal ablation recommended	1B	Strong	Moderate
Reflux in the small saphenous vein - thermal and nonthermal ablation recommended	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - either thermal or nonthermal ablation suggested	2C	Weak	Low
Varicose veins (CEAP class C2)			
Reflux in the great or small saphenous vein - recommend against concomitant initial ablation and treatment of incompetent perforating veins	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - recommend against concomitant initial ablation and treatment of incompetent perforating veins	2C	Weak	Low
Persistent or recurrent symptoms after previous complete ablation - treatment of perforating vein incompetence suggested	2C	Weak	Low
Symptomatic reflux and associated varicosities			
Reflux in the great or small saphenous vein - ablation and concomitant phlebectomy or ultrasound-guided foam sclerotherapy recommended	1C	Strong	Low
Reflux in the anterior accessory or posterior accessory great saphenous vein - ablation and concomitant phlebectomy or ultrasound-guided foam sclerotherapy suggested	2C	Weak	Low

CEAP: Clinical Etiology Anatomy Pathophysiology; QOE: quality of evidence; SOR: strength of recommendation.

[a] Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.
b Ligation and stripping can be performed if endovenous ablation is not feasible.

American Vein and Lymphatic Society
In 2015, the AVLS (previously named the American College of Phlebology) published guidelines on the treatment of superficial vein disease.

AVLS gave a Grade 1 recommendation based on high quality evidence that compression is an effective method for the management of symptoms, but when patients have a correctable source of reflux, definitive treatment should be offered unless contraindicated. AVLS recommends against a requirement for compression therapy when a definitive treatment is available. AVLS gave a strong recommendation based on moderate quality evidence that endovenous thermal ablation is the preferred treatment for saphenous and accessory saphenous vein incompetence, and gave a weak recommendation based on moderate quality evidence that mechanochemical ablation may also be used to treat venous reflux.

In 2017, AVLS published guidelines on the treatment of refluxing accessory saphenous veins. The College gave a Grade 1 recommendation based on level C evidence that patients with symptomatic incompetence of the accessory saphenous veins be treated with endovenous thermal ablation or sclerotherapy to reduce symptomatology. The guidelines noted that although accessory saphenous veins may drain into the great saphenous vein before it drains into the common femoral vein, they can also empty directly into the common femoral vein.

National Institute for Health and Care Excellence
In 2013, the NICE updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins. NICE stated that:

"1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but

significant risks of foam embolization (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.

1.2 During the consent process, clinicians should inform patients that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischaemic attacks and stroke."

In 2015, NICE published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation, and surgery for varicose veins.

In 2016, NICE revised its guidance on endovenous mechanochemical ablation, concluding that "Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure...."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05633277	Outcomes of Sclerotherapy of the Ulcer Bed Compared to a Combination of Ablation and Injections	30	Mar 2024
		180	Dec 2021

NCT04737941	Finnish Venous Ulcer Study	248	Mar 2026
NCT03820947[a]	Global, Post-Market, Prospective, Multi-Center, Randomized Controlled Trial of the VenaSeal™‡ Closure System vs. Surgical Stripping or Endothermal Ablation (ETA) for the Treatment of Early & Advanced Stage Superficial Venous Disease	500	Apr 2028
Unpublished			
NCT03392753	Randomized Controlled Trial of Mechanochemical Ablation Versus Cyanoacrylate Adhesive for the Treatment of Varicose Veins	167	Dec 2021
NTR4613[a]	Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial)	160	Apr 2020

NCT: national clinical trial. NTR: Netherlands Trial Registry.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 08/26/2002
Current Effective Date: 02/01/2024

08/15/2002	Medical Policy Committee review
08/26/2002	Managed Care Advisory Council approval
10/05/2004	Medical Director review
11/16/2004	Medical Policy Committee review. Format revision. Clinical criteria added.
11/29/2004	Managed Care Advisory Council approval
10/05/2005	Medical Director review
10/18/2005	Medical Policy Committee review. Format revision. No substance change to policy.

Treatment of Varicose Veins/Venous Insufficiency

Policy # 00034
Original Effective Date: 08/26/2002
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10/27/2005	Quality Care Advisory Council approval
07/07/2006	Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Patient selection criteria changed to include all saphenous varicose veins as eligible for coverage with criteria.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Policy revised to include small saphenous and great saphenous vein greater than 12mm. Rationale/Source updated.
06/04/2008	Medical Director review
06/18/2008	Medical Policy Committee approval. No change to coverage eligibility.
06/04/2009	Medical Director review
06/17/2009	Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2011	Medical Policy Committee review
06/15/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. Policy extensively rewritten. Title changed. Added “echosclerotherapy, also known as deep ultrasound-guided sclerotherapy (DUGS), usually with a catheter infusion of a foam sclerosant, and other protocols for sclerotherapy, including the COMPASS protocol” to list of investigational indications.
06/04/2013	The “not medically necessary” statement for treatment of greater or lesser saphenous veins clarified by removal of the term “cosmetic”.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Mechanochemical ablation of any vein added as investigational. “The Company considers treatment of telangiectasia such as spider veins, angiomata, and hemangiomata cosmetic and is not a covered benefit” was changed from not medically necessary.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. No change to coverage.

03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Microfoam sclerotherapy considered medically necessary. Added "or microfoam sclerotherapy" to the not medically necessary policy statement under accessory saphenous veins.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. The requirement of failure of compression therapy was removed from the policy statements on ulceration secondary to venous stasis and recurrent superficial thrombophlebitis; terminology was changed from greater and lesser to great and small saphenous veins. Cyanoacrylate adhesive of any vein added to INV statement. CEAP clinical classification info added.
01/01/2017	Coding update: Removal of ICD-9 Diagnosis Codes and CPT coding update
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. Added coverage for ultrasound-guided microfoam sclerotherapy.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Sclerotherapy of perforator veins when criteria are not met added as investigational.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Cyanoacrylate adhesive may be considered medically necessary. A statement was added on concurrent treatment of the accessory saphenous veins.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. No change to coverage.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. No change to coverage
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. No change to coverage.

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11/02/2023 Medical Policy Committee review
11/08/2023 Medical Policy Implementation Committee approval. For Symptomatic Varicose Tributaries added when vein size is 2.5 mm or greater in diameter measured by recent ultrasound to coverage statement. Added investigational denial when criteria are not met statement. Added phlebectomy to Sclerotherapy or phlebectomy of isolated tributary veins without prior or concurrent treatment of saphenous veins investigational statement. Added When services are not covered statement to policy along with a note. References updated.
Next Scheduled Review Date: 11/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Treatment of Varicose Veins/Venous Insufficiency

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0524T, 36465, 36466, 36468, 36470, 36471, 36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37500, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785, 37799 Delete code effective 10/01/2023: 49185
HCPCS	S2202
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.