

Corporate Medical Policy

Varicose Veins of the Lower Extremities, Treatment for

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Description of Procedure or Service

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

Background

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. Since 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 considers the clinical, etiologic, anatomic, and pathologic (CEAP) characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment of venous reflux/venous insufficiency is aimed at reducing abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of elevation of the extremities, graded compression, and wound care when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or in the deep venous system. The competence of any single valve is not static and may be pressure dependent. For example, accessory saphenous veins may have independent saphenofemoral or saphenopopliteal junctions that become incompetent when the great or small saphenous veins are eliminated, and blood flow is diverted through the accessory veins.

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 typically includes the following:

1. Identification by preoperative Doppler ultrasonography of the valvular incompetence
2. Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction

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3. Removal of the superficial vein from circulation, for example by stripping of the great and/or small saphenous veins
4. 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 include: sclerotherapy, cyanoacrylate adhesive, and thermal ablation using cryotherapy, high frequency radiowaves (200–300 kHz), or laser energy.

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 resulting in the occlusion of the vessel. The success of the treatment 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 to be 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 commonly produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., 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 that is proposed to provide smaller and more consistent bubble size than what is produced with physician-compounded sclerosant foam.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation (MOCA™) 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 with endovenous thermal ablation techniques (radiofrequency (RF) ablation or endovenous laser ablation (EVLT)).

Thermal Ablation

Radiofrequency ablation is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within 1–2 cm of the 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 activated and slowly removed along the course of the saphenous vein. Cryoablation uses extreme cold to cause injury to the vessel. The objective of endovenous techniques is to cause injury to 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.

Cyanoacrylate Adhesive

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 to seal surgical incisions or other skin wounds.

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Transilluminated Powered Phlebectomy

Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or hook phlebectomy. This procedure uses two instruments: an illuminator which also provides irrigation, and a resector, which has an oscillating tip and can perform suction. 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 the 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 TIPP might result in decreased operative time, decreased complications such as bruising, and faster recovery compared to the established procedures.

Treatment of Perforator Veins

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally addressed with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may be occasionally utilized for the closure of incompetent perforator veins that cannot be reached by less invasive procedures. Subfascial endoscopic perforator surgery (SEPS) is a less-invasive surgical procedure for treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin and the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and radiofrequency has also been reported.

Other

Deep vein valve replacement is being investigated.

Outcomes of interest for venous interventions include healing and recurrence, recanalization of the vein, and neovascularization. Recanalization is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques.

Neovascularization is the proliferation of new blood vessels in tissue, and occurs more frequently following vein stripping. Direct comparisons of durability for endovenous and surgical procedures are complicated by these different mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

Regulatory Status

The following devices have received specific U.S. Food and Drug Administration (FDA) marketing clearance for the endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ system (a radiofrequency device) received FDA clearance through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." The VNUS RFS™ and RFS*Flex*™ devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins." The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit received FDA clearance 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."

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- A modified Erbe Erbokryo® cryosurgical unit (Erbe USA) received FDA clearance for marketing in 2005. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.
- The Trivex® system (InaVein, LLC) is a device for transilluminated powered phlebectomy that received FDA clearance through the 510(k) process in October 2003. According to the label, the intended use is for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.”
- Varithena™ (formerly known as Varisolve® (BTG PLC, London) is a sclerosant microfoam made with a proprietary gas mix. It was approved by FDA in 2013 under a new drug application for the treatment of incompetent great saphenous veins, accessory saphenous veins, tributary veins, and visible varicosities of the great saphenous vein system above and below the knee.
- The ClariVein® Infusion Catheter (Vascular Insights) received marketing clearance through the 510(k) process in 2008 (K071468). It is used for mechanochemical ablation. Predicate devices were listed as 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.
- In 2015, the VenaSeal® Closure System (Sapheon, a part of Medtronic) was approved by the FDA through the premarket approval 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.

Note: This policy does not address varicose veins/insufficiency of the ovarian, internal iliac or gonadal veins.

Related Policies

Ovarian, Internal Iliac and Gonadal Vein Embolization, Ablation and Sclerotherapy

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

BCBSNC will provide coverage for treatment for varicose veins of the lower extremities when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Coverage is provided for endovenous procedures used to support the normal function of your veins, and is limited to one procedure per limb per lifetime. Benefits are also provided for sclerotherapy vein treatment and are limited to three procedures per limb per lifetime.

When treatment for varicose veins of the lower extremities is covered

Great or Small Saphenous Veins

Treatment of the great or small saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive may be

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considered **medically necessary** for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

There is demonstrated saphenous reflux and CEAP 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 3 months has not improved the symptoms.

Accessory Saphenous Veins

Treatment of accessory saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive may be considered **medically necessary** for symptomatic varicose veins/venous insufficiency when the following criteria have been 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

- 1) There is demonstrated accessory saphenous reflux; AND
- 2) 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 3 months has not improved the symptoms.

Symptomatic Varicose Tributaries

The following treatments are considered **medically necessary** 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):

- Stab avulsion
- Hook phlebectomy
- Sclerotherapy
- Transilluminated powered phlebectomy
- Microfoam sclerotherapy
- Ligation, division, and/or excision

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

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- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND
- The venous insufficiency is not secondary to deep venous thromboembolism.

When treatment for varicose veins of the lower extremities is not covered

Treatment of 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 is considered cosmetic and **not medically necessary**.

Treatment of accessory saphenous veins by surgery, endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive that does not meet the criteria described above is considered cosmetic and **not medically necessary**.

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 is considered **investigational**.

Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is **not medically necessary**.

Treatment of telangiectasia such as spider veins, angiomas, and hemangiomas is considered cosmetic and **not medically necessary**.

Techniques for conditions not specifically listed above are **investigational**, including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins
- Sclerotherapy of perforator veins
- Sclerotherapy 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

Policy Guidelines

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 CVD
- C4a Pigmentation and eczema
- C4b Lipodermatosclerosis and atrophie blanche
- C4c Corona phlebectatica
- C5 Healed venous ulcer
- C6 Active venous ulcer
- C6r Recurrent active venous ulcer

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- S Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
- A Asymptomatic

Coverage of sclerotherapy is limited to 3 sessions per leg and coverage of microphlebectomy is limited to one session per leg, to be accomplished over a period of not more than 6 months from the primary procedure. Primary procedures may include ligation/division/stripping/excision, ERFA, or EVLA/EVLT.

Sclerotherapy coverage does not include treatment of reticular veins, spider veins or telangiectasias. Sclerotherapy is not covered for treatment of saphenofemoral or saphenopopliteal junction incompetence or saphenous vein (GSV, LSV, or accessory saphenous vein) reflux.

Compressive therapy is the use of surgical grade compression hose (minimum 20-30 mm Hg) that has been prescribed by a physician with the trial use documented in the medical record.

Rationale

Saphenous Veins

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive thermal endovenous 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 use of both radiofrequency ablation (RFA) and endovenous laser ablation. Evidence has suggested that ligation and stripping leads 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 a meaningful 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. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For physician compounded sclerotherapy, there is high variability in success rates of this procedure and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration 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 a meaningful improvement in the net health outcome.

Based on the available evidence, clinical input, and clinical practice guidelines, the use of endovenous RFA, endovenous laser ablation, and microfoam sclerotherapy are considered to improve outcomes when used in the saphenous veins. For treatment of saphenous tributaries at the same time or following treatment of the saphenous vein, stab avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy improve outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation, the evidence includes four RCTs with six month to two year results that compared MOCA to thermal ablation, a prospective cohort with follow-up out to five years, and retrospective case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that mechanochemical ablation does not require multiple needle sticks with tumescent anesthesia and may result in less pain during the procedure. Results to date have been

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mixed regarding a reduction in intraprocedural pain compared to thermal ablation procedures. Occlusion rates at six months to two 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 two to five years. The possibility of later clinical recurrence is supported by a prospective cohort study with five-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 of the single arm studies, longer follow-up in 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 the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes two RCTs and a prospective cohort. 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 cyanoacrylate adhesive 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 two 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 cyanoacrylate adhesive ingredient (N-butyl cyanoacrylate) that is currently available outside of the U.S. found no significant differences in vein closure between cyanoacrylate adhesive and thermal ablation controls at 24-month follow-up. The cyanoacrylate adhesive 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 reported high closure rates at 30 months. Overall, results indicate that outcomes from cyanoacrylate adhesive 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 a meaningful 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 and multicenter series. 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 the effects of the technology on health outcomes.

Varicose Tributary Veins

For individuals who have varicose tributary veins who receive ablation of tributary veins (stab avulsion, sclerotherapy, or phlebectomy), 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 phlebectomy 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 a meaningful improvement in the net health outcome.

Perforator Veins

For individuals who have perforator vein reflux who receive ablation of perforator veins (eg, subfascial endoscopic perforator surgery), 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 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

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compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any 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. Although only one case series has been identified showing an improvement in health outcomes, 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 a meaningful improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 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, S2202

There is no specific code for transilluminated powered phlebectomy. Codes 37765, 37766 or 37799 could be used.

There are codes specific to mechanochemical ablation: 36473, 36474

There is no specific code for microfoam sclerotherapy. Providers might elect to use codes describing sclerotherapy (36468-36471) or the unlisted code 37799. Use of codes 36475-36476 would be inappropriate as the procedure is not ablation therapy.

If code 76942 is used for ultrasound guidance of sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

ICD-10 diagnosis codes: I83.001, I83.002, I83.003, I83.004, I83.005, I83.008, I83.009, I83.011, I83.012, I83.013, I83.014, I83.015, I83.018, I83.019, I83.021, I83.022, I83.023, I83.024, I83.025, I83.028, I83.029, I83.10, I83.11, I83.12, I83.201, I83.202, I83.203, I83.204, I83.205, I83.208, I83.209, I83.211, I83.212, I83.213, I83.214, I83.215, I83.218, I83.219, I83.221, I83.222, I83.223, I83.224, I83.225, I83.228, I83.229, I83.811, I83.812, I83.813, I83.819, I83.891, I83.892, I83.893, I83.899, I83.90, I83.91, I83.92, I83.93

CPT provides clarification regarding the intended use for 37241 as follows:

- *For sclerosis of veins or endovenous ablation of incompetent **extremity veins**, use 36468–36479*
- *Do **not** report 37241 in conjunction with 36468, 36470, 36471, 36475–36479, 75894, 75898 in the same surgical field*

Examples of intended use of 37241 (not an all-inclusive list):

- *Embolization/occlusion of gastric/esophageal varices;*
- *Embolization/occlusion of varicoceles;*
- *Embolization/occlusion of incompetent ovarian vein for pelvic congestion syndrome;*
- *Embolization/occlusion of patent perforators siphoning flow from dialysis access fistula;*
- *Embolization/occlusion of patent perforators siphoning flow from lower extremity venous bypass grafts;*
- *Injection/occlusion/embolization of vascular malformations that are primarily venous;*
- *Injection/occlusion/embolization of vascular malformations that are primarily lymphatic.*

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BCBSNC 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.

Scientific Background and Reference Sources

Policy entitled: VNUS Closure System

Chandler J, Pichot O, Sessa C, et al. Treatment of primary venous insufficiency by endovenous saphenous vein obliteration. *Vascular Surgery*. 2000; 34(3): 201-214.

Goldman M. Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow-up. *Dermatol Surg* 2000; 26(5): 452-456.

Consultant Review - 6/2000

Medical Policy Advisory Group - 9/14/2000

Specialty Matched Consultant Advisory Group - 10/2000

New policy entitled: Venous Insufficiencies

BCBSA Medical Policy Reference Manual, 5/30/97

Sabiston: Textbook of Surgery, 15th Ed., 1997, W. B. Saunders Company

Medline search, 1999 - 2000

New policy entitled: Venous Insufficiency

Medline search, 1999-2001

Medical Policy Advisory Group 3/2001

BCBSA Medical Policy Reference Manual, 7.01.76; 5/31/01

BCBSA Medical Policy Reference Manual, 7.01.76; 5/15/02

Specialty Matched Consultant Advisory Panel review 8/2002

BCBSA Medical Policy Reference Manual, 7.01.55; 5/15/02

BCBSA Medical Policy Reference Manual, 7.01.90; 7/17/03

BCBSA Medical Policy Reference Manual, 7.01.76; 7/17/03

Specialty Matched Consultant presentation to Medical Policy Advisory Group, 12/04/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.55, 7/17/03.

BCBSA Medical Policy Reference Manual, 7.01.76; 12/17/03

Specialty Matched Consultant Advisory Panel - 8/2004

From policy entitled: Endoluminal Radiofrequency or Laser Ablation for Venous Insufficiency

Specialty Matched Consultant presentation to BCBSNC Internal Medical Directors, 8/9/05

CEAP Classification of Chronic Venous Insufficiency retrieved from a PowerPoint presentation by Andrew C. Stanley, M.D., Section of Vascular Surgery at the University of Vermont. Varicose Veins: Causes, Symptoms and Management. Retrieved on 8/10/05 from http://www.med.uvm.edu/downloads/CMS_VaricoseVeins_PowerPoint.pdf#search='Classification%20of%20varicose%20veins'

BCBSNC Internal Medical Directors' review 6/06

From policy entitled: Sclerotherapy as a Treatment of Varicose Veins

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Specialty Matched Consultant presentation to Medical Directors, 8/9/05

BCBSNC Internal Medical Directors' review 6/06

From policy entitled: Varicose Vein Excision and Ligation

Specialty Matched Consultant presentation to BCBSNC Internal Medical Directors, 8/9/05

CEAP Classification of Chronic Venous Insufficiency retrieved from a PowerPoint presentation by Andrew C. Stanley, M.D., Section of Vascular Surgery at the University of Vermont. Varicose Veins: Causes, Symptoms and Management. Retrieved on 8/10/05 from http://www.med.uvm.edu/downloads/CMS_VaricoseVeins_PowerPoint.pdf#search='Classification%20of%20varicose%20veins'

BCBSNC Internal Medical Directors' review 6/06

New policy entitled: Varicose Veins, Treatment for

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.55, 11/9/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.55, 8/17/05

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.55, 10/10/06

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.90, 8/17/05

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Specialty Matched Consultant - 4/1/08

BCBSNC Internal Medical Directors - 4/16/08

Specialty Matched Consultant Advisory Panel - 9/4/08

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 3/8/12

Specialty Matched Consultant Advisory Panel – 12/2012

Varicose Veins of the Lower Extremities, Treatment for

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 3/14/13

Specialty Matched Consultant Advisory Panel – 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 1/9/14

Specialty Matched Consultant Advisory Panel – 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 11/13/14

Specialty Matched Consultant Advisory Panel – 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 11/12/15

Specialty Matched Consultant Advisory Panel – 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 5/8/2017

Specialty Matched Consultant Advisory Panel – 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 5/4/2018

Medical Director review 8/2018

Specialty Matched Consultant Advisory Panel – 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 1/17/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 5/2/2019

Specialty Matched Consultant Advisory Panel – 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.124, 5/21/2020

Specialty Matched Consultant Advisory Panel – 11/2020

Policy Implementation/Update Information

Policy entitled: VNUS Closure System

7/00 Original policy issued.

9/00 Medical Policy Advisory Group review. Approved. No change in criteria.

New policy entitled: Venous Insufficiencies

12/00 New policy issued. Combined policy for VNUS Closure System with new policy on Echosclerotherapy. Name changed from VNUS Closure System to Venous Insufficiencies. System coding changes.

New policy entitled: Venous Insufficiency

4/01 Revised. Policy renamed. Added criteria for Varicose Vein Excision and Ligation and Sclerotherapy. Echosclerotherapy and VNUS Closure System were combined. Medical Policy Advisory Group approved. System changes.

Varicose Veins of the Lower Extremities, Treatment for

- 10/01 Revised. Added section on Endoluminal Radiofrequency Ablation for Varicose Veins as investigational. Typos corrected. Coding format changes.
- 8/02 Specialty Matched Consultant Advisory Panel review. Revised "Description" section for clarity. VNUS Closure System section removed. Endoluminal Radiofrequency Ablation for Varicose Veins section includes VNUS Closure System. Endoluminal Radiofrequency Ablation section revised to indicate procedure is no longer investigational and criteria added. Added section on Endoluminal Laser Ablation for Varicose Veins as investigational. Criteria clarified in sections for Varicose Vein Excision and Ligation and Sclerotherapy.
- 11/02 Added statement to Endoluminal Radiofrequency Ablation section to indicate that the procedure is not covered unless the coverage criteria is met.
- 8/03 Policy reviewed. Description rewritten to provide additional information. Additional information added to Sclerotherapy section. Removed Echosclerotherapy section. Added statement "use of surgical pressure gradient stockings (use of nonprescription support hose are not sufficient);" to the coverage criteria. Codes adjusted for Endoluminal Radiofrequency Ablation for Varicose Veins section of policy. Code 37204 removed from policy and code S2130 added.
- 1/04 Combined Endoluminal Radiofrequency Ablation and Laser Ablation sections with revisions as appropriate. Endoluminal Laser Ablation now covered. Section IV is now titled "Subfascial Endoscopic Perforator Surgery (SEPS)" and is investigational in the treatment of chronic venous insufficiency. Benefits Application and Billing/Coding sections revised. Added CPT codes 37765, 37766 to Billing/Coding section for Varicose Vein Excision and Ligation. Typos corrected.
- 4/22/04 Added new first quarter HCPCS code S2131 to the Billing /Coding section III, "Endoluminal Radiofrequency or Laser Ablation.
- 11/11/04 Specialty Matched Consultant Advisory Panel review - 8/27/04. Under Section I - Varicose Vein Excision and Ligation, "When Covered" added #3. "Doppler ultrasonographic documentation of saphenofemoral junction incompetence and greater saphenous vein reflux or saphenopopliteal junction incompetence and lesser saphenous vein reflux." Added codes 37700 & 37780 to Billing/ Coding section. Under Section II - Sclerotherapy, Reference to the COMPASS procedure added; Under "When Covered" A. added #3. "Doppler ultrasonographic documentation of reflux of the saphenofemoral junction or reflux isolated to the perforator veins of the upper thigh." Under "When not Covered", #4 following thrombophlebitis, added "(except as indicated above)". Added code S2202 to Billing/Coding section for Sclerotherapy. Under "When Covered" section for Endoluminal Radiofrequency or Laser Ablation, # 3., added e. "Endoluminal laser ablation of the lesser saphenous vein may be considered medically necessary when doppler ultrasonography documents saphenopopliteal junction incompetence and lesser saphenous vein reflux. The other medical necessity criteria listed in numbers 1. (significant medical problems) and 2. (trial of conservative measures) must be met." Under "Billing/Coding" section, deleted code 37799 and statements "There is no specific code for endoluminal laser ablation for treatment of varicose veins. Code 37799 may be used." S2131 is the appropriate code for endoluminal laser ablation. References added. Notice given 11/11/04. Effective date 1/20/05
- 1/20/05 Added 2005 CPT codes 36475, 36476, 36478, 36479 to Billing/Coding section for Endoluminal Radiofrequency or Laser Ablation and to final Billing/Coding section that includes all codes in policy.
- 2/02/06 Removed deleted CPT codes 37720 & 37730 from Billing/Coding section for Varicose Vein Excision and Ligation and from final Billing/Coding section that includes all codes in policy. Added 2006 CPT codes 37718 & 37722 to same sections.

Varicose Veins of the Lower Extremities, Treatment for

10/2/06 Policy separated into Varicose Vein Excision and Ligation, Sclerotherapy as a Treatment of Varicose Veins, and Endoluminal Radiofrequency or Laser Ablation for Venous Insufficiency. Venous Insufficiency policy archived.

From policy entitled: Endoluminal Radiofrequency or Laser Ablation for Venous Insufficiency

7/24/06 Notification of new policy. This policy is NOT effective until 10/2/06. Prior to 10/2/06 refer to policy number SUR6817, Venous Insufficiency. The Venous Insufficiency policy will be archived on 10/2/06. Notification given 7/24/06. Effective date 10/2/06. (pmo)

From policy entitled: Sclerotherapy as a Treatment of Varicose Veins

7/24/06 Notification of new policy. This policy is NOT effective until 10/2/06. Prior to 10/2/06 refer to policy number SUR6817, Venous Insufficiency. The Venous Insufficiency policy will be archived on 10/2/06. Notification given 7/24/06. Effective date 10/2/06. (pmo)

From policy entitled: Varicose Vein Excision and Ligation

7/24/06 Notification of new policy. This policy is NOT effective until 10/2/06. Prior to 10/2/06 refer to policy number SUR6817, Venous Insufficiency. The Venous Insufficiency policy will be archived on 10/2/06. CPT codes 37720 and 37730 removed from Billing/Coding section (codes deleted in 2005) and added CPT codes 37718, 37722 and 37760. Notification given 7/24/06. Effective date 10/2/06. (pmo)

New policy entitled: Varicose Veins, Treatment for

5/19/08 New policy issued. Policy combines and clarifies the following separate policies: Endoluminal Radiofrequency or Laser Ablation for Venous Insufficiency, Sclerotherapy as a Treatment of Varicose Veins and Varicose Vein Excision and Ligation. (pmo)

10/6/08 Revisions under "When Covered" section:

A.1.a. Varicose vein ligation and excision (VVLE/varicose vein ligation and stripping (VVLS) for treatment of GSV, LSV, or accessory vein reflux.

A.2. added "accessory saphenous vein" to list of "all proximal sources of reflux".

A. Note-added "and coverage of microphlebectomy is limited to one session per leg"; added reticular veins to list "Sclerotherapy coverage does not include treatment of....."; added (GSV, LSV, or accessory saphenous vein) following "saphenous vein" in next to last sentence.

B.7. Now reads: "Procedure (CPT) codes for proposed interventions specifying the vein(s) to be treated with each procedure (e.g. GSV, LSV, accessory saphenous vein, perforator, varicose tributaries, reticular veins, spider veins, telangiectasia) and whether Left, Right, or Bilateral; and for sclerotherapy also stating the number of sessions for each leg."

Revisions under "When Not Covered" section:

3. Added "or accessory saphenous vein" to investigational list.

7. Added "or more than one session of microphlebectomy per leg".

Added 9. "Surgical removal, EVLT, and/or ERFA can be performed safely and effectively on multiple veins of the same leg as part of a single surgery. Therefore, staging of surgical procedures on different dates of service to treat more than one incompetent saphenous vein (GSV, LSV, accessory saphenous vein) in the same leg is considered to be not medically necessary."

Other:

Reference sources added. Specialty Matched Consultant Advisory Panel review - 9/4/08.

Notification given 10/6/08. Effective date 1/5/09. (pmo)

Varicose Veins of the Lower Extremities, Treatment for

- 1/5/10 Policy reformatted. CPT code 37761 effective January 1, 2010 added to Billing/Coding section. System Application Guidelines not updated due to conversion to the QMP real time database. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 7/20/2010 Description section extensively revised. The sections for when treatment for varicose veins is and is not covered were reformatted. The following was added to the When Varicose Vein Treatment Is Covered section: "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 (greater, lesser, 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 insufficiency is not secondary to deep venous thromboembolism." The following statements were added to the **When Varicose Vein Treatment Is Not Covered** section: "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 is considered investigational. Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary." Also "Endovenous cryoablation of any vein" is investigational and not covered. Definition of "compressive therapy" moved to **Policy Guidelines** section. Rationale for coverage added to Policy Guidelines section. The following statements were added to the Billing/Coding section: "There is no specific CPT code for transilluminated powered phlebectomy. CPT codes 37765, 37766 or 37799 could be used. If CPT 76942 is used for ultrasound guidance of sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure". References updated. Notification given 7/20/10 for effective date of 10/26/10. (adn)
- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/10. Policy accepted as written. (adn)
- 3/1/11 Correction-the following statement was removed from paragraph 2 of the Policy Guidelines section: "Also, sclerotherapy, ERFA and EVLA/EVLT are not covered for treatment of incompetent deep perforator veins." (adn)
- 12/20/11 Routine annual review.Added additional covered indication to bulleted list under "Symptomatic Varicose Tributaries. "Ligation, division, and/or excision" is also covered. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)
- 9/18/12 Added the following statement to When Covered section: "The greater or lesser saphenous veins were surgically treated at least 3 months prior to treatment of accessory saphenous veins, in cases where greater or lesser saphenous reflux is also present". Medical Director review. (sk)
- 1/1/13 Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)
- 4/1/13 Added diagnosis codes 454.0 – 454.9 to Billing/Coding section. (sk)
- 5/14/13 Senior Medical Director review. Information on endovenous mechanochemical ablation added to policy. Reference added. No change to policy intent. (sk)
- 7/1/13 ICD-10 diagnosis codes added to Billing/Coding section. (sk)
- 12/31/13 Specialty Matched Consultant Advisory Panel review 11/20/2013. No change to Policy statement. Coding update. CPT codes 37241 and 37244 added to policy. (sk)

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- 7/1/14 Reference added. Removed ICD-10 effective date. No change to Policy statement. (sk)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/2014. No change to Policy statement. (sk)
- 12/30/14 Description section updated with information on Varithena™. Policy Guidelines updated. Microfoam sclerotherapy added to When Covered section. Code 36469 deleted. Reference added. (sk)
- 2/29/16 Reference added. Specialty Matched Consultant Advisory Panel review 11/18/2015. 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. CEAP classification system added to policy, Cyanoacrylate adhesive of any vein added to investigational statement. (sk)
- 10/25/16 Under Benefits Application section, added statement “Coverage is provided for endovenous procedures used to support the normal function of your veins, and is limited to one procedure per limb per lifetime. Benefits are also provided for sclerotherapy vein treatment and are limited to three procedures per limb per lifetime.” Notification given 10/25/2016 for policy effective date 12/30/16. (sk)
- 12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. Codes 36473 and 36474 added to Billing/Coding section. (sk)
- 12/15/17 Reference added. Policy Guidelines updated. Codes 36465, 36466, 36482, and 36483 added to Billing/Coding section for effective date 1/1/2018. ICD-9 codes removed from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
- 9/7/18 Reference added. Title changed from Varicose Veins, Treatment for to Varicose Veins of the Lower Extremities, Treatment for. Codes 37241, 37244 removed from Billing/Coding section. Related policy Ovarian, Internal Iliac, and Gonadal Vein Embolization, Ablation and Sclerotherapy added to Description section. Coding guidance added to Billing/Coding section. (sk)
- 12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. Code 0524T added to Billing/Coding section for effective date 1/1/2019. (sk)
- 2/26/19 Reference added. Policy Guidelines related to cyanoacrylate adhesive updated. (sk)
- 8/13/19 Reference added. Cyanoacrylate adhesive may be considered medically necessary. Policy Guidelines related to cyanoacrylate adhesive updated. (sk)
- 10/15/19 Medical Director review. Microfoam sclerotherapy added to medically necessary treatments for symptomatic varicose tributaries. (sk)
- 12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
- 12/8/20 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and

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