

Medical Policy



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DESCRIPTION

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgical approaches, thermal ablation, and sclerotherapy. The application of each of these treatment options is influenced by the severity of the

symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent) treatments.

The venous system of the lower extremities consists of the superficial veins (this includes the greater and lesser saphenous, and accessory or duplicate veins that travel in parallel with the greater and lesser 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 to Class 6:

- Class 0 – No visible venous disease
- Class 1 – Telangiectasia or Reticular veins
- Class 2 – Varicose veins
- Class 3 – Varicose veins with edema
- Class 4 – Varicose veins with skin changes without ulceration
- Class 5 – Varicose veins with a healed ulcer
- Class 6 – Varicose veins skin changes with an active ulcer

Definitions

Varicose Veins are dilated, elongated, tortuous, subcutaneous veins three millimeters or greater in size.

Telangiectases (i.e. spider veins, spider burst, web veins, thread veins, dilated venules) are permanently dilated blood vessels less than 1 mm in diameter.

Reticular Veins are abnormal dilations of the normal plexuses venosus appearing as a bluish or greenish net and are usually 2-4 mm in diameter.

Venulectasias are bluish vessels sometimes distended above the skin surface and most often 1-2 mm in diameter.

Venous anatomy can vary significantly between individuals by the presence or absence of accessory veins. Extensions of the great saphenous vein include the anterior, posterior, and superficial accessories and the anterior and posterior thigh circumflex veins. Extensions of the lesser saphenous vein include the cranial extension (vein of Giacomini) and the superficial accessory.

In most persons varicose veins do not cause symptoms and do not require medical treatment. Varicose vein surgery is one of the most commonly performed cosmetic procedures.

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 greater or lesser saphenous veins are eliminated and blood flow is diverted through the accessory veins.

Saphenous Veins and Tributaries

Saphenous veins include the greater and lesser saphenous and accessory saphenous veins that travel in parallel with the greater or lesser 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
3. Removal of the superficial vein from circulation, for example by stripping of the greater and/or lesser 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 have been investigated. These include sclerotherapy, transilluminated powered phlebectomy, 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 produced by

forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment and is considered an off-label use. A proprietary microfoam sclerosant (Varisolve, BTG PLC, London) with a controlled density and more consistent bubble sizes is being developed in Europe.

Thermal Ablation

Radiofrequency (RFA) 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 greater 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 lesser saphenous vein.

Stab Phlebectomy/Micro-Incisional Phlebectomy

A small incision(s) is made over a localized area of superficial varicose veins along the leg. The veins are isolated and dissected free of neighboring tissue and tied with sutures or stripped out bluntly.

Transilluminated Powered Phlebectomy

Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or hook phlebectomy. This procedure uses 2 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 US 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 RF has also been reported.

Other

Deep vein valve replacement is being investigated.

Outcomes of interest for venous interventions include healing and recurrence, recannulation of the vein, and neovascularization. Recannulation (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 greater saphenous vein of the thigh in patients with superficial vein reflux."
- 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 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.”
- Varisolve® (BTG PLC, London) is a sclerosant microfoam made with a proprietary gas mix. A phase II safety study for the FDA has been completed. In late October 2009, the sponsor submitted a request to the FDA for a protocol assessment to agree on the design, endpoints and statistical analyses for the phase III trial.

POLICY

I. Greater Lesser Saphenous Veins

- A. Treatment of the greater or lesser saphenous veins by surgery (ligation and stripping) or endovenous radiofrequency or laser ablation may be considered **medically necessary** for symptomatic varicose veins/venous insufficiency when all the following criteria have been met:
1. There is demonstrated saphenous reflux;
AND
 2. There is documentation of one or more of the following indications:
 - a. Ulceration secondary to venous stasis that fails to respond to compressive therapy; OR
 - b. Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; OR
 - c. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
 - d. --Persistent pain, swelling, itching, burning, or other symptoms or significant refractory edema or refractory stasis dermatitis when 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.
 AND
 3. Physical / visible findings that support medically significant venous hypertension are clearly documented.
- B. Treatment of greater or lesser saphenous veins by surgery or endovenous radiofrequency or laser ablation that do not meet the criteria described above is considered **not medically necessary**.
- C. Treatment of varicose veins for cosmetic purposes is **not covered**.

II. Accessory Saphenous Veins

A. Treatment of accessory saphenous veins by surgery (ligation and stripping) or endovenous radiofrequency or laser ablation may be considered **medically necessary** for symptomatic varicose veins/venous insufficiency when all the following criteria have been met:

1. The greater or lesser saphenous veins had been previously eliminated (at least 3 months);

AND

2. There is demonstrated accessory saphenous reflux;

AND

3. There is documentation of one or more of the following indications:

- a. Ulceration secondary to venous stasis that fails to respond to compressive therapy; OR
- b. Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; OR
- c. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
- d. --Persistent pain, swelling, itching, burning, or other symptoms or significant refractory edema or refractory stasis dermatitis when associated with accessory vein 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.

AND

4. Physical / visible findings that support medically significant venous hypertension are clearly documented.

B. Treatment of accessory saphenous veins that do not meet the criteria described above is considered **not medically necessary**.

C. Treatment of varicose veins for cosmetic purposes is **not covered**.

III. Symptomatic Varicose Tributaries

A. The following treatments are considered **medically necessary** as a component of the treatment of symptomatic varicose tributaries (none of these techniques has been shown to be superior to another):

1. Stab avulsion
2. Hook phlebectomy
3. Sclerotherapy
4. Transilluminated powered phlebectomy

B. Physical findings must support medical necessity.

- C. Sclerotherapy as the sole treatment of varicose vein tributaries in the presence of saphenofemoral or saphenopopliteal reflux is considered **not medically necessary**.
- D. Treatment of tributary veins less than 3 mm is considered **cosmetic and not covered**.

IV. Perforator Veins

- A. Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered **medically necessary** as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met:
 - 1. There is demonstrated perforator reflux; AND
 - 2. The superficial saphenous veins (greater, lesser, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; AND
 - 3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND
 - 4. The venous insufficiency is not secondary to deep venous thromboembolism.
- B. Treatment of incompetent perforator veins without refractory stasis ulceration is considered **not medically necessary** as discussed in references 3 and 41:
 - 1. "Patients with isolated reflux in perforator veins...are generally asymptomatic; reflux at multiple valve sites is required for symptom expression."
 - 2. "Reflux in perforator veins that are smaller than 4mm in diameter is not considered to be clinically significant."
 - 3. "In complex venous disease, comprehensive correction is neither feasible nor necessary; partial correction of multifocal disease often relieves symptoms."
 - 4. "The role of interruption of the perforator vein is controversial because of doubts about the pathologic significance of reflux involving this vein and because its specific efficacy is uncertain."
 - 5. "The role of perforator vein ablation awaits results, of properly conducted randomized controlled trials."
 - 6. Perforator reflux often resolves following saphenous ablation.
- C. Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is **not medically necessary**.

V. Telangiectasia

Treatment of telangiectasia such as spider veins, angiomata, and hemangiomata is considered **cosmetic and not covered**.

VI. Other

A. Techniques for conditions not specifically listed above are considered **not medically necessary**, including, but not limited to:

1. Sclerotherapy, stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, greater or lesser saphenous, or accessory saphenous veins.
2. Sclerotherapy of isolated tributary veins without prior or concurrent evaluation of saphenous reflux.

B. Techniques for conditions not specifically listed above are considered **experimental / investigational**, including, but not limited to:

1. Endovenous radiofrequency or laser ablation of tributary veins.
2. Endovenous cryoablation of any vein.

Policy Guidelines

1. A clear and complete description of the physical exam of the lower extremities that documents the medical necessity of treatment for venous insufficiency for medical, not cosmetic purposes, is required. Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is **not covered**. Photographs may be requested.
2. Up to 20 injections in each leg may be treated in any one session and up to 3 sclerotherapy sessions for each leg may be considered medically necessary if selection criteria are met.
3. Following successful ablation of the greater saphenous vein, tributary veins can become more prominent, but usually improve over time; therefore, delaying treatment of these smaller veins will minimize the number of veins that need treatment.
4. Patients with combined deep and superficial venous insufficiency are often not good candidates for ablation therapy. Varicose vein recurrence and ulcer recurrence rates following intervention are much higher. However, deep vein insufficiency is not a contraindication to superficial vein treatment.
5. There is little evidence to support that ultrasound guidance makes a significant difference in outcomes from sclerotherapy when compared to non-ultrasound guided techniques.

Claims Submission Instructions

1. CPT code 36470 should be used when only one vein is injected on a given date of service.
2. CPT code 36471 should be used when more than one vein in the same leg is injected on a given date of service.
3. If both legs are injected, right and left modifier should be used on claims with the codes to indicate which leg is being treated. The following coding conventions should be used:
 - One vein on the left; two veins on the right: 36470 LT and 36471 RT. Injections for each leg should be reported on a separate line.
 - One vein on each leg: Use 36470 RT and 36470 LT.
 - Two veins on the right; three on the left: 36471 RT and 36471 LT.
 - In each case, the correct quantity to bill is one unit per code.
4. For less than 10 phlebectomies, CPT code 37799 should be used, modifier 22 added and box 19 of the claim form populated with "phlebectomies less than 10".

Reimbursement

1. The use of the following ultrasound guidance procedures (76937, 76942, 76998, 76999, 93965, 93970, 93971, S2202) during varicose vein surgery is considered content of service.
2. CPT codes 93965, 93970 or 93971 Doppler ultrasound should not be billed for intraoperative procedures. If these codes are billed separately as the initial diagnostic tool for mapping, the claim will be allowed if medically necessary. Any additional scans over the initial mapping may be reviewed for medical necessity.
3. Selective catheter placement is content of service of a covered procedure.
4. Reimbursement for sclerotherapy will be limited to 3 sessions.

RATIONALE

Literature review

Treatment of Saphenous Reflux

Compression Therapy

A 2009 Cochrane review on compression for venous ulcers included a total of 39 randomized, controlled trials (RCTs), with 47 different comparisons. (1) Objective measures of healing were the time to complete healing, the proportion of ulcers healed within the trial period (typically 12 weeks), the change in ulcer size, and the rate of change in ulcer size. Evidence from 7 trials indicated that venous ulcers healed more rapidly with compression than without. Findings from 6 trials suggested that multi-component systems (bandages or stockings) were more effective than single-component compression. In addition, multi-component systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although this meta-analysis did not include time to healing, studies included in the review reported that the mean time to ulcer healing was approximately 2 months, while the median time to healing in other reports was 3 to 5 months.

A Cochrane review on compression stockings for the initial treatment of varicose veins in patients without venous ulceration was published in 2011. (2) Included in the review were 7 studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] classification C2 to C4). Six of the studies compared different types or pressures of stockings. Subjectively, participants' symptoms improved, but results were not compared with a control arm. Due primarily to inadequate reporting, the methodologic quality of the included trials was unclear. Meta-analyses were not performed due to inadequate reporting and suspected heterogeneity. The authors concluded that there is insufficient high-quality evidence to determine whether or not compression stockings are effective as the sole and initial treatment of varicose veins in patients without venous ulceration, or whether any type of stocking is superior to any other type.

Ligation and Stripping

Systematic literature reviews published in 2008 indicate a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery. (3, 4) In general, recurrence rates after ligation and stripping are estimated at around 20%. Jones and colleagues reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping. (5) At 1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy. (6) At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

A 2011 Cochrane review compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus ligation/stripping for saphenous vein varices. (7) Included in the review were 13 reports from 5 studies with a combined total of 450 patients. Many of the comparisons between endovenous ablation and ligation/stripping failed to reach statistical significance. The authors concluded that current evidence suggests that endovenous radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are at least as effective as surgery in the treatment of great saphenous varicose veins. No randomized trials comparing sclerotherapy with ligation/stripping met the study inclusion criteria, and there were thus insufficient data to comment on ultrasound-guided sclerotherapy.

Endovenous Radiofrequency Ablation

In 2008, Luebke and colleagues reported a meta-analysis of 8 studies that included a total of 224 patients who underwent RFA and 204 patients who underwent stripping. (8) There was no significant difference between RFA and surgery in immediate or complete greater saphenous vein occlusion, incomplete greater saphenous vein closure, freedom from reflux, recurrent varicose veins, recanalization, or neovascularization between the 2 treatments. There were significant reductions in tenderness and ecchymosis at 1 week and fewer hematomas at 72 hours, 1 week, and 3 weeks with RFA. Quality-of-life results, including return to normal activity and return to work, favored RF over surgery. The authors noted that rates of recanalization, retreatment, occlusion, and reflux may alter with longer follow-up and that further RCTs with longer follow-up are needed.

Long-term outcomes of endovenous RFA were reported from the Closure Study Group clinical registry in 2005. (9) Thirty-four centers (1,006 patients, 1,222 limbs) participated in the registry, with 12 centers contributing 5-year data (406 limbs). The registry included data on the treatment

of 52 lesser saphenous veins and 16 accessory saphenous veins. Follow-up at 1 week showed a 97% anatomical success rate and a decrease in pain in 50% (from 85% to 30%) of patients. An additional 162 failures were identified over the 5 years of follow-up; 129 veins were found to have recanalization, and 33 limbs had reflux in the groin. Logistic regression analysis (risk factors of gender, age, body mass index [BMI], vein diameter, and catheter pullback speed) showed that BMI was associated with long-term failure. The rate of pull-back speed of the catheter during treatment was associated with failure to occlude or recanalization.

Endovenous Laser Ablation

A systematic review of EVLA versus surgery was published in 2009. (10) Fifty-nine studies were included, with 7 studies that directly compared EVLA and surgery. Randomized and nonrandomized studies directly comparing outcomes for EVLA or surgery were included for the assessment of safety or effectiveness, while case series with a minimum patient population of 100 were included for the assessment of safety alone. For all studies, it was calculated that 5,759 patients (6,702 limbs) were treated with EVLA and 6,395 patients (7,727 limbs) underwent surgery. Few differences were apparent between treatments with respect to clinical effectiveness outcomes, although long-term follow-up was lacking. Nonclinical effectiveness outcomes generally favored EVLA over surgery in the first 2 months after treatment. The authors concluded that while EVLA offers short-term benefits and appears to be as clinically effective as surgery up to 12 months after treatment, clinical trials with a minimum of 3 years of follow-up are required to establish the enduring effectiveness of EVLA.

In 2009 Theivacumar et al. reported 2-year follow-up from 118 consecutive patients treated with either EVLA (69 limbs) or ligation and stripping (n=60 limbs). (11) Sixty-eight of the patients agreed to be randomized to treatment; the remainder declined randomization but received one of the 2 treatments and agreed to follow-up. The rationale for the selection of treatment in the nonrandomized population was not described. Rates of clinical recurrence (7%) were similar in the 2 treatment groups at 2 years. Recanalization of the residual greater saphenous vein, reflux in the accessory greater saphenous vein, and reflux in incompetent perforator veins accounted for the majority of cases of clinical recurrence (6%) in both groups. Neovascularization was observed in only 1% of limbs treated with endoluminal ablation and 18% of limbs treated with ligation and stripping (2% were clinically significant at 2 years). Early neovascularization has been associated with clinical recurrence at 5 years.

The 2011 literature update identified 2 RCTs on EVLA. Rasmussen et al. randomized 121 patients (137 legs) to EVLA (n=69) or to ligation and stripping (n=68). (12) The incidence of clinical recurrence was found to increase gradually from 6 months onward. At 2-year follow-up, outcomes were similar between the 2 groups. In the EVLA group, there were 3 (4%) technical failures, 18 (26%) clinical recurrences, 6 (8%) cases of reflux into the anterior accessory saphenous vein, 2 (3%) cases of reflux in the groin, and 7 (10%) cases of reflux in perforator veins. In the ligation and stripping group, there were 2 (3%) technical failures, 25 (37%) recurrences, 3 (4%) cases of reflux in the accessory vein, 3 (4%) cases of reflux in the groin, and 15 (22%) cases of reflux in perforator veins. Another trial compared EVLA with ligation and stripping in 200 limbs (100 in each group). (13) At 1-year follow-up, 98% of the limbs were reported to be free of symptoms. At 2-year follow-up, the EVLA group had 2 veins completely reopened and 5 partially reopened, which was significantly greater than in the ligation and stripping group.

Endovenous Cryoablation

Klem and colleagues reported a randomized trial in 2009 that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins. (14) The percentage of patients with greater saphenous vein remaining was 44% in the endovenous cryoablation group and 15% in the conventional stripping group. The Aberdeen Varicose Vein Questionnaire also showed better results for conventional stripping (score of 11.7) in comparison with cryoablation (score of 8.0). There were no differences between the groups in Short-Form-36 (SF-36) subscores, and neural damage was the same (12%) in both groups.

Disselhoff and colleagues reported 2 and 5 year outcomes from a randomized trial that compared cryostripping with EVLA. (15, 16) Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP C2) with saphenofemoral incompetence and greater saphenous vein reflux. At 10 days after treatment, EVLA had better results than cryostripping with respect to pain score over the first 10 days (2.9 vs. 4.4), resumption of normal activity (75% vs. 45%) and induration (15% vs. 52%). At 2 year follow-up, freedom from recurrent incompetence was observed in 77% of patients after EVLA and 66% of patients after cryostripping (not significantly different). At 5 years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization was found in 62% of patients treated with EVLA and 51% of patients treated with cryostripping (not significantly different). Neovascularization was more common after cryostripping, but incompetent tributaries were more common after EVLA. There was no significant difference between groups in the Venous Clinical Severity Score or Aberdeen Varicose Vein Severity Score at either 2 or 5 years.

Sclerotherapy

A comprehensive systematic review of sclerotherapy commissioned and funded by the U.K.'s National Institute for Health and Clinical Excellence (NICE) in 2006 reviewed 67 studies, including 9 RCTs, 1 registry report, 8 nonrandomized comparative studies, 43 case series, and 6 case reports. (17, 18) The report concluded that sclerotherapy "appears to be efficacious in occluding incompetent veins, including both main trunk and minor vein disease, however its longer-term efficacy in terms of recurrence or new varicosities is less certain," and that "Estimates were based mainly on data from nonrandomized studies with a high dropout rate and no details of methods of follow-up, and as such may be prone to attrition bias." More recent randomized trials using ultrasound-guided foam sclerotherapy of the greater saphenous vein (with or without ligation) showed high variability in success rates between centers (ranging from 25% to 100%) and a decline in success rates from 85% at 3-week follow-up to 53% at 2 years. (19, 20) Other studies indicate efficacy rates ranging from 12% to 76% for liquid sclerosant and from 57% to 84% for foam sclerosant. (21)

A systematic review from 2008 found that foam sclerotherapy of varicose veins is associated with a higher recurrence rate in patients with saphenofemoral incompetence compared to the rates of endovenous laser therapy or RF obliteration, while a 2009 systematic review suggested that outcomes from sclerotherapy are worse than those of surgery (ligation and stripping) for saphenous vein reflux. (22, 23) Although long-term sequelae have not been reported, transient adverse effects have been found in up to 8% of patients, including visual disturbance, migraine, shortness of breath, dizziness, and numbness. (24) Bubbles appear in the right heart between 9 and 59 seconds after injection, and emboli have been detected in the middle cerebral artery following sclerotherapy of saphenous trunks and varices. (24) Deep venous occlusion after

ultrasound-guided sclerotherapy has also been reported; risk was found to be greater when treating veins 5 mm in diameter or greater (odds ratio [OR]: 3.7) and injecting 10 mL or more of foamed sclerosant (OR: 3.6). (25)

Blaise et al. reported 3-year follow-up from a multicenter double-blind randomized trial (143 patients) that compared treatment of the greater saphenous vein with either 1% or 3% polidocanol foam. (26) Additional treatment with foam sclerotherapy was carried out at 6 weeks, 3 and 6 months if required to abolish persistent venous reflux. There were 49 additional injections in the 1% polidocanol group and 29 additional injections in the 3% group. At 3-year follow-up, venous reflux was observed in 21% of patients in the 1% group and 22% of patients in the 3% polidocanol group.

Treatment of Tributary Varicosities

Sclerotherapy and Phlebectomy

Early studies established ligation and stripping as the gold standard for the treatment of saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A 2006 Cochrane Review, based primarily on RCTs from the 1980s, concluded that, "The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins." (27) Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system, e.g., post- or adjunctive treatment to other procedures such as surgery. (23)

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. For example, of 1,009 patients recruited for an RCT, 64 patients were found to have minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. (28) At baseline, 92% had symptoms of heaviness, 69% had cosmetic concerns, 53% reported itching, and 30% reported relief of symptoms through the use of compression hosiery. At 1 year follow-up, there was an improvement in clinicians' assessment of the anatomical extent of varicose veins, with 85% of patients in the sclerotherapy group improved compared to 29% of patients in the conservative-therapy group. Symptoms of aching were better or eliminated in 69% of the sclerotherapy group and 28% of the group treated with conservative therapy. Cosmetic concerns were improved in 85% of the sclerotherapy patients and 14% of controls.

The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. In 2012, Yamaki et al. reported a prospective randomized controlled trial that compared visual foam sclerotherapy vs. ultrasound-guided foam sclerotherapy of the greater saphenous vein together with visual foam sclerotherapy for varicose tributary veins. (29) A total of 51 limbs in 48 patients were treated with ultrasound-guided foam sclerotherapy plus visual foam sclerotherapy of the varicose tributaries, and 52 limbs in 49 patients were treated with foam sclerotherapy alone. At 6-month follow-up, complete occlusion was found in 23 limbs (45.1%) treated with ultrasound-guided and visual-guided foam sclerotherapy and in 22 limbs (42.3%) treated with visual sclerotherapy alone. Reflux was absent in 30 limbs (58.8%) treated with ultrasound and visual guidance and in 37 (71.2%) treated with visual guidance alone (not significantly different). The authors note that for the treatment of tributary veins in clinical practice, most patients receive direct injection of foam without ultrasound guidance.

Transilluminated Powered Phlebectomy (TIPP)

A 2008 meta-analysis included 5 studies that compared TIPP with conventional surgery. (30) Results showed a significant advantage of TIPP over the conventional treatment for number of incisions, mean cosmetic score, and duration of the procedure. However, TIPP also increased the incidence of hematoma and resulted in worse mean pain scores. Included in the meta-analysis was a randomized clinical trial by Chetter et al. that compared TIPP (n=29) with a multiple stab incision procedure (n=33). (31) A single surgeon performed all but 2 of the procedures, and there was no difference in operating time. Patients treated with TIPP had an average of 5 incisions, compared with 20 for the multiple stab procedure. However, blinded evaluation revealed that bruising or discoloration was higher for the TIPP group at both 1 and 6 weeks after surgery. At 6 weeks after surgery, patients in the TIPP group showed no improvement in pain (-2 points on the Burford pain scale), while patients in the multiple stab incision group had a significant improvement in pain score compared with presurgical baseline (-20 points). At 6 weeks after surgery, quality-of-life measures had improved in the multiple-stab incision group but not in the TIPP group. Thus, although TIPP had the advantage of fewer surgical incisions, in this single-center study, it was associated with a more prolonged recovery due to more extensive bruising, prolonged pain, and reduced early postoperative quality of life. The current literature does not show an advantage of TIPP over conventional treatment.

Treatment of Perforator Reflux

A systematic literature review published in 2008 indicates insufficient evidence for the role of incompetent perforator vein surgery. (4) These conclusions were based on 4 RCTs published since 2000 that compared superficial vein surgery with conservative therapy in advanced chronic venous insufficiency (CEAP category C5/6). The 4 trials included 2 level I (large subject population) and 2 level II (small subject population) studies. Two of the trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other 2 treated the greater saphenous vein alone. The 2 randomized studies in which the greater saphenous vein alone was treated (including the ESCHAR trial) showed a significant reduction in ulcer recurrence in comparison with conservative therapy. (32, 33) A 2011 community hospital-based multicenter, double-blind, randomized trial found no clinical benefit (self-reported symptoms) from adding subfascial endoscopic perforator surgery (SEPS) to saphenous surgery in 75 patients with varicose ulcers (CEAP C5 or C6) and incompetent perforators. (34)

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, one study showed that reversal of perforator vein incompetence (41% of 68 previously incompetent perforators) was more common than new perforator vein incompetence (22% of 183 previously competent perforators) following superficial vein surgery. (35) O'Donnell discusses additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. (4) Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

Subfascial Endoscopic Perforator Surgery (SEPS)

In 2004, Tenbrook and colleagues published a review of the literature of SEPS, which included 19 case series and one randomized trial. (36) In total, the reviewed studies included 1,031 patients with 1,140 treated limbs. The authors concluded that SEPS was associated with excellent results in terms of ulcer healing and prevention of recurrence. However, the authors also noted that

randomized trials are required to define the relative contributions of compression therapy, superficial venous surgery, and SEPS in the management of severe venous disease. A 2009 meta-analysis of SEPS for chronic venous insufficiency concludes that "Its [SEPS] use should not be employed routinely and could only be justified in patients with persistent ulceration thought to be of venous origin, and in whom any superficial reflux has already been ablated and post-thrombotic changes excluded." (37) The authors also state that "introduction of less invasive techniques for perforator vein ablation, such as ultrasound-guided sclerotherapy or radiofrequency ablation, may diminish the role of SEPS in the future."

Other Treatments

A 2008 review of procedures for management of varicose veins recommends duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short RF catheter for the treatment of symptomatic residual perforator vein incompetence. (38) Ablation of incompetent perforator veins with laser or RFA had been shown to be technically feasible, although no studies had been identified that showed an improvement in clinical outcomes (e.g., ulcer healing or recurrence). (18-20, 26) The 2011 literature update identified one study of EVLA for perforating veins in 33 patients with a CEAP classification of 4 (skin changes), 5 (healed ulcer), or 6 (active ulcer). (39) All incompetent saphenous trunks were treated simultaneously (63% of limbs). At 3-month follow-up, occlusion was achieved in 78% of the perforating veins. Five patients (15%) had active ulcers at baseline; 4 of the 5 ulcers had healed by 6 weeks after EVLA. Evidence regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion. (25)

Summary

Although randomized, controlled trials with longer follow-up are needed to evaluate long-term durability, and repeat treatments may be required, evidence indicates that endovenous treatment of saphenous veins with radiofrequency or laser ablation improves short-term clinical outcomes (e.g., pain and return to work) in comparison with surgery. In contrast, results from a recent randomized, controlled trial of cryoablation indicate that this therapy is inferior to conventional stripping. Sclerotherapy as the sole treatment of saphenofemoral or saphenopopliteal reflux has not been demonstrated to be as effective as available alternatives.

The literature indicates that sclerotherapy of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins may be considered medically necessary. Evidence is insufficient to evaluate the health benefit of sclerotherapy as a sole treatment of varicose tributaries without prior or concurrent treatment of the saphenous veins. No studies have been identified that compare radiofrequency 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 literature indicates that the routine ligation/ablation of incompetent perforator veins is not medically 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 (i.e., ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (e.g., deep vein valve replacement). Therefore, treatment of incompetent perforator veins may be considered medically necessary in this specific situation.

Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. SEPS has been shown to be 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 in comparison with surgical interventions. For sclerotherapy, concerns have been raised about the risk of deep vein occlusion, and evidence is currently insufficient to evaluate the safety or efficacy of this treatment for incompetent perforator veins.

Practice Guidelines and Position Statements

The Society for Vascular Surgery and the American Venous Forum published clinical practice guidelines in 2011. (40) The recommendations are rated as strong=1 or weak=2, based on a level of evidence that is either high quality=A, moderate quality=B, or low quality=C, and include the following:

Compression therapy for venous ulcerations and varicose veins: Compression therapy is recommended as the primary treatment to aid healing of venous ulceration (GRADE 1B, strong recommendation, moderate quality evidence). To decrease the recurrence of venous ulcers, they recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A, strong recommendation, high quality evidence). They recommend use of compression therapy for patients with symptomatic varicose veins (GRADE 2C, weak recommendation, low-quality evidence) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B, strong recommendation, moderate quality evidence).

Treatment of the incompetent great saphenous vein: Endovenous thermal ablation (radiofrequency or laser) is recommended over chemical ablation with foam (GRADE 1B, strong recommendation, moderate quality evidence) or high ligation and stripping (GRADE 1B, strong recommendation, moderate quality evidence) 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.

Varicose tributaries: Phlebectomy or sclerotherapy are recommended to treat varicose tributaries (GRADE 1B, strong recommendation, moderate quality evidence). Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy (GRADE 2C, weak recommendation, low quality evidence).

Perforating vein incompetence: Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended (CEAP class C2; GRADE 1B, strong recommendation, moderate quality evidence), but there is a GRADE 2B recommendation (weak recommendation, moderate quality evidence) for 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) by subfascial endoscopic perforating vein surgery, sclerotherapy, or thermal ablations (GRADE 1C, weak recommendation, low quality evidence).

In 2009, the American College of Radiology published appropriateness criteria for the treatment of lower-extremity venous insufficiency. (41) The following is a summary of treatment options:

Compression Stockings: Graduated compression stockings are routinely used to control venous insufficiency symptoms. They provide external support that can constrict dilated veins and restore competence to incompetent valves. Compression stockings are particularly helpful during pregnancy, and they are frequently used following venous ablation treatment.

Surgery: Great saphenous vein (GSV) stripping with branch ligation had historically been the primary treatment option for venous insufficiency. The GSV is ligated near the groin. Ligation alone can preserve the vein for subsequent harvesting in case of arterial bypass; however, ligation alone has proven unsatisfactory for preventing the occurrence of reflux, so it is often supplemented by vein stripping. Ambulatory phlebectomy is primarily used to treat surface varicose veins. It can be performed as an adjunct to endovenous ablation or stripping. This procedure involves making tiny punctures or incisions through which the varicose veins are removed. Other surgical methods to treat venous insufficiency have been described, including SEPS for treating venous ulcers and valvular surgery for treating reflux caused by incompetent valves of the deep veins.

Injection Sclerotherapy: Injection sclerotherapy is a common treatment for telangiectasias and can be used to treat smaller varicose veins. The sclerotherapy solution can be in liquid form or can be injected as "foam" (mixed with a gas such as air). Sclerotherapy has not been shown to have long-term effectiveness for large veins, such as the GSV.

Endovenous Ablation: Endovenous ablation is a minimally invasive alternative to surgery. It is a percutaneous procedure that can be used to treat the GSV, small saphenous vein (SSV), and other superficial veins. Endovenous ablation uses RFA or laser energy (EVLA) applied inside the vein to cause occlusion. Small prospective trials comparing EVLA and RFA with conventional surgery in patients with GSV reflux have shown favorable results. One study demonstrated that EVLA is comparable to surgery in abolishing reflux and improving disease-specific quality of life and that it allows earlier return to normal activity. A recent systematic literature review comparing the safety and efficacy of EVLA and surgery involving saphenous ligation and stripping as treatments for varicose veins showed few differences in clinical effectiveness outcomes, although long-term follow-up was lacking. A meta-analysis suggested that EVLA and RFA are at least as effective as surgery in treating lower-extremity varicose veins. After 3 years, the estimated pooled success rates for treatment were 78% for surgical stripping, 77% for foam sclerotherapy, 84% for RFA, and 94% for laser therapy.

Adjunctive Treatments: Adjunctive treatments may be required to help eliminate venous insufficiency. Patients with venous insufficiency and associated venous occlusion or stenosis of the common iliac vein (e.g., May-Thurner syndrome) may require venous recanalization with angioplasty and stenting to achieve a patent conduit for venous return. Patients with pelvic venous insufficiency may require percutaneous embolization of the ovarian veins. Patients with deep venous thrombosis are typically treated with anticoagulation to reduce the risk of thrombus propagation, embolization, and post-thrombotic syndrome. One study suggested that endovenous ablation of the saphenous vein can be considered as a viable treatment alternative in patients with venous insufficiency and previous deep venous thrombosis.

Complications: All forms of lower-extremity venous insufficiency treatment are subject to recurrence. Additional risks of vein ligation and stripping surgery include: anesthetic risk, scarring, pain, bleeding, deep venous injury or thrombosis, nerve injury, and infection.

Complications of the endovenous ablation procedure include bruising, swelling, transient numbness, and rarely deep venous thrombosis.

In 2003, the Society of Interventional Radiography (SIR) published a position statement (42) that considered endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins under the following conditions:

1. The endovenous treatment of varicose veins may be medically necessary when one of the following indications (A–E) is present:
 - A. Persistent symptoms interfering with activities of daily living in spite of conservative/nonsurgical management. Symptoms include aching, cramping, burning, itching, and/or swelling during activity or after prolonged standing.
 - B. Significant recurrent attacks of superficial phlebitis
 - C. Hemorrhage from a ruptured varix
 - D. Ulceration from venous stasis where incompetent varices are a contributing factor
 - E. Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above)
2. and; A trial of conservative, nonoperative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.
3. and; The patient's anatomy is amenable to endovenous ablation.

In a joint statement published in 2007, the American Venous Forum and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency. (43) The document recommended that reporting in clinical studies should include the symptoms of venous disease, history of disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation may include patients with reflux in an incompetent greater saphenous vein or smaller saphenous vein or in a major tributary branch of the greater or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory greater saphenous vein. The presence of reflux in these veins is important to document using duplex ultrasound imaging, and the ultrasound criteria used to define reflux should be indicated. It was also stated that in current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 to 1.0 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

In 2003 and 2004, the U.K.'s National Institute for Health and Clinical Excellence (NICE) published guidance on radiofrequency ablation of varicose veins and on endovenous laser treatment of the long saphenous vein. (44, 45) NICE concluded that the evidence on the safety and efficacy appeared adequate to support the use of these procedures provided that the normal arrangements were in place for consent, audit, and clinical governance. The evidence on efficacy at this time was limited to case series with limited follow-up. Clinicians were encouraged to collect longer-term follow up data.

NICE issued updated guidance on ultrasound-guided foam sclerotherapy for varicose veins in 2009. (46) The guidance states that "...current evidence on ultrasound-guided foam sclerotherapy for varicose veins shows that it is efficacious in the short term. The evidence on safety includes systemic side effects in some patients. Therefore, this procedure should only be

used with special arrangements for clinical governance, consent and audit." In addition, evidence of long-term efficacy is limited, and clinicians are encouraged to collect longer-term follow-up data.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 36468 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
- 36469 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face
- 36470 Injection of sclerosing solution: single vein
- 36471 Injection of sclerosing solution; multiple veins, same leg
- 36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
- 36476 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
- 36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
- 36479 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
- 37250 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel (List separately in addition to code for primary procedure)
- 37251 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)
- 37500 Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
- 37700 Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
- 37718 Ligation, division, and stripping, short saphenous vein
- 37722 Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
- 37735 Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
- 37760 Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg
- 37761 Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg

- 37765 Stab phlebectomy of varicose veins, 1 extremity; 10-20- stab incisions
- 37766 Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
- 37780 Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
- 37785 Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
- 37799 Unlisted procedure, vascular surgery
- 76937 Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)
- 76942 Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
- 76998 Ultrasonic guidance, intraoperative
- 76999 Unlisted ultrasound procedure (e.g. diagnostic, interventional)
- 93965 Non-invasive physiologic studies of extremity veins, complete bilateral study (e.g. Doppler waveform analysis with responses to compression and other maneuvers, phleborheography, impedance plethysmography)
- 93970 Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
- 93971 Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study
- S2202 Echosclerotherapy

- There is no specific CPT code for transilluminated powered phlebectomy. Providers might elect to use CPT codes describing stab phlebectomy (37765 or 37766) or unlisted vascular surgery procedure (37799).
- Note: The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. If ultrasound guidance (CPT code 76942) is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

DIAGNOSIS

- 454.0 Varicose veins of lower extremities; with ulcer
- 454.1 Varicose veins of lower extremities; with inflammation
- 454.2 Varicose veins of lower extremities; with ulcer and inflammation
- 454.8 Varicose veins of lower extremities; with other complications
- 454.9 Varicose veins of lower extremities; asymptomatic varicose veins

REVISIONS

10-11-2010	Description section updated In Policy section: <ul style="list-style-type: none"> ▪ Revised policy language to current policy from the following: "BCBSKS will cover the treatment of varicose veins by ligation and stripping, endovenous laser or radiofrequency ablation, stab phlebectomy, or sclerotherapy, according to the following guidelines (must meet all five conditions listed below): 1. The patient must have undergone at least a 3 month trial of conservative medical therapy such as leg elevation, compressive elastic stockings (support
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	<p>hose) and weight loss (when appropriate). This must be documented in the medical record.</p> <ol style="list-style-type: none"> 2. One of the following conditions can be attributed to the varicosities: <ol style="list-style-type: none"> a. Pain in the affected extremities with impairment of mobility and activities of daily living, b. Significant recurrent superficial phlebitis, c. Skin ulcerations, d. Bleeding, e. Refractory dependent edema not attributed to other causes, f. Other complications from venous stasis such as dermatitis, 3. Documentation that tributary veins treated are 3 mm in diameter or larger. 4. Documentation of valvular incompetence of the greater, lesser accessory, or saphenous veins by Doppler or duplex ultrasound scanning when these specific veins are being treated. A clear description of the varicose vein related physical exam findings. Documentation by photograph(s) may be requested. <p><u>Not Medically Necessary / Experimental / Excluded Services / Content of Service</u></p> <ol style="list-style-type: none"> 1. Sclerotherapy and /or surgical interventions, for the treatment of telangiectasia veins, reticular veins, or other tributary veins less than 3 mm in diameter are considered cosmetic. 2. The following codes for the treatment of varicose veins are cosmetic and not covered: <ul style="list-style-type: none"> ▪ 36468 - Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk ▪ 36469 - Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face 3. The use of the following ultrasound guidance procedures (76937, 76942, 76998, 76999, 93965, 93970, 93971, S2202) during varicose vein surgery is considered content of service. 4. Sclerotherapy for the greater saphenous vein or varicose veins greater than 7 mm is considered ineffective and denied not medically necessary. 5. Selective catheter placement is content of service of a covered procedure. 6. CPT codes 93965, 93970 or 93971 should not be billed for intraoperative procedures. If these codes are billed separately as the initial diagnostic tool for mapping, the claim will be allowed if medically necessary. Any additional scans over the initial mapping will be reviewed for medical necessity. 7. Treatment of incompetent perforator veins is considered not medically necessary as demonstrated in references 20 and 21: <ul style="list-style-type: none"> ▪ "Patients with isolated reflux in perforator veins...are generally asymptomatic; reflux at multiple valve sites is required for symptom expression." ▪ "Reflux in perforator veins that are smaller than 4mm in diameter is not considered to be clinically significant." ▪ "In complex venous disease, comprehensive correction is neither feasible nor necessary; partial correction of multifocal disease often relieves symptoms." ▪ "The role of interruption of the perforator vein is controversial because of doubts about the pathologic significance of reflux involving this vein and because its specific efficacy is uncertain." ▪ "The role of perforator vein ablation awaits result, of properly conducted
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	<p>randomized controlled trials."</p> <p><u>Billing Instructions for Sclerotherapy</u></p> <ol style="list-style-type: none"> 1. CPT code 36470 should be used when only one vein is injected on a given date of service. 2. CPT code 36471 should be used when more than one vein in the same leg is injected on a given date of service. 3. If both legs are injected, right and left modifier should be used on claims with the codes to indicate which leg is being treated. The following coding conventions should be used: <ul style="list-style-type: none"> ▪ One vein on the left; two veins on the right: 36470 LT and 36471 RT. Injections for each leg should be reported on a separate line. ▪ One vein on each leg: Use 36470 RT and 36470 LT. ▪ Two veins on the right; three on the left: 36471 RT and 36471 LT. ▪ In each case, the correct quantity to bill is <u>one</u> unit per code. 4. CPT code 37799, when used for stab phlebectomy less than 10 with a diagnosis code of 454.0, 454.1, 454.2, or 454.8, modifier 22 should be added and box 19 of the claim form populated with "stab phlebectomy less than 10". <p>Endovenous ablation (36475, 36476, 36478 and 36479) other than the greater, accessory or small saphenous vein will be reimbursed at 25% of full.</p> <p>Refunds will be sought on all claims not meeting policy and documentation requirements or inappropriately billed."</p> <ul style="list-style-type: none"> ▪ Removed the following language: "Miscellaneous C.E.A.P. Classifications of Venous Disorders a. Classification "C" Class 0 – No visible venous disease Class 1 – Telangiectasia or Reticular veins Class 2 – Varicose Veins Class 3 – Varicose Veins with edema Class 4 – Varicose veins with skin changes without ulceration Class 5 – Varicose veins with a healed ulcer Class 6 – Varicose veins skin changes with an active ulcer <p>After this number:</p> <ul style="list-style-type: none"> ▪ the letter "a" is assigned if the patient is asymptomatic, or ▪ the letter "s" is assigned if the patient experiences symptoms <ol style="list-style-type: none"> b. Etiology "E" Indicate if the vein is "c" congenital disease, "p" primary disease (not due to another cause) or "s" secondary venous disease, usually due to prior deep venous thrombosis. c. Anatomic Findings "As" or "Ad" Is usually based on Duplex ultrasound examination. The options are as follows: <u>Superficial Veins (As)</u> <ol style="list-style-type: none"> 1. Telangiectasias or reticular veins 2. Greater saphenous vein - above the knee 3. Greater saphenous vein - below the knee
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	<p>4. Lesser (short) saphenous vein 5. Nonsaphenous <u>Deep veins (Ad)</u> 1. Inferior vena cava 2. Common iliac 3. Internal iliac 4. External iliac 5. Pelvic: gonadal, broad ligament, etc. 6. Common femoral 7. Deep femoral 8. Superficial femoral 9. Popliteal 10. Crural: anterior tibial, posterial tibial, peroneal 11. Muscular: gastrocnemius, soleus, etc. <u>Perforating Veins</u></p> <ul style="list-style-type: none"> • Thigh • Calf <p>d. Pathophysiologic Component "P" "r" for reflux, "o" for obstruction, or "r, o" for both reflux and obstruction may be used In addition, a disability score for chronic venous insufficiency may be used, with:</p> <ul style="list-style-type: none"> ▪ "0" denoting a patient who is asymptomatic, and thus has no disability ▪ "1" denoting a patient who is symptomatic but can function without a support device ▪ "2" denoting a patient who can work an 8 hour day <i>only</i> with a support device ▪ "3" denoting a patient who is unable to work even with a support device <p>Example of the C.E.A.P. documentation: Rt leg: C1a,2a,3s-Ep-As1,2,3-Pr-1 Lt leg: C1a,2a-Ep-As1-P-0</p> <p>Policy Guidelines section added</p> <p>Rationale section added</p> <p>In Coding section: ▪ Updated wording, no codes removed or added.</p> <p>Rationale section updated</p>
<p>05-04-2011</p>	<p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Clarified policy by including within the Greater or Lesser Saphenous Veins, Accessory Saphenous Veins, and Symptomatic Varicose Tributaries sections of the policy the following: "B. Physical findings that support medically significant venous hypertension must be clearly documented." and "D. Treatment of varicose veins for cosmetic purposes is not covered." ▪ Clarified Policy Guidelines by: <ul style="list-style-type: none"> ▪ Adding to #1: "Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is not covered." to read "1. A clear and complete

	<p>description of the physical exam of the lower extremities that documents the medical necessity of treatment for venous insufficiency for medical, not cosmetic purposes, is required. Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is not covered. Photographs may be requested."</p> <ul style="list-style-type: none"> ▪ Revising #2: From "...up to 3 sclerotherapy sessions for both legs..." to "...up to 3 sclerotherapy sessions for each leg..." to read "Up to 20 injections in each leg may be treated in any one session and up to 3 sclerotherapy sessions for each leg may be considered medically necessary if selection criteria are met." ▪ Added to Policy Guidelines: "5. Patients with combined deep and superficial venous insufficiency are often not good candidates for ablation therapy. Varicose vein recurrence and ulcer recurrence rates following intervention are much higher." ▪ Removed from Policy Guidelines: "The severity of signs and symptoms of venous disease tends to correlate with the degree of reflux identified by duplex ultrasound." ▪ The intent of the policy language was not changed. <p>Rationale section update</p> <p>Revision section:</p> <ul style="list-style-type: none"> ▪ Removed revision details for 01-04-2008 and 07-18-2008 <p>References updated</p>
<p>09-06-2011</p>	<p>Description section updated.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Within the subsection of Greater or Lesser Saphenous Veins moved the following wording as a stand alone Item B. to be included with the medically necessary criteria as item A. 3. to read, "Physical findings that support medically significant venous hypertension are clearly documented." This change was made to be clearer that in addition to meeting the medical necessity criteria, physical findings that support medically significant venous hypertension must be clearly documented. ▪ Within the subsection of Accessory Saphenous Veins moved the following wording as a stand alone Item B. to be included with the medically necessary criteria as item A. 4. to read, "Physical findings that support medically significant venous hypertension are clearly documented." This change was made to be clearer that in addition to meeting the medical necessity criteria, physical findings that support medically significant venous hypertension must be clearly documented. ▪ Within the subsection of Symptomatic Varicose Tributaries, Item A. was liberalized from, "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..." to "The following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries..." ▪ Within the subsection of Symptomatic Varicose Tributaries, Item B. was revised from "Physical findings that support medically significant venous hypertension must be clearly documented." to "Physical findings must support medical necessity."

	Rationale section updated
	References updated
09-11-2012	Description section updated
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In I A 2 c and II A 3 c revised wording from "Recurrent hemorrhage or bleeding episodes..." to "Hemorrhage or recurrent bleeding episodes..." No policy intent change was made. ▪ In I A 3 and II A 4 clarified the wording from "Physical findings..." to "Physical / visible findings..." ▪ Added to IV Perforator Veins <p>"A. 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:</p> <ol style="list-style-type: none"> 1. There is demonstrated perforator reflux; AND 2. The superficial saphenous veins (greater, lesser, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; AND 3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND 4. The venous insufficiency is not secondary to deep venous thromboembolism." <ul style="list-style-type: none"> ▪ Moved from Policy Guidelines to IV B the not medically necessary indication of: "6. Perforator reflux often resolves following saphenous ablation." ▪ Added the not medically necessary indication of IV C: " C. Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary." ▪ In Policy Guidelines #4 added, "However, deep vein insufficiency is not a contraindication to superficial vein treatment." ▪ In Policy Guidelines Reimbursement sub-section item 1 revised, "...reimbursed at 25% of full." to read, "1. Endovenous ablation (36475, 36476, 36478 and 36479) other than the greater saphenous vein will be reimbursed at 50% of full."
	Rationale section updated
	<p>In Revision section:</p> <ul style="list-style-type: none"> ▪ Removed revision details for dates: 04-22-2009, 11-18-2009, 01-01-2010
	References updated
03-08-2013	<p>In the Reimbursement section:</p> <ul style="list-style-type: none"> ▪ Removed the reimbursement limitation stating, "Endovenous ablation (36475, 36476, 36478 and 36479) other than the greater saphenous vein will be reimbursed at 50% of full."

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