Corporate Medical Policy
Treatment of Varicose Veins/Venous Insufficiency

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Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract language, the member’s contract language takes precedence.

Medical Policy

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, 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 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 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 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 phlebotomy, 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 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.

**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 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, 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

Greater or Lesser Saphenous Veins

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 the following criteria have been met:
There is demonstrated saphenous reflux; AND
There is documentation of one or more of the following indications:

- Ulceration secondary to venous stasis that fails to respond to compressive therapy; OR
- Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; 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.

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 cosmetic and **not medically necessary**.

**Accessory Saphenous Veins**

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 the following criteria have been met:

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

There is demonstrated accessory saphenous reflux; AND

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

- Ulceration secondary to venous stasis that fails to respond to compressive therapy; OR
- Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; 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.

Treatment of accessory saphenous veins by surgery or endovenous radiofrequency or laser ablation that do not meet the criteria described above is considered cosmetic and **not medically necessary**.

**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

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.

**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 (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.

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

**Telangiectasia**

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

**Other**

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

- Sclerotherapy of perforator, greater or lesser saphenous, or accessory saphenous veins.
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins.
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, greater or lesser saphenous, or accessory saphenous veins.
- Endovenous radiofrequency or laser ablation of tributary veins.
- Endovenous cryoablation of any vein.

**Administrative and Contractual Guidance**

**Benefit Determination Guidance**

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.
For New England Health Plan (NEHP) members an approved referral authorization is required.

Benefits for FEP members may vary. Please consult the FEP Service Plan Brochure.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through a self-funded (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s plan documents or contact the customer service department.

BlueCard/National Account Issues

State or federal mandates (e.g., FEP) may dictate that all devices, drugs, or biologics approved by the U.S Food and Drug Administration (FDA) may not be considered investigational and thus these devices may be assessed only on the basis of their medical necessity.

Treatment of some varicose veins may be considered cosmetic in nature if not associated with significant clinical symptoms and documented reflux at the saphenofemoral or saphenopopliteal junction, and thus contract exclusions for cosmetic therapies may apply to coverage eligibility. The distinction between cosmetic and medically necessary treatment of varicose veins is an ongoing issue for Plans. Photographs or chart notes in conjunction with the results of duplex ultrasound scanning demonstrating incompetent veins may be required to establish medical necessity. Note that the term "varicose veins" does not apply to the telangiectatic dermal veins, which may be described as "spider veins" or "broken blood vessels." While abnormal in appearance, these veins typically are not associated with any other symptoms (such as pain or heaviness), and their treatment is considered cosmetic.

Plans whose contract language regarding medical necessity includes criteria regarding cost effectiveness may wish to consider the relative cost of stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy. Based on currently available evidence, health outcomes for stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy appear to be comparable. If more costly than stab avulsion or hook phlebectomy, transilluminated powered phlebectomy would be considered not medically necessary using the Medical Policy Reference Manual definition of medical necessity. Benefit or contract language describing the "least costly alternative" may also be applicable for this choice of treatment.

Billing and Coding/Physician Documentation Information

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: If ultrasound guidance (CPT code 76942) is used to guide sclerotherapy of the varicose tributaries, it would be considered incidental to the injection procedure (36475-36476; 36478-36479).

Follow the links listed below for attachments, coding tables and instructions.

Attachment I- CPT Code List & Instructions
Attachment II- ICD-PCS (procedure codes)
Attachment III- Eligible Diagnosis Codes

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Eligible Providers
Surgeons

Related Policies
Cosmetic and Reconstructive Procedures

Policy Implementation/Update information

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Scientific Background and Reference Resources

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, 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 about 2 months, while the median time to healing in other reports was 3 to 5 months.
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. (2, 3) 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. (4) 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. (5) At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

Endovenous Radiofrequency Ablation

In 2008, Luebke and colleagues reported a meta-analysis of 8 studies that included a total of 224 patients who underwent endovenous radiofrequency ablation and 204 patients who underwent stripping. (6) There was no significant difference between radiofrequency ablation 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 radiofrequency ablation. Quality of life results, including return to normal activity and return to work, favored radiofrequency over surgery. The authors noted that rates of recanalization, retreatment, occlusion, and reflux may alter with longer follow-up and that further randomized, controlled trials with longer follow-up are needed.

Long-term outcomes of endovenous radiofrequency ablation were reported from the Closure Study Group clinical registry in 2005. (7) 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 endovenous laser ablation (EVLA) versus surgery was published in 2009. (8) 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). (9) 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.

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. (10) 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 SF-36 subscores, and neural damage was the same (12%) in both groups.

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 randomized controlled trials, 1 registry report, 8 nonrandomized comparative studies, 43 case series, and 6 case reports. (11, 12) 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. (13, 14) Other studies indicate efficacy rates ranging from 12% to 76% for liquid sclerosant and from 57% to 84% for foam sclerosant. (15)

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 radiofrequency obliteration, while a 2009 systematic review suggested that outcomes from
sclerotherapy are worse than those of surgery (ligation and stripping) for saphenous vein reflux. (16, 17) 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. (18) 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. (18) 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 of 3.7) and injecting 10 mL or more of foamed sclerosant (odds ratio of 3.6). (19)

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 randomized, controlled trials 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.” (20) 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. (17)

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. For example, out of 1,009 patients recruited for a randomized, controlled trial, 64 patients were found to have minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. (21) 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 clinician’s 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.

Transilluminated Powered Phlebectomy (TIPP)

A 2008 meta-analysis included 5 studies that compared TIPP with conventional surgery. (22) 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). (23) 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. (3) These conclusions were based on 4 randomized, controlled trials 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 where the greater saphenous vein alone was treated (including the ESCHAR trial) showed a significant reduction in ulcer recurrence in comparison with conservative therapy. (24, 25) In addition, 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. (26) O'Donnell discusses additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. (3) 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. (27) 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.” (28) 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.”

A 2008 review of procedures for management of varicose veins recommends duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short radiofrequency catheter for the treatment of symptomatic residual perforator vein incompetence. (29) Ablation of incompetent perforator veins with
laser or radiofrequency ablation has been shown to be technically feasible, although no studies were identified that showed an improvement in clinical outcomes (e.g., ulcer healing or recurrence). (18-20, 26) Evidence regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion. (19)

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 no studies were identified showing an improvement in health outcomes, endovenous ablation with specialized radiofrequency probes has also 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.

Technology Assessments, Guidelines and Position Statements

In 2003, the Society of Interventional Radiography (SIR) published a position statement (30) 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)

and;

2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.

3. 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. (31) 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. (32-33) 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. (34) 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.
References:


Approved by BCBSVT Medical Directors

Date Approved

Spencer Borden MD
Chair, Medical Policy Committee

Robert Wheeler MD
Chief Medical Officer

Attachment I
CPT Code List & Instructions

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
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<tr>
<td>CPT</td>
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<td>Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk</td>
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<td>CPT</td>
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<td>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</td>
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### Attachment II
**ICD-PCS (procedure codes)**

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Attachment III

Click HERE for Applicable ICD (diagnosis) code lists