

POLICY TITLE	TREATMENT OF VARICOSE VEINS/VENOUS INSUFFICIENCY
POLICY NUMBER	MP- 1.061

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I. 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 **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:

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- Incompetence of the accessory saphenous vein is isolated, OR 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 **not medically necessary**.

Symptomatic Varicose Tributaries

The following treatments are considered **medically necessary** as a component of the treatment of symptomatic varicose tributaries. These must be performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins if there is pathology 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**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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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 **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
- Mechanochemical ablation of any vein

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above procedures.

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II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

- | | |
|--------------------------|-----------------|
| [N] Capital Cares 4 Kids | [N] Indemnity |
| [N] PPO | [N] SpecialCare |
| [N] HMO | [N] POS |
| [Y] SeniorBlue HMO* | [Y] FEP PPO** |
| [Y] SeniorBlue PPO* | |

* For stab phlebectomy, compression sclerotherapy, SEPS, and radiofrequency and endovenous laser ablation for vein size and medical necessity indications, refer to Novitas Solutions Inc. Local Coverage Determination (LCD) L27539 Treatment of Varicose Veins of the Lower Extremities.

** Refer to FEP Medical Policy Manual MP-7.01.124 Treatment of Varicose Veins/Venous Insufficiency. The FEP Medical Policy manual can be found at:

III. DESCRIPTION/BACKGROUND

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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.

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

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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

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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 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

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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 RFSFlex 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.

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- 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.
- The ClariVein® Infusion Catheter received marketing clearance through the 510(k) process in 2008 (K071468). It is used for mechanochemical ablation. Predicate devices were listed as the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature.

IV. RATIONALE

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Treatment of Saphenous Reflux

Compression Therapy

A 2009 Cochrane review on compression for venous leg ulcers included a total of 39 randomized controlled trials (RCTs), with 47 different comparisons.(1) The review was updated in 2012, and included 48 RCTs with 59 different comparisons.(2) Most of the RCTs were small. 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 8 trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. In addition, multicomponent systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses 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.(3) 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

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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. (4, 5) In general, recurrence rates after ligation and stripping are estimated at around 20%. Jones et al 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.(6) 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.(7) 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. (8) 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 RFA

In 2008, Luebke et al reported a meta-analysis of 8 studies that included a total of 224 patients who underwent RFA and 204 patients who underwent stripping. (9) 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 RFA 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.

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Long-term outcomes of endovenous RFA were reported from the Closure Study Group clinical registry in 2005.(10) Thirty-four centers (1006 patients, 1222 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. (11) 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 5759 patients (6702 limbs) were treated with EVLA and 6395 patients (7727 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. Large clinical trials published subsequent to the systematic review are described below.

The 2012 RELACS study was a practical design that randomized 400 patients to EVLA performed by a surgeon at 1 site or to ligation and stripping performed by a different surgeon at a second location.(12) Fifty-four patients withdrew from the study after receiving the randomization result (from an independent site), due primarily to preference for the other treatment. At 2-year follow-up, there was no significant difference between the groups for clinically recurrent varicose veins, medical condition on the Homburg Varicose Vein Severity Score, or disease-related quality of life. Saphenofemoral reflux was detected by ultrasonography more frequently after endovenous laser treatment (EVLT) (17.8% vs 1.3%). This study will follow patients for 5 years. 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. In the 2013 MAGNA trial, 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or foam sclerotherapy.(14) At 1-year follow-up, the anatomic success rates were similar between EVLA and stripping (88.5% and 88.2%, respectively), which were superior to foam sclerotherapy (72.2%). Ten percent of the stripping

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group showed neovascularization. Health-related quality of life improved in all groups. The CEAP classification improved in all groups with no significant difference between the groups. Transient adverse events were reported in 11 patients after stripping, 7 after EVLA, and 5 after sclerotherapy.

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).(15) 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.

Rasmussen et al randomized 121 patients (137 legs) to EVLA (n=69) or to ligation and stripping (n=68). (16) 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. Ninety-eight percent of patients were available for 5-year follow-up.(17) There was a trend toward greater recanalization following EVLA, but this was not associated with increased clinical recurrence (EVLA, 36%; stripping, 35%) or in the percentage of reoperations (EVLA, 38.6%; stripping, 37.7%).

Literature on isolated treatment of the anterior accessory saphenous vein is limited. In a 2009 study, outcomes from a cohort of 33 patients who underwent EVLA of the anterior accessory saphenous vein were compared with 33 matched controls undergoing EVLA of the greater saphenous vein.(18) In 21 of the patients (64%) in the accessory saphenous vein group, there had been no previous treatment of the greater saphenous vein. At 12-month follow-up, there was no evidence of reflux in these patients, and the treated accessory saphenous vein was not visible with ultrasound. The Aberdeen Varicose Vein Symptom Severity Score had improved in both groups, with no significant difference between the 2 groups. Patient satisfaction scores were also similar.

Endovenous Cryoablation

Klem et al 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.

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(19) 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, 11.7) in comparison with cryoablation (score, 8.0). There were no differences between the groups in SF-36 subscores, and neural damage was the same (12%) in both groups.

Disselhoff et al reported 2 and 5 year outcomes from a randomized trial that compared cryostripping with EVLA. (20, 21) 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 in 2006 reviewed 67 studies, including 9 RCTs, 1 registry report, 8 nonrandomized comparative studies, 43 case series, and 6 case reports.(22,23) 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. (24, 25) Other studies indicate efficacy rates ranging from 12% to 76% for liquid sclerosant and from 57% to 84% for foam sclerosant. (26)

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 RFA obliteration, while a 2009 systematic review suggested that outcomes from sclerotherapy are worse than those of surgery (ligation and stripping) for saphenous vein reflux.(27,28) 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.(29) Bubbles appear in the right heart between 9

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and 59 seconds after injection, and emboli have been detected in the middle cerebral artery following sclerotherapy of saphenous trunks and varices.(29) 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).(30)

In the 2013 MAGNA trial (described above), 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or foam sclerotherapy.(14) At 1-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both EVLA and stripping (88.5% and 88.2%, respectively). Twenty-one patients in the sclerotherapy group had partial occlusion with reflux, though the clinical complaint was completely relieved. A 2012 study was a noninferiority trial of foam sclerotherapy versus ligation and stripping in 430 patients. (31) Analysis was per protocol. Forty patients (17%) had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in the 2 groups (11.3% sclerotherapy vs 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. There were 2 serious adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within 1 week of treatment.

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.(32) 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.

The VANISH-2 study is an FDA-regulated 5-year randomized, double-blind multicenter trial that compares 0.5% or 1.0% polidocanol microfoam versus either endovenous placebo or a subtherapeutic dose of polidocanol foam.(33) Patients with unsuccessful or incomplete treatment at the primary outcome assessment (week 8) could receive open-label foam sclerotherapy. At the 8-week assessment, there was elimination of reflux and/or occlusion of the previously incompetent vein in 85.6% of the combined 0.5% and 1.0% groups, 59.6% of patients in the 0.125% “subtherapeutic” group, and 1.8% of the placebo group. The improvement in the venous clinical severity score was significantly better in the 0.5% and 1.0% groups (-5.10) compared with placebo (-1.52), but was not reported for the 0.125% group. This is 1 of 2 pivotal Phase 3 studies undertaken to obtain marketing approval from FDA. Longer-term evaluation is in progress.

Mechanochemical Ablation

No RCT results were identified with mechanochemical ablation (MCA). Several prospective series and cohort studies have been reported. One study compared postoperative pain and early

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quality of life in 68 patients treated with either RFA or MCA of great saphenous veins. (34) Patients who did not want to be treated with MCA were offered treatment with RFA; this study design could potentially lead to selection bias. There was no significant difference between the groups in procedural pain. Compared with RFA, patients treated with MCA had a 14.3-mm reduction in pain measured on a 100-mm visual analog scale (VAS) measured over the first 3 postoperative days (6.2 vs 20.5) and a 13.8-mm reduction in pain (4.8 vs 18.6 mm) over the first 2 weeks. Patients treated with ClariVein also had an earlier return to normal activities (1.2 vs 2.4 days) and return to work (3.3 vs 5.6 days). There was a similar improvement in quality of life for the 2 groups when measured at 6 weeks.

A prospective multicenter series evaluated the efficacy of MCA of the great saphenous vein in 126 patients in a community setting. (35) Veins were selected that were greater than 4 mm and less than 12 mm in diameter, with an average diameter of 7.3 mm. Closure rates were 100% at 1 week, 98% at 3 months, and 94% at 6 months. The venous clinical severity score decreased from a score of approximately 9 pretreatment to about 3 at 6 months. In 2012, Elias and Raines reported an industry-sponsored safety and efficacy study of MCA with the ClariVein® system. (36) Thirty greater saphenous veins in 29 patients were treated with this device. Greater saphenous veins with diameters greater than 12 mm were excluded. At 6-month follow-up, 1 vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events were reported. Another prospective series evaluated MCA of the small saphenous vein in 50 consecutive patients. (37) Only patients with a vein diameter of 2.5 to 11 mm were included. The dose of sclerosant was increased after the first 15 patients. At the 6-week assessment, all treated veins were occluded and at 1-year follow-up, 94% remained occluded. The median VAS score for pain during the procedure was 2 of 10. There were no major complications. Controlled studies with a greater number of subjects and longer follow-up are needed.

A 2013 review of MCA notes that a 5-year 840 patient randomized trial comparing ClariVein with RFA began in 2012 in Europe. (38) This trial will provide needed data on the comparative effectiveness of MCA, measured at a longer duration and in a larger population.

Other Treatments

Both steam injection and microwave ablation for endovenous treatment of varicose veins were reported outside of the U.S. (39, 40) These procedures have not been approved or cleared for marketing by FDA.

Section Summary

There are a number of large randomized trials on endovenous ablation of the saphenous veins. Comparison with ligation and stripping at 2-year follow-up supports use of both RFA and EVLT. Evidence suggests that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization. Controlled studies with longer follow-up are needed to

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determine the long-term efficacy of these treatments with greater certainty. Two RCTs suggest that cryotherapy is not as effective as available alternatives. For sclerotherapy, there is high variability in success rates of the procedure and reports of serious adverse events. MCA is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared to thermal ablation techniques is that it does not require tumescent anesthesia and may result in less postoperative pain. To date, the ClariVein procedure has been assessed in relatively few patients and for short durations. Thus, there is insufficient evidence to permit conclusions regarding the safety and efficacy of mechanochemical ablation.

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.”(41) 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. (28)

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. For example, of 1009 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. (42) 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 RCT that compared visual foam sclerotherapy versus ultrasound-guided foam sclerotherapy of the greater saphenous vein together with visual foam sclerotherapy for varicose tributary veins. (43) 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

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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

A 2008 meta-analysis included 5 studies that compared transilluminated powered phlebectomy (TIPP) with conventional surgery. (44) 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 an RCT by Chetter et al that compared TIPP (n=29) with a multiple stab incision procedure (n=33). (45) 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.

Section Summary

Evidence indicates that both sclerotherapy and TIPP are as effective as stab phlebectomy in eliminating varicose tributaries. However, there is limited evidence that TIPP is associated with more pain, bruising, discoloration, and a longer recovery.

Treatment of Perforator Reflux

A systematic literature review published in 2008 indicates insufficient evidence for the role of incompetent perforator vein surgery.(5) 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.(46,47) A 2011 community hospital-based multicenter, double-blind,

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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.(48)

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, 1 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.(49) O’Donnell discusses additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency.(5) 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

In 2004, Tenbrook et al published a review of the literature of subfascial endoscopic perforator surgery (SEPS), which included 19 case series and 1 randomized trial. (50) In total, the reviewed studies included 1031 patients with 1140 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 postthrombotic changes excluded.”(51) 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 RFA catheter for the treatment of symptomatic residual perforator vein incompetence.(52) 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 1 study of EVLA for perforating veins in 33 patients with a CEAP classification of 4 (skin changes), 5 (healed ulcer), or 6 (active ulcer).(53) 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

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EVLA. Evidence regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion. (30)

Summary

Although randomized controlled trials (RCTs) 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 RCT 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, and there is insufficient evidence on mechanochemical ablation.

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 1 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.

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Practice Guidelines and Position Statements

The Society for Vascular Surgery and the American Venous Forum published clinical practice guidelines in 2011.(54) 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. (55) 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

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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, 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 postthrombotic 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.

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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 (56) 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, nonoperative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.

And;

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. (57) 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

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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 Care Excellence (NICE) published guidance on radiofrequency ablation of varicose veins and on endovenous laser treatment of the long saphenous vein. (58,59) 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 2013. (60) The guidance states that:

“1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but significant risks of foam embolization (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.

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

NICE issued guidance on endovenous mechanochemical ablation in 2013, concluding that current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins is inadequate in quantity and quality. (61) Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

In 2013, NICE published practice guideline on the diagnosis and management of varicose veins in the leg. (62) NICE recommends a study of the clinical and cost effectiveness of

- Concurrent phlebectomies or foam sclerotherapy for varicose tributaries during truncal endothermal ablation for varicose veins
- Truncal endothermal ablation without concurrent phlebectomies or foam sclerotherapy
- Truncal endothermal ablation with phlebectomies or foam sclerotherapy, if needed, 6-12 weeks later

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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V. DEFINITIONS

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ABLATION is the removal of a part, pathway, or function by surgery, chemical destruction, electrocautery or radiofrequency.

BASIC ACTIVITIES OF DAILY LIVING- Include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

CHRONIC VENOUS INSUFFICIENCY refers to a collection of venous disorders that includes reflux disease and obstructive physiology. Symptoms include pain, edema and skin irritation. Physical exam reveals ankle edema, subcutaneous fibrosis, hyperpigmentation, lipodermatosclerosis, eczema and dilation of subcutaneous veins and ulcers

COSMETIC SURGERY is an elective procedure performed primarily to restore a person’s appearance by surgically altering a physical characteristic that does not prohibit normal function, but is considered unpleasant or unsightly.

ECHOSCLEROTHERAPY is the use of a duplex ultrasound during sclerotherapy to guide the injections and enhance the precision of saphenous vein sclerotherapy.

ENDOLUMINAL means within the lumen of a tubular structure, such as a blood vessel.

ENDOSCOPIC refers to a medical procedure that uses a device with a light attached to look at the inside of a body cavity or organ.

FASCIA is the fibrous connective tissue of the body that can be separated from other specifically organized structures, such as tendons and ligaments.

MECHANOCHEMICAL ABLATION (ENDOVENOUS) IS a procedure where a tube with a rotating hollow wire at its tip is inserted into the affected vein in the leg. As the tube is pulled back out of the vein, the wire is rotated, damaging the lining of the vein. At the same time, a chemical is injected through the hollow wire into the vein. This causes the vein to become inflamed, then shrivel and close.

MICROVASCULAR pertains to the portion of the circulatory system that is composed of the capillary network.

NECROTIZING refers to causing the death of tissues or organisms.

SUBFASCIAL means beneath a fascia.

TELANGIECTASIA is a vascular lesion formed by dilation of a group of small blood vessels

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the

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applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes ®							
36470	36471	36475	36476	36478	36479	37500	37700
37718	37722	37735	37760	37761	37765	37766	37780
37785							

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Not all covered services are eligible for separate reimbursement.

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ICD-9-CM Diagnosis Code*	Description
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 THE LOWER EXTREMITIES WITH OTHER COMPLICATIONS

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

Cosmetic and therefore not covered:

CPT Codes ®							
36468	36469						

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Not covered:

HCPCS Code	Description
S2202	Echosclerotherapy

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
I83.001	Varicose veins of unspecified lower extremity with ulcer of thigh
I83.002	Varicose veins of unspecified lower extremity with ulcer of calf
I83.003	Varicose veins of unspecified lower extremity with ulcer of ankle
I83.004	Varicose veins of unspecified lower extremity with ulcer of heel and midfoot
I83.005	Varicose veins of unspecified lower extremity with ulcer other part of foot
I83.008	Varicose veins of unspecified lower extremity with ulcer other part of lower leg
I83.009	Varicose veins of unspecified lower extremity with ulcer of unspecified site
I83.011	Varicose veins of right lower extremity with ulcer of thigh
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel and midfoot

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ICD-10-CM Diagnosis Code*	Description
I83.015	Varicose veins of right lower extremity with ulcer other part of foot
I83.018	Varicose veins of right lower extremity with ulcer other part of lower leg
I83.019	Varicose veins of right lower extremity with ulcer of unspecified site
I83.021	Varicose veins of left lower extremity with ulcer of thigh
I83.022	Varicose veins of left lower extremity with ulcer of calf
I83.023	Varicose veins of left lower extremity with ulcer of ankle
I83.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025	Varicose veins of left lower extremity with ulcer other part of foot
I83.028	Varicose veins of left lower extremity with ulcer other part of lower leg
I83.029	Varicose veins of left lower extremity with ulcer of unspecified site
I83.10	Varicose veins of unspecified lower extremity with inflammation
I83.11	Varicose veins of right lower extremity with inflammation
I83.12	Varicose veins of left lower extremity with inflammation
I83.201	Varicose veins of unspecified lower extremity with both ulcer of thigh and inflammation
I83.202	Varicose veins of unspecified lower extremity with both ulcer of calf and inflammation
I83.203	Varicose veins of unspecified lower extremity with both ulcer of ankle and inflammation
I83.204	Varicose veins of unspecified lower extremity with both ulcer of heel and midfoot and inflammation
I83.205	Varicose veins of unspecified lower extremity with both ulcer other part of foot and inflammation
I83.208	Varicose veins of unspecified lower extremity with both ulcer of other part of lower extremity and inflammation
I83.209	Varicose veins of unspecified lower extremity with both ulcer of unspecified site and inflammation
I83.211	Varicose veins of right lower extremity with both ulcer of thigh and inflammation
I83.212	Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213	Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214	Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
I83.215	Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218	Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.219	Varicose veins of right lower extremity with both ulcer of unspecified site and inflammation
I83.221	Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222	Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223	Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224	Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225	Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228	Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation

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ICD-10-CM Diagnosis Code*	Description
I83.229	Varicose veins of left lower extremity with both ulcer of unspecified site and inflammation
I83.811	Varicose veins of right lower extremities with pain
I83.812	Varicose veins of left lower extremities with pain
I83.813	Varicose veins of bilateral lower extremities with pain
I83.819	Varicose veins of unspecified lower extremities with pain
I83.891	Varicose veins of right lower extremities with other complications
I83.892	Varicose veins of left lower extremities with other complications
I83.893	Varicose veins of bilateral lower extremities with other complications
I83.899	Varicose veins of unspecified lower extremities with other complications
1187.2	Venous, insufficiency (chronic, peripheral)

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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MP 1.061	CAC 11/26/02
	CAC 2/25/03
	CAC 2/24/04
	CAC 12/14/04
	CAC 1/31/06
	CAC 1/30/07
	CAC 1/29/08
	CAC 5/27/08
	CAC 11/25/08
	CAC 7/28/09
	CAC 11/24/09 Minor revision- added sclerosing agent must be FDA-approved.
	CAC 11/30/10 Consensus review
	CAC 7/26/11 Adopt BCBSA. Documentation requirement for the treatment of the greater or lesser saphenous vein varicosities that the veins are noted to be at least five (5) millimeters in diameter by visual inspection or ultrasound was removed from the policy. Documentation requirement for sclerotherapy for the treatment of superficial varices that the bulging veins are by visual inspection or ultrasound are noted to be 3mm but less than 6mm in diameter was also removed from the policy. Through adopting BCBSA, the policy is now organized into the following sections: Treatment of Greater or Lesser Saphenous Veins, Accessory Saphenous Veins, Symptomatic Varicose Tributaries, Perforator Veins, Telangiectasia, and Other which will facilitate administration. An FEP variation was added.
	CAC 8/28/12 Wording changes for clarification to section on Treatment of symptomatic varicose tributaries. No other changes to policy statements. References updated. FEP variation changed to reference FEP policy manual MP-7.01.124 Treatment of Varicose Veins/Venous Insufficiency. Codes reviewed 8/13/12 klr
CAC 7/30/13 Minor. Policy statement on accessory saphenous veins was modified to include isolated incompetence of the accessory saphenous vein as medically necessary. Endovenous mechanochemical ablation for varicose veins was added to the policy as investigational. Added rationale section. Admin code review complete.	
CAC 5/20/14 Consensus review. References and rationale updated. No changes to the policy statements. Coding reviewed.	
9/25/14 Admin update- removal of ‘cosmetic’ language. No change to medical necessity.	

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