Medical Policy

BlueCross BlueShield of Kansas
An independent licensee of the Blue Cross Blue Shield Association

Title: Varicose Veins

Professional
Original Effective Date: January 1, 2004
Revision Date(s): August 17, 2004; August 24, 2004; May 19, 2005; December 15, 2005; February 17, 2006; October 10, 2006; October 31, 2006; February 6, 2007; September 7, 2007; October 16, 2007; January 4, 2008; July 18, 2008, April 22, 2009; November 18, 2009; January 1, 2010; October 11, 2010; May 4, 2011; September 6, 2011; September 11, 2012; March 8, 2013; December 24, 2014; January 1, 2016; February 1, 2019
Current Effective Date: February 1, 2019

Institutional
Original Effective Date: April 22, 2009
Revision Date(s): November 18, 2009; January 1, 2010; October 11, 2010; May 4, 2011; September 6, 2011; October 11, 2012; March 8, 2013; December 24, 2014; January 1, 2016; February 1, 2019
Current Effective Date: February 1, 2019

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

Populations	Interventions	Comparators	Outcomes
Individuals: • With varicose veins/venous insufficiency and saphenous vein reflux	Interventions of interest are: • Endovenous thermal ablation (radiofrequency or laser)	Comparators of interest are: • Conservative therapy • Ligation and stripping	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With varicose veins/venous insufficiency and saphenous vein reflux	Interventions of interest are: • Microfoam sclerotherapy	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radiofrequency or laser ablation	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/venous insufficiency and saphenous vein reflux	Interventions of interest are: • Mechanochemical ablation	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radiofrequency or laser ablation • Microfoam sclerotherapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/venous insufficiency and saphenous vein reflux	Interventions of interest are: • Cyanoacrylate adhesive	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radiofrequency or laser ablation	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/venous insufficiency and saphenous vein reflux	Interventions of interest are: • Cryoablation	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radiofrequency or laser ablation	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose tributary veins	Interventions of interest are: • Ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With perforator vein reflux	Interventions of interest are: • Ablation (eg, subfascial endoscopic perforator surgery) of perforator veins	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

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

Objective

The objective of this evidence review is to evaluate the safety and efficacy of ablative, chemical, and adhesive technologies used to treat varicose veins/venous insufficiency arising from reflux in the saphenous, tributary, and perforator veins.

Background

VENOUS REFLUX / VENOUS INSUFFICIENCY

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

Definitions

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

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

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

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

Treatment

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

and small saphenous veins are eliminated, and blood flow is diverted through the accessory veins.

Treatment of Saphenous Veins and Tributaries

Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux 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, eg, by stripping of the great and/or small saphenous veins
4. Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy

Minimally invasive alternatives to ligation and stripping have been investigated. They include sclerotherapy, transilluminated powered phlebectomy (TIPP), and thermal ablation using cryotherapy, high-frequency radio waves (200–300 kHz), or laser energy.

Thermal Ablation

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

Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately occluding the vessel. Treatment success depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are commonly produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment.

Endovenous Mechanochemical Ablation
Endovenous mechanochemical ablation uses both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3,500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without need for the tumescent anesthesia used with endovenous thermal ablation techniques (radiofrequency ablation [RFA], endovenous laser ablation.

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

Transilluminated Powered Phlebectomy
Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion and hook phlebectomy. This procedure uses 2 instruments: an illuminator, which also provides irrigation, and a resector, which has an oscillating tip and suction pump. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of 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 decrease surgical time, decrease complications such as bruising, and lead to a faster recovery than 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 treated 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 occasionally be used to close 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 surgery can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and RFA has also been reported.

Regulatory Status

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

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

The following devices were cleared for marketing by FDA through the 501(k) process for endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ System, a radiofrequency device, was cleared by FDA through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." In 2005, the VNUS RFS™ and RFSFlex™ devices were cleared by FDA for "use in vessel and tissue coagulation including treatment of incompetent (ie, refluxing) perforator and tributary veins." In 2008, the modified VNUS® ClosureFast™ Intravascular Catheter was cleared by FDA through the 510(k) process. FDA product code: GEI.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit was cleared by FDA through the 510(k) process "…for use in the endovascular coagulation of the great saphenous vein of the thigh in patients with superficial vein reflux." FDA product code: GEX.
- In 2005, a modified Erbe Erbokryo® cryosurgical unit (Erbe USA) was approved by FDA for marketing. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.
- In 2003, the Trivex® system (InaVein), a device for transilluminated powered phlebectomy, was cleared by FDA through the 510(k) process for "ambulatory

phlebectomy procedures for the resection and ablation of varicose veins." FDA product code: DNQ.

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

POLICY

I. SAPHENOUS VEINS - Great or Small Saphenous Veins

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

1. There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology], class C2 or greater
   AND
2. There is documentation of 1 or more of the following indications:
   a. Ulceration secondary to venous stasis
      OR
   b. Recurrent superficial thrombophlebitis
      OR
   c. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
      OR
   d. All of the following:
      1) Persistent pain, swelling, itching, burning, or other symptoms associated with saphenous reflux
         AND
      2) the symptoms significantly interfere with activities of daily living
         AND
      3) conservative management including compression therapy for at least 3 months has not improved the symptoms

B. Treatment of great or small saphenous veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy that does not meet the criteria described above is considered **not medically necessary.**

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

II. ACCESSORY SAPHENOUS VEINS

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

1. One of the following:
   a. Incompetence of the accessory saphenous vein is isolated
      OR
   b. The great or small saphenous veins had been previously eliminated (at least 3 months)

   AND
2. There is demonstrated accessory saphenous reflux
   AND
3. There is documentation of 1 or more of the following indications:
   a. Ulceration secondary to venous stasis
      OR
   b. Recurrent superficial thrombophlebitis
      OR
   c. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
      OR
   d. All of the following:
      1) Persistent pain, swelling, itching, burning, or other symptoms associated with saphenous reflux
         AND
      2) the symptoms significantly interfere with activities of daily living
         AND
      3) conservative management including compression therapy for at least 3 months has not improved the symptoms

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

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

III. SYMPTOMATIC VARICOSE TRIBUTARIES

A. When physical findings support medical necessity, the following treatments are considered **medically necessary** as a component of the treatment of symptomatic varicose tributaries (none of these techniques has been shown to be superior to another):
   1. Stab avulsion
   2. Hook phlebectomy
   3. Sclerotherapy
   4. Transilluminated powered phlebectomy

B The sole treatment of varicose vein tributaries in the presence of saphenofemoral or saphenopopliteal reflux is considered **not medically necessary**.

C. Treatment of tributary veins less than 3 mm is considered **cosmetic and not covered.**

IV. PERFORATOR VEINS

A. Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered **medically necessary** as a treatment of leg ulcers associated with chronic venous insufficiency when all the following conditions have been met:
   1. There is demonstrated perforator reflux
      AND
   2. The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated
      AND
   3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months
      AND
   4. The venous insufficiency is not secondary to deep venous thromboembolism

B. Treatment of incompetent perforator veins without refractory stasis ulceration is considered **not medically necessary** as discussed in references 3 and 47:
   1. "Patients with isolated reflux in perforator veins…are generally asymptomatic; reflux at multiple valve sites is required for symptom expression."
   2. "Reflux in perforator veins that are smaller than 4mm in diameter is not considered to be clinically significant.
   3. "In complex venous disease, comprehensive correction is neither feasible nor necessary; partial correction of multifocal disease often relieves symptoms."

4. "The role of interruption of the perforator vein is controversial because of doubts about the pathologic significance of reflux involving this vein and because its specific efficacy is uncertain."
5. "The role of perforator vein ablation awaits results, of properly conducted randomized controlled trials."
6. Perforator reflux often resolves following saphenous ablation.

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

V. Telangiectasia

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

VI. Other Veins

A. Techniques for conditions not specifically listed above are **experimental / investigational** including, but not limited to:
1. Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins
2. Sclerotherapy of perforator veins
3. Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
4. Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins.
5. Endovenous radiofrequency or laser ablation of tributary veins
6. Mechanochemical ablation of any vein
7. Cyanoacrylate adhesive of any vein
8. Endovenous cryoablation of any vein

Policy Guidelines

1. The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. Table PG1 provides is the Clinical portion of the CEAP.

Table PG1. Clinical Portion of the CEAP Classification System

Class	Definition
C0	No visible or palpable signs of venous disease
C1	Telangiectasies or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation and eczema
C4b	Lipodermatosclerosis and atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer
S	Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction

A	Asymptomatic

Adapted from http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf.
CEAP: Clinical, Etiologic, Anatomic, Pathophysiologic classification system.

2. A clear and complete description of the physical exam of the lower extremities that documents the medical necessity of treatment for venous insufficiency for medical, not cosmetic purposes, is required. Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is **not covered**. Photographs may be requested.

3. Up to 20 injections in each leg may be treated in any one session and up to 3 sclerotherapy sessions for each leg may be considered medically necessary if selection criteria are met.

4. Following successful ablation of the greater saphenous vein, tributary veins can become more prominent, but usually improve over time; therefore, delaying treatment of these smaller veins will minimize the number of veins that need treatment.

5. Patients with combined deep and superficial venous insufficiency are often not good candidates for ablation therapy. Varicose vein recurrence and ulcer recurrence rates following intervention are much higher. However, deep vein insufficiency is not a contraindication to superficial vein treatment.

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

<u>Claims Submission Instructions</u>

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

Reimbursement

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

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through March 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Outcomes of interest for venous interventions include healing and recurrence, recanalization of the vein, and neovascularization. Recanalization is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques. Neovascularization is the proliferation of new blood vessels in tissue and occurs more frequently following vein stripping. Direct comparisons of the durability of endovenous and surgical procedures are complicated by these mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

The following section addresses the efficacy of the conventional treatments, specifically on the appropriate length of a trial of compression therapy and evaluation of recurrence rates for surgical treatment (ie, ligation and stripping) compared with compression therapy.

CONVENTIONAL TREATMENT OF SAPHENOUS REFLUX

Compression Therapy

A Cochrane review by O'Meara et al (2009) evaluated compression for venous leg ulcers included 39 RCTs with 47 different comparisons.[1] This review was updated in 2012 and included 48 RCTs with 59 different comparisons.[2] Most 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. Also, 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 by Shingler et al (2011) assessed compression stockings as initial treatment for varicose veins in patients without venous ulceration.[3] Selected were 7 studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2-C4). Six studies compared different types or pressures of stockings. Subjectively, participants' symptoms improved, but results were not compared with a control arm. Due primarily to inadequate reporting, the methodologic quality of the selected trials was unclear. Meta-analyses were not performed due to inadequate reporting and suspected heterogeneity. Reviewers concluded that there was insufficient high-quality evidence to determine whether compression stockings were effective as the sole and initial treatment of varicose veins in patients without venous ulceration, or whether any type of stocking was superior to another type.

Ligation and Stripping

Systematic literature reviews have indicated 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 20% in short-term follow-up. Jones et al (1996) reported on the results of a trial that randomized 100 patients with varicose veins to ligation alone or ligation plus stripping.[6] At 1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar (1994) reported on the results of a trial that randomized 181 limbs to ligation and stripping or to ligation plus sclerotherapy.[7] At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

ENDOVENOUS THERMAL ABLATION (LASER OR RADIOFREQUENCY)

Systematic Reviews

An updated Cochrane review by Nesbitt et al (2014) compared endovenous ablation (radiofrequency and laser) with foam sclerotherapy or ligation and stripping for saphenous vein varices.[8] Included in the review were 13 randomized studies (total N=3081 patients). The overall quality of the evidence was moderate. There was no significant difference between sclerotherapy and surgery in the rate of recurrence, as rated by clinicians (odds ratio [OR], 1.74; p=0.06) or for symptomatic recurrence (OR=1.28). For endovenous laser ablation vs surgery, there were no significant differences between the treatment groups for clinician-reported or symptomatic recurrence, or for recanalization. Neovascularization and technical failure were reduced in the laser group (OR=0.05, p<0.001; OR=0.29, p<0.001, respectively). For endovenous

radiofrequency ablation (RFA) vs surgery, there were no significant differences between groups in clinician-reported recurrence, recanalization, neovascularization, or technical failure. Reviewers concluded that sclerotherapy, endovenous laser ablation, and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins.

A Cochrane review by Paravastu et al (2016) compared endovenous laser ablation or RFA with surgical repair for short saphenous veins with reflux at the saphenopopliteal junction.[9] Three RCTs identified compared endovenous laser ablation with surgery. There was moderate-quality evidence that recanalization or persistence of reflux at 6 weeks occurred less frequently after endovenous laser ablation than after surgery (OR=0.07; 95% confidence interval [CI], 0.02 to 0.22), and low-quality evidence that recurrence of reflux was lower after endovenous laser ablation at 1 year (OR=0.24; 95% CI, 0.07 to 0.77).

Randomized Controlled Trials

The largest RCT was reported by Brittenden et al (2014) and compared foam sclerotherapy, endovenous laser ablation, and surgical treatment in 798 patients.[10] The trial was funded by the U.K.'s National Institute for Health Research. Veins greater than 15 mm in diameter were excluded from the trial. At the 6-week follow-up visit, patients assigned to treatment with foam or laser had the option of treatment with foam for any residual varicosities; this optional treatment was performed in 38% of patients in the foam group and 31% of patients in the endovenous laser ablation group. Disease-specific quality of life (QOL) was similar for the laser and surgery groups. The frequency of procedural complications was similar for the foam sclerotherapy (6%) and surgery (7%) groups but was lower for the laser group (1%).

The 2012 RELACS study randomized 400 patients to endovenous laser ablation performed by a surgeon at 1 site or to ligation and stripping performed by a different surgeon at a second location.[11] At 2-year follow-up, there were no significant differences between groups for clinically recurrent varicose veins, medical condition measured on the Homburg Varicose Vein Severity Score, or disease-related QOL. Saphenofemoral reflux was detected by ultrasonography more frequently after endovenous laser treatment (17.8% vs 1.3%). The follow-up rate at 5 years was 81%.[12] Same-site recurrences were more frequent in the endovenous laser ablation group (18% with endovenous laser ablation vs 5% with surgery, p=0.002), but different-site recurrences were more frequent in the surgically treated group (50% with surgery vs 31% with endovenous laser ablation, p=0.002). Overall, there was no significant difference in recurrence rates between groups. There were also no significant differences between groups in disease severity or QOL at 5 years.

Christenson et al (2010) compared endovenous laser ablation 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 endovenous laser ablation 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 endovenous laser ablation, ligation and stripping, or foam sclerotherapy.[14] At 1-year follow-up, the anatomic success rates were similar for endovenous laser ablation (88.5%) and stripping (88.2%), which were both superior to foam sclerotherapy (72.2%). Ten percent of the stripping group showed neovascularization. At 5 years, health-related QOL and CEAP classification improved in all groups with no significant differences among them.[15] Grade I neovascularization was higher in the conventional surgery group (27% vs 3%, p<0.001), while grade II neovascularization did not differ significantly between surgical (17%) and endovenous laser ablation (13%) groups.

The literature on the isolated treatment of the anterior accessory saphenous vein is limited. In a study by Theivacumar et al (2009), outcomes from a cohort of 33 patients who underwent endovenous laser ablation of the anterior accessory saphenous vein were compared with 33 matched controls undergoing endovenous laser ablation of the great saphenous vein.[16] For 21 (64%) of the patients in the accessory saphenous vein group, there had been no previous treatment of the great 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. Aberdeen Varicose Veins Questionnaire (AVVQ) scores had improved in both groups, with no significant difference between them. Patient satisfaction scores were also similar.

Section Summary: Endovenous Thermal Ablation (Laser or Radiofrequency)
There are a number of large RCTs and systematic reviews of RCTs assessing endovenous ablation using radiofrequency or laser energy of the saphenous veins. Comparison with ligation and stripping at 2- to 5-year follow-up has indicated similar recurrence rates for the different treatments. Evidence has suggested that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization, resulting in similar outcomes for endovenous thermal ablation and surgery. Laser ablation and RFA have similar success rates.

SCLEROTHERAPY

Physician-Compounded Sclerotherapy

Hamann et al (2017) conducted a meta-analysis of RCTs reporting 5-year follow-up.[17] The meta-analysis (3 RCTs, 10 follow-up studies) included 611 legs treated with endovenous laser ablation, 549 treated with high ligation and stripping, 121 with sclerotherapy, and 114 with high ligation and endovenous laser ablation. Ultrasound-guided sclerotherapy had significantly worse outcomes than the other 3 treatments, with anatomic success rates of 34% for sclerotherapy compared with 83% to 88% for the other 3 treatments ($p<0.001$).

In the 2013 MAGNA trial (previously described), 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to endovenous laser ablation, ligation and stripping, or physician-compounded foam sclerotherapy (1 mL aethoxysclerol 3%: 3 cc air).[14] At 1-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both endovenous laser ablation (88.5%) and stripping (88.2%). Twenty-one patients in the sclerotherapy group had partial occlusion with reflux, though the clinical complaint was completely relieved. At 5-year follow-up, obliteration or absence of the great saphenous vein was observed in only 23% of patients treated with sclerotherapy compared with 85% of patients who underwent conventional surgery and 77% of patients who underwent endovenous laser ablation.[15] Thirty-two percent of legs treated initially with sclerotherapy required 1 or more reinterventions during follow-up compared with 10% in the conventional surgery and endovenous laser ablation groups. However, clinically relevant grade II neovascularization was higher in the conventional surgery (17%) and endovenous laser ablation (13%) groups than in the sclerotherapy group (4%). EuroQol-5D scores improved equally in all groups.

A noninferiority trial by Shadid et al (2012) compared foam sclerotherapy with ligation and stripping in 430 patients.[18] The analysis was per protocol. Forty (17%) patients had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in both 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. Two serious adverse events in the sclerotherapy group (deep venous thrombosis, pulmonary emboli) occurred within 1 week of treatment.

Microfoam Sclerotherapy

In 2013, polidocanol (Varithena) microfoam was approved under a new drug application for the treatment of varicose veins. Efficacy data derived from 2 randomized, blinded, multicenter studies.[19] One compared polidocanol at 0.5%, 1.0%, and 2.0% with endovenous placebo or a subtherapeutic dose of polidocanol foam. The primary end point was an improvement in symptoms at week 8, as measured by the Varicose Vein Symptoms Questionnaire. The improvement in symptoms was greater in the pooled polidocanol treatment group ($p<0.001$) and in each of the individual dose-concentration groups compared with vehicle alone. Secondary and tertiary end points (appearance, duplex ultrasound response, QOL) were also significantly better for the polidocanol groups compared with controls. This second study, called VANISH-2, was published by Todd et al (2014).[20] At the 8-week assessment, there was the 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% group, and 1.8% of the placebo group. Analysis of data from both studies showed a dose-response from 0.5% to 2.0% for improvement in appearance and from 0.5% to 1.0% for Duplex responders. The polidocanol 1.0% dose was selected for the U.S. Food and Drug Administration approval. Safety analysis found deep vein thrombosis detected by ultrasound in 2.8% of polidocanol-treated patients, with 1% of patients having proximal symptomatic thrombi; these patients were treated with anticoagulants. There was no sign of an increase in neurologic adverse events, and there were no adverse cardiac or cardiopulmonary effects following treatment with polidocanol injectable foam. Rates of occlusion with Varithena are similar to those reported for endovenous laser ablation or stripping. A randomized trial comparing endovenous laser ablation and stripping with this new preparation of foam sclerotherapy is needed to evaluate its comparative effectiveness. Evaluation out to 5 years is continuing.

Vasquez et al (2017) reported on a double-blinded RCT that evaluated the addition of polidocanol microfoam to endovenous thermal ablation.[21] A total of 117 patients who were candidates for both endovenous thermal ablation and treatment of visible varicosities received endovenous thermal ablation plus placebo (n=38) or polidocanol 0.5% (n=39) or 1% (n=40). At 8-week follow-up, physician-blinded vein appearance was significantly better with the combined polidocanol groups ($p=0.001$), but the improvement in patient ratings was not statistically significant. At 6-month follow-up, the percentages of patients who achieved a clinically meaningful change were significantly higher in both physician (70.9% vs 42.1%, $p=0.001$) and patient (67% vs 50%, $p=0.034$) ratings. The proportion of patients who received additional treatment for residual varicosities between week 8 and month 6 was modestly reduced (13.9% for the polidocanol vs 23.7% for placebo, $p=0.037$).

Section Summary: Sclerotherapy

For physician-compounded sclerotherapy, there is high variability in success rates of the procedure and some reports of serious adverse events. By comparison, rates of occlusion with the Food and Drug Administration–approved microfoam sclerotherapy (polidocanol 1%) are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy indicated that once occluded, recurrence rates at 2 years are similar to those of ligation and stripping. The addition of polidocanol microfoam to endovenous thermal ablation does not appear to improve health outcomes substantially.

MECHANOCHEMICAL ABLATION

Randomized Trials

Two publications (Bootun et al [2016], Lane et al [2017]) reported on early results from an RCT of 170 patients that compared ClariVein with RFA (see Table 1).[22,23] Maximum visual analog scale pain scores (out of 100) during the procedure were significantly lower in the mechanochemical ablation group (median, 15 mm) than in the RFA group (median, 34 mm; p=0.003). Average visual analog scale pain scores during the procedure were also modestly lower in the mechanochemical ablation group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific QOL, and generic QOL scores were similar between groups at 1 and 6 months. However, only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point (see Table 2). The second randomized trial (Lam et al [2016]) reported interim results of a dose-finding study, finding greater closure with use of polidocanol 2% or 3% (liquid) than with polidocanol 1% (microfoam).[24]

Table 1. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Bootun et al (2016)[22]; Lane et al (2017)[23]				1.Primary outcome was pain during the procedure	1. Outcomes only out to 6 mo

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 2. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Bootun et al (2016)[22]; Lane et al (2017)[23]		1. Patients not blinded to treatment (assessors of duplex ultrasound were blinded)		1. 76% follow-up at 1 mo and 71% follow-up at 6 mo		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Systematic Reviews

Systematic reviews have included both of the 2 trials described above and within-subject comparisons. Sun et al (2017) included the 2 trials described above and 11 reports from prospective observational within-subjects comparisons.[25] They found mechanochemical endovenous ablation to be effective in the short-term with minimal complications, but lack of outcomes standardization precluded comparison with other techniques. Potential sources of bias in studies assessed included patient self-selection and lack of blinding, combined with subjective patient-reported outcomes measures. Overall, the quality of evidence was rated as low or very low.

By comparison, Witte et al (2017) evaluated 13 studies with 10 cohorts (1521 veins) using to the MINORS study rating score.[26] The trials by Bootun et al (2016) and Lane et al (2017) as well as Lam et al ([2016] described above) were rated as good quality. All studies were considered to have appropriate endpoints, unbiased assessment, and appropriate follow-up periods. Limitations of some studies included nonconsecutive enrollment, retrospective designs, and losses to follow-up of greater than 5%. None of the studies was designed to compare success with endothermal ablation. In the available cohort studies, short-term anatomic success ranged from 87% to 92% for the veins, with success rates of 91% (n=136; 95% CI, 85% to 95%) at 2 years and 87% (n=48; 95% CI, 75% to 94%) at 3 years. The longest follow-up study reported anatomic success (closure rates) of 87% at 3 years but with slightly lower clinical success (83%).[27]

Section Summary: Mechanochemical Ablation

Mechanochemical ablation is a combination of liquid sclerotherapy and mechanical abrasion. The evidence on mechanochemical ablation includes an RCT with short-term results that compared mechanochemical ablation with RFA and case series with follow-up out to 3 years. The short-term results of the RCT suggested that intraprocedural pain is slightly lower with mechanochemical ablation than with RFA. However, mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in RCTs with a larger number of patients is needed to evaluate the efficacy and durability of this procedure compared with established procedures.

CYANOACRYLATE ADHESIVE

The VenaSeal pivotal study (VeClose), a multicenter noninferiority trial with 222 patients, compared VenaSeal with RFA for the treatment of venous reflux.[28,29] The primary end point (the proportion of patients with complete closure of the target great saphenous vein at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs 2.4 for RFA, p=0.11). Ecchymosis at day 3 was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA (p<0.01). Scores on the AVVQ and Venous Clinical Severity Score improved to a similar extent in both groups. The mean time to

return to work in a prospective cohort of 50 patients reported by Gibson and Ferris (2017) was 0.2 days.[30]

Eroglu et al (2017) reported closure rates of 94.1% at 30 months in a prospective cohort of 159 patients.[31] Thirty-three-month follow-up was reported by Zierau (2015) for 467 (58.7%) of 795 veins treated at 1 institution in Germany.[32] An inflammatory reddening of the skin was observed at 1 week posttreatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins reexamined, the sealing rate was 97.7%. This series had a high loss to follow-up.

Section Summary: Cyanoacrylate Adhesive
Evidence assessing cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with 3 months of follow-up and case series with longer follow-up. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at 3 months. Longer follow-up in trials with a larger number of patients is needed to determine the durability of this treatment.

CRYOABLATION
Klem et al (2009) reported on a randomized trial that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins.[33] Forty-four percent of patients had residual great saphenous vein remaining with cryoablation while 15% had residual vein remaining with conventional stripping. AVVQ scores also showed better results for conventional stripping (score, 11.7) than cryoablation (score, 8.0). There were no differences between groups in 36-Item Short-Form Health Survey summary scores or neural damage (12% in both groups).

Disselhoff et al (2008, 2011) reported on 2- and 5-year outcomes from a randomized trial that compared cryoablation with endovenous laser ablation.[34,35] Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP class C2) with saphenofemoral incompetence and great saphenous vein reflux. At 10 days after treatment, endovenous laser ablation provided better results than cryoablation with respect to pain scores over the first 10 days (2.9 vs 4.4), resumption of normal activity (75% vs 45%), and induration (15% vs 52%), all respectively. At 2-year follow-up, freedom from recurrent incompetence was observed in 77% of patients after endovenous laser ablation and in 66% of patients after cryoablation (p=*NS*). At 5 years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization were found in 62% of patients treated with endovenous laser ablation and in 51% of patients treated with cryoablation (p=*NS*). Neovascularization was more common after cryoablation, but incompetent tributaries were more common after endovenous laser ablation. There were no significant differences between groups in the Venous Clinical Severity Score or AVVQ scores at either the 2 or 5-month follow-ups for endovenous laser ablation.

Section Summary: Cryoablation
Two RCTs have suggested that cryotherapy is ineffective for treating varicose veins compared with available alternatives.

TRIBUTARY VARICOSITIES
Sclerotherapy and Phlebectomy
Early studies established ligation and stripping as the criterion standard for treating saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A Cochrane review by Tisi et al (2006), 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."[36] Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system (eg, post- or adjunctive treatment to other procedures such as surgery).[37] El-Sheikha et al (2014) reported on a small randomized trial of concomitant or sequential (if needed) phlebectomy following endovenous laser ablation for varicose veins.[38] QOL and clinical severity scores were similar between the groups by 1 year, with 16 (67%) of 24 patients in the sequential phlebectomy group receiving a secondary intervention.

The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. For example, Yamaki et al (2012) reported on a prospective RCT that compared visual foam sclerotherapy plus ultrasound-guided foam sclerotherapy of the great saphenous vein with visual foam sclerotherapy for varicose tributary veins.[39] Fifty-one 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 (45.1%) limbs treated with ultrasound plus visually guided foam sclerotherapy and in 22 (42.3%) limbs treated with visual sclerotherapy alone. Reflux was absent in 30 (58.8%) limbs treated with ultrasound plus visual guidance and in 37 (71.2%) treated with visual guidance alone (p=*NS*). The authors noted that, for the treatment of tributary veins in clinical practice, most patients receive a direct injection of foam without ultrasound guidance.

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. For example, as reported by Michaels et al (2006), of 1009 patients recruited for an RCT, 64 patients had minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment.[40] At baseline, 92% had symptoms of heaviness, 69% had cosmetic concerns, 53% reported itching, and 30% reported relief of symptoms using compression hosiery. At 1-year follow-up, there was an improvement in clinicians' assessment of the anatomic extent of varicose veins, with 85% of patients in the sclerotherapy group showing improvement compared with 29% of patients in the conservative therapy group. Symptoms of aching were milder or eliminated in 69% of the sclerotherapy group and 28% of the group treated with conservative therapy.

Transilluminated Powered Phlebectomy

A meta-analysis by Luebke and Brunkwall (2008) included 5 studies that compared transilluminated powered phlebectomy (TIPP) with conventional surgery.[41] Results showed a significant advantage of TIPP over the conventional treatment for the 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 (2006) that compared TIPP (n=29) with a multiple stab incision procedure (n=33).[42] 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, the blinded evaluation revealed that bruising or discoloration was higher for the TIPP group at 1 and 6 weeks postsurgery. At 6 weeks after surgery, patients in the TIPP group showed no reductions in pain (-2 points on the Burford Pain Scale), while patients in the multiple stab incision group had a significant reduction in pain scores compared with presurgical baseline (-20 points). Six weeks postsurgery, QOL measures had improved in the multiple stab incision group but not in the TIPP group. Thus, although TIPP required fewer surgical incisions, in this single-center study, it was associated with longer recovery due to more extensive bruising, prolonged pain, and reduced early postoperative QOL.

Section Summary: Tributary Varicosities
The evidence on the use of stab avulsion, sclerotherapy, and phlebectomy includes RCTs and systematic reviews of RCTs. The literature has indicated that sclerotherapy is effective for the treatment of tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). TIPP is effective at removing varicosities; outcomes are comparable with available alternatives such as stab avulsion and hook phlebectomy. However, there is limited evidence that TIPP is associated with more pain, bruising, discoloration, and a longer recovery, and the current literature does not show an advantage of TIPP over conventional treatment.

PERFORATOR REFLUX
A systematic literature review by O'Donnell (2008) indicated that there was a lack of evidence on the role of incompetent perforator vein surgery performed in conjunction with superficial saphenous vein surgery.[5] These conclusions were based on 4 RCTs published since 2000 that compared superficial vein surgery with conservative therapy for advanced chronic venous insufficiency (CEAP classes C5-C6). The 4 trials included 2 level I (large subject population) and 2 level II (small subject population) studies. Two trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other 2 treated the great saphenous vein alone. The 2 randomized studies (2004, 2007) in which the great saphenous vein alone was treated (including the ESCHAR trial) showed a significant reduction in ulcer recurrence compared with conservative therapy.[43,44] A community hospital–based multicenter, double-blind, randomized trial reported by Nelzen and Fransson (2011) found no clinical benefit (self-reported symptoms) from adding subfascial endoscopic perforator surgery to saphenous surgery in 75 patients with varicose ulcers (CEAP classes C5-C6) and incompetent perforators.[45]

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, Blomgren et al (2005) showed that reversal of perforator vein incompetence (28 [41%] of 68 previously incompetent perforators) was more common than new perforator vein incompetence (41 [22%] of 183 previously competent perforators) following superficial vein surgery.[46] O'Donnell (2008) discussed 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
Tenbrook et al (2004) reviewed the literature on subfascial endoscopic perforator surgery, which included 19 case series and 1 randomized trial.[47] In total, the selected studies included 1031 patients with 1140 treated limbs. Reviewers concluded that subfascial endoscopic perforator surgery was associated with excellent results regarding ulcer healing and prevention of recurrence. However, they also noted that randomized trials are required to define the relative contributions of compression therapy, superficial venous surgery, and subfascial endoscopic perforator surgery in the management of severe venous disease. Van Gent et al (2015) reported on 10-year follow-up from a randomized trial that compared conservative treatment with subfascial endoscopic perforator surgery for venous leg ulcers.[48] Patients (196 legs) returned to the clinic annually, and analysis was conducted with the last-observation carried forward. The primary outcome (incidence ulcer-free) was significantly higher in the surgical group (58.9%)

than in the conservative treatment group (39.6%; p=0.007). The number of incompetent perforator veins at follow-up was a risk factor for not being ulcer-free (OR=18.5, p<0.001). The relatively high rate of recurrence in the surgically treated group might have been due to limited or no stripping of the superficial veins at the time of subfascial endoscopic perforator surgery.

In a meta-analysis of subfascial endoscopic perforator surgery for chronic venous insufficiency, Luebke and Brunkwall (2009) concluded that "Its 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."[49] Reviewers also stated that the "introduction of less invasive techniques for perforator vein ablation, such as ultrasound-guided sclerotherapy or radiofrequency ablation, may diminish the role of subfascial endoscopic perforator surgery in the future."

Other Treatments

In a review of procedures for management of varicose veins, Hirsch and Dillavou (2008) recommended duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a short RFA catheter for the treatment of symptomatic residual perforator vein incompetence.[50] Ablation of incompetent perforator veins with laser or RFA has been shown to be technically feasible, although no studies have been identified that showed improvements in clinical outcomes (eg, ulcer healing or recurrence). A literature update by Hissink et al (2010) identified 1 study of endovenous laser ablation for perforating veins assessing 33 patients with CEAP classifications of C4 (skin changes), C5 (healed ulcer), or C6 (active ulcer).[51] 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 (15%) patients had active ulcers at baseline; 4 of the 5 ulcers had healed by 6 weeks after endovenous laser ablation. Evidence on the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion.[52]

Section Summary: Perforator Reflux

The literature has shown that the routine ligation and ablation of incompetent perforator veins is not necessary for treating varicose veins and venous insufficiency concurrent with superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating and ablating incompetent perforator veins. Subfascial endoscopic perforator surgery 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 RFA probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared with surgical interventions.

SUMMARY OF EVIDENCE

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive endovenous thermal ablation (radiofrequency or laser), the evidence includes RCTs and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at 2- to 5-year follow-up has supported the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead to more neovascularization, while thermal

ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For physician-compounded sclerotherapy, there is high variability in success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that, once occluded, recurrence rates at 2 years are similar to those of ligation and stripping. Together, this evidence indicates that the more consistent occlusion with the microfoam sclerotherapy preparation will lead to recurrence rates similar to ligation and stripping in the longer term. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation, the evidence includes 2 RCTs and case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that mechanochemical ablation does not require multiple needle sticks with tumescent anesthesia and may result in less pain during the procedure. One RCT with high loss to follow-up has been published, and a larger RCT is comparing mechanochemical ablation with RFA has reported early results. These short-term results have suggested that intraprocedural pain is lower with mechanochemical ablation than with RFA. However, liquid sclerotherapy is not as effective as thermal ablation techniques for saphenous veins, and mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in larger RCTs is needed to evaluate its efficacy and durability compared with established procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes an RCT and case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RFA at 3 months in a multicenter noninferiority trial. Longer follow-up in a larger number of patients is needed to determine the durability of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Varicose Tributary Veins

For individuals who have varicose tributary veins who receive ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events,

quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Perforator Veins

For individuals who have perforator vein reflux who receive ablation (eg, subfascial endoscopic perforator surgery) of perforator veins, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating or ablating incompetent perforator veins. Subfascial endoscopic perforator surgery 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 compared with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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

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

PRACTICE GUIDELINES AND POSITION STATEMENTS

Society for Vascular Surgery and American Venous Forum

The Society for Vascular Surgery and the American Venous Forum published joint clinical practice guidelines in 2011.[53] Table 3 provides the recommendations.

Table 3. Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases

Recommendation	Grade[a]	SOR	QOE
Compression therapy for venous ulcerations and varicose veins			

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

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

Society of Interventional Radiography

In 2003, the Society of Interventional Radiography published a position statement 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[54]:

"The endovenous treatment of varicose veins may be medically necessary when:

1. 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, American Venous Forum and Society of Interventional Radiography recommended reporting standards for endovenous ablation for the treatment of venous insufficiency.[55] They recommended that reporting in clinical studies should include the symptoms of venous disease, history of the disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation might include patients with reflux in an incompetent great saphenous vein or smaller saphenous vein or a major tributary branch of the great or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory great 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.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins in 2013.[56] NICE stated that:

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

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

NICE revised its guidance on endovenous mechanochemical ablation in 2016, concluding that "Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure…."[57]

In 2013, NICE published guidance on the diagnosis and management of varicose veins in the leg.[58] In 2015, NICE published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation, and surgery for varicose veins.[59] Five-year trial results are currently being evaluated.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03392753	Mechanochemical Ablation Compared to Cyanoacrylate Adhesive	180	Dec 2019

NTR4613[a]	Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial)	160	Apr 2020
NCT01936168	Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA)	460	Dec 2020
NCT02627846	A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein®) in the Management of Superficial Venous Insufficiency (LAMA)	140	Sep 2030

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

CODING

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

CPT/HCPCS

36465 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)
36466 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg
36468 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
36470 Injection of sclerosing solution: single vein
36471 Injection of sclerosing solution; multiple veins, same leg
36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

36479 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
36482 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
37500 Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
37700 Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718 Ligation, division, and stripping, short saphenous vein
37722 Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735 Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37760 Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg
37761 Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765 Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766 Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
37780 Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785 Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
37799 Unlisted procedure, vascular surgery
76937 Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)
76942 Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
76998 Ultrasonic guidance, intraoperative
76999 Unlisted ultrasound procedure (e.g. diagnostic, interventional)
93970 Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
93971 Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study
0524T Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring (Effective 01-01-2019)
S2202 Echosclerotherapy

- There is no specific CPT code for transilluminated powered phlebectomy. Providers might elect to use CPT codes describing stab phlebectomy (37765 or 37766) or unlisted vascular surgery procedure (37799).
- There are CPT codes specific to mechanochemical ablation: 36473, 36474. Before 2017 mechanochemical ablation procedures were reported with procedure code 37799.
- There is no specific CPT for microfoam sclerotherapy. Providers might elect to use CPT codes describing sclerotherapy (36468-36471) or the unlisted vascular surgery procedure code 37799. Use of codes 36475-36476 would be inappropriate as the procedure is not ablation therapy.
- Note: The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. If ultrasound guidance (CPT code 76942) is used to guide sclerotherapy of the varicose tributaries, it would be considered content of service to the injection procedure.

ICD-10 Diagnoses (Effective October 1, 2015)

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
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
I83.021	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
I83.11	Varicose veins of right lower extremity with inflammation
I83.12	Varicose veins of left lower extremity with 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
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
I83.891	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

I83.91 Asymptomatic varicose veins of right lower extremity
I83.92 Asymptomatic varicose veins of left lower extremity
I83.93 Asymptomatic varicose veins of bilateral lower extremities

REVISIONS	
05-04-2011	Description section updated
	In Policy section: ▪ Clarified policy by including within the Greater or Lesser Saphenous Veins, Accessory Saphenous Veins, and Symptomatic Varicose Tributaries sections of the policy the following: "B. Physical findings that support medically significant venous hypertension must be clearly documented." and "D. Treatment of varicose veins for cosmetic purposes is not covered." ▪ Clarified Policy Guidelines by: ▪ Adding to #1: "Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is not covered." to read "1. A clear and complete description of the physical exam of the lower extremities that documents the medical necessity of treatment for venous insufficiency for medical, not cosmetic purposes, is required. Physical findings that support medically significant venous hypertension must be clearly documented. Treatment of varicose veins for cosmetic purposes is not covered. Photographs may be requested." ▪ Revising #2: From "…up to 3 sclerotherapy sessions for both legs…" to "…up to 3 sclerotherapy sessions for each leg…" to read "Up to 20 injections in each leg may be treated in any one session and up to 3 sclerotherapy sessions for each leg may be considered medically necessary if selection criteria are met." ▪ Added to Policy Guidelines: "5. Patients with combined deep and superficial venous insufficiency are often not good candidates for ablation therapy. Varicose vein recurrence and ulcer recurrence rates following intervention are much higher." ▪ Removed from Policy Guidelines: "The severity of signs and symptoms of venous disease tends to correlate with the degree of reflux identified by duplex ultrasound." ▪ The intent of the policy language was not changed.
	Rationale section update
	Revision section: ▪ Removed revision details for 01-04-2008 and 07-18-2008
	References updated
09-06-2011	Description section updated.
	In Policy section: ▪ Within the subsection of Greater or Lesser Saphenous Veins moved the following wording as a stand alone Item B. to be included with the medically necessary criteria as item A. 3. to read, "Physical findings that support medically significant venous hypertension are clearly documented." This change was made to be clearer that in addition to meeting the medical necessity criteria, physical findings that support medically significant venous hypertension must be clearly documented. ▪ Within the subsection of Accessory Saphenous Veins moved the following wording as a stand alone Item B. to be included with the medically necessary criteria as item A. 4. to read, "Physical findings that support medically significant venous hypertension are clearly documented." This change was made to be clearer that in addition to meeting the medical

REVISIONS	
	necessity criteria, physical findings that support medically significant venous hypertension must be clearly documented. ▪ Within the subsection of Symptomatic Varicose Tributaries, Item A. was liberalized from, "The following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins…" to "The following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries.." ▪ Within the subsection of Symptomatic Varicose Tributaries, Item B. was revised from "Physical findings that support medically significant venous hypertension must be clearly documented." to "Physical findings must support medical necessity."
	Rationale section updated
	References updated
09-11-2012	Description section updated
	In Policy section: ▪ In I A 2 c and II A 3 c revised wording from "Recurrent hemorrhage or bleeding episodes…" to "Hemorrhage or recurrent bleeding episodes…" No policy intent change was made. ▪ In I A 3 and II A 4 clarified the wording from "Physical findings…" to "Physical / visible findings…" ▪ Added to IV Perforator Veins "A. Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met: 1. There is demonstrated perforator reflux; AND 2. The superficial saphenous veins (greater, lesser, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; AND 3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND 4. The venous insufficiency is not secondary to deep venous thromboembolism." ▪ Moved from Policy Guidelines to IV B the not medically necessary indication of: "6. Perforator reflux often resolves following saphenous ablation." ▪ Added the not medically necessary indication of IV C: " C. Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary." ▪ In Policy Guidelines #4 added, "However, deep vein insufficiency is not a contraindication to superficial vein treatment." ▪ In Policy Guidelines Reimbursement sub-section item 1 revised, "…reimbursed at 25% of full." to read, "1. Endovenous ablation (36475, 36476, 36478 and 36479) other than the greater saphenous vein will be reimbursed at 50% of full."
	Rationale section updated
	In Revision section: ▪ Removed revision details for dates: 04-22-2009, 11-18-2009, 01-01-2010
	References updated
03-08-2013	In the Reimbursement section: ▪ Removed the reimbursement limitation stating, "Endovenous ablation (36475, 36476, 36478 and 36479) other than the greater saphenous vein will be reimbursed at 50% of full."
12-24-2014	Description section updated
	In Policy section:

REVISIONS	
	▪ In Item I A and II A removed "Physical / visible findings that support medically significant venous hypertension are clearly documented." And added "…or microfoam sclerotherapy…" to read "…by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, or microfoam sclerotherapy may be considered medically necessary for…" ▪ In Item I B added "…or microfoam sclerotherapy…" to read "…by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy that do not meet the criteria described above is considered not medically necessary." ▪ In Item II A added "1. Incompetence of the accessory saphenous vein is isolated, OR" to read "Incompetence of the accessory saphenous vein is isolated, OR The greater or lesser saphenous veins had been previously eliminated (at least 3 months);" ▪ In Item III A added "When physical findings support medical necessity," (formerly standalone Item III B) to read, "When physical findings support medical necessity, the following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries (none of these techniques has been shown to be superior to another):" ▪ In new Item III B removed "Sclerotherapy as" to read, "The sole treatment of varicose vein tributaries…" ▪ In Policy Guidelines added "5. It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries." ▪ In Policy Guidelines removed "There is little evidence to support that ultrasound guidance makes a significant difference in outcomes from sclerotherapy when compared to non-ultrasound guided techniques."
	Rationale section updated
	In Coding section: ▪ Removed CPT Code: 36469 (Effective January 1, 2015) ▪ Coding comments updated ▪ ICD-10 Codes added
	In Revision section ▪ Removed Revision details for 10-11-2010.
	References updated
01-01-2016	In Coding section: ▪ Removed CPT codes: 37250, 37251
02-01-2019	Policy published 01-01-2019. Policy effective 02-01-2019.
	Description section updated
	In Policy section: ▪ Throughout the policy removed "lesser" and added "small" to read "great or small saphenous veins" ▪ In Item I revised to read "SAPHENOUS VEINS – Great or Small Saphenous Veins" ▪ In Item I A 1 added "and CEAP [Clinical, Etiology, Anatomy, Pathophysiology], class C2 or greater" to read "There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology], class C2 or greater" ▪ In Item I A 2a and II A 3a removed "that fails to respond to compressive therapy" to read "Ulceration secondary to venous stasis" ▪ In Item I A 2b and II A 3b removed "that fails to respond to compressive therapy" to read "Recurrent superficial thrombophlebitis" ▪ In Item I A 2d1) removed "or significant refractory edema or refractory stasis dermatitis when" to read "Persistent pain, swelling, itching, burning, or other symptoms associated with saphenous reflux" ▪ In Item II A 3d1) removed "or significant refractory edema or refractory stasis dermatitis when" and "accessory vein" to read "Persistent pain, swelling, itching, burning, or other symptoms associated with saphenous reflux"

REVISIONS	
	▪ In Item II B added "veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy" to read "Treatment of accessory saphenous veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy, that do not meet the criteria described above is considered not medically necessary." ▪ In Item III A removed "When physical findings support medical necessity" and added "when performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins" to read "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):" ▪ In Item III B removed "The sole", "in the presence of saphenofemoral or saphenopopliteal reflux" and not medically necessary" and added "symptomatic", "when performed either at the same time or following prior treatment of saphenous veins using any other techniques than noted above" and "experimental / investigational" to read "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 reflux is considered experimental / investigational" ▪ In Item VI added "Veins" to read "Other Veins" ▪ In Item VI A revised "not medically necessary" to "experimental / investigational" to read "Techniques for conditions not specifically listed above are experimental / investigational, including, but not limited to:" ▪ In Item VI A added "techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins", "Sclerotherapy of perforator veins", "Mechanochemical ablation of any vein", "Cyanoacrylate adhesive of any vein" to read " 1. Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins 2. Sclerotherapy of perforator veins 3. Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins 4. Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins. 5. Endovenous radiofrequency or laser ablation of tributary veins 6. Mechanochemical ablation of any vein 7. Cyanoacrylate adhesive of any vein 8. Endovenous cryoablation of any vein" ▪ Policy Guidelines updated
	Rationale section updated
	In Coding section: ▪ Added CPT Codes: 36465, 36466, 36473, 36474, 36482, 36483, 0524T ▪ Removed CPT Code: 93965
	References updated

REFERENCES

1. O'Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. *Cochrane Database Syst Rev.* Jan 21 2009(1):CD000265. PMID 19160178
2. O'Meara S, Cullum N, Nelson EA, et al. Compression for venous leg ulcers. *Cochrane Database Syst Rev.* Nov 14 2012;11:CD000265. PMID 23152202

3. Shingler S, Robertson L, Boghossian S, et al. Compression stockings for the initial treatment of varicose veins in patients without venous ulceration. *Cochrane Database Syst Rev.* Nov 9 2011;11(11):CD008819. PMID 22071857
4. Howard DP, Howard A, Kothari A, et al. The role of superficial venous surgery in the management of venous ulcers: a systematic review. *Eur J Vasc Endovasc Surg.* Oct 2008;36(4):458-465. PMID 18675558
5. O'Donnell TF, Jr. The present status of surgery of the superficial venous system in the management of venous ulcer and the evidence for the role of perforator interruption. *J Vasc Surg.* Oct 2008;48(4):1044-1052. PMID 18992425
6. Jones L, Braithwaite BD, Selwyn D, et al. Neovascularisation is the principal cause of varicose vein recurrence: results of a randomised trial of stripping the long saphenous vein. *Eur J Vasc Endovasc Surg.* Nov 1996;12(4):442-445. PMID 8980434
7. Rutgers PH, Kitslaar PJ. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. *Am J Surg.* Oct 1994;168(4):311-315. PMID 7943585
8. Nesbitt C, Bedenis R, Bhattacharya V, et al. Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices. *Cochrane Database Syst Rev.* Jul 30 2014;7(7):CD005624. PMID 25075589
9. Paravastu SC, Horne M, Dodd PD. Endovenous ablation therapy (laser or radiofrequency) or foam sclerotherapy versus conventional surgical repair for short saphenous varicose veins. *Cochrane Database Syst Rev.* Nov 29 2016;11:CD010878. PMID 27898181
10. Brittenden J, Cotton SC, Elders A, et al. A randomized trial comparing treatments for varicose veins. *N Engl J Med.* Sep 25 2014;371(13):1218-1227. PMID 25251616
11. Rass K, Frings N, Glowacki P, et al. Comparable effectiveness of endovenous laser ablation and high ligation with stripping of the great saphenous vein: two-year results of a randomized clinical trial (RELACS study). *Arch Dermatol.* Jan 2012;148(1):49-58. PMID 21931012
12. Rass K, Frings N, Glowacki P, et al. Same site recurrence is more frequent after endovenous laser ablation compared with high ligation and stripping of the great saphenous vein: 5 year results of a randomized clinical trial (RELACS Study). *Eur J Vasc Endovasc Surg.* Nov 2015;50(5):648-656. PMID 26319476
13. Christenson JT, Gueddi S, Gemayel G, et al. Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up. *J Vasc Surg.* Nov 2010;52(5):1234-1241. PMID 20801608
14. Biemans AA, Kockaert M, Akkersdijk GP, et al. Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. *J Vasc Surg.* Sep 2013;58(3):727-734 e721. PMID 23769603
15. van der Velden SK, Biemans AA, De Maeseneer MG, et al. Five-year results of a randomized clinical trial of conventional surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy in patients with great saphenous varicose veins. *Br J Surg.* Sep 2015;102(10):1184-1194. PMID 26132315
16. Theivacumar NS, Darwood RJ, Gough MJ. Endovenous laser ablation (EVLA) of the anterior accessory great saphenous vein (AAGSV): abolition of sapheno-femoral reflux with preservation of the great saphenous vein. *Eur J Vasc Endovasc Surg.* Apr 2009;37(4):477-481. PMID 19201621
17. Hamann SAS, Giang J, De Maeseneer MGR, et al. Editor's Choice - Five Year results of great saphenous vein treatment: a meta-analysis. *Eur J Vasc Endovasc Surg.* Dec 2017;54(6):760-770. PMID 29033337
18. Shadid N, Ceulen R, Nelemans P, et al. Randomized clinical trial of ultrasound-guided foam sclerotherapy versus surgery for the incompetent great saphenous vein. *Br J Surg.* Aug 2012;99(8):1062-1070. PMID 22627969
19. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Summary Review: 205098 Varithena. 2013; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/205098Orig1s000SumR.pdf. Accessed April 27, 2018.

20. Todd KL, 3rd, Wright D, for the Vanish-Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. *Phlebology.* Oct 2014;29(9):608-618. PMID 23864535
21. Vasquez M, Gasparis AP, Varithena 017 Investigator G. A multicenter, randomized, placebo-controlled trial of endovenous thermal ablation with or without polidocanol endovenous microfoam treatment in patients with great saphenous vein incompetence and visible varicosities. *Phlebology.* May 2017;32(4):272-281. PMID 26957489
22. Bootun R, Lane T, Dharmarajah B, et al. Intra-procedural pain score in a randomised controlled trial comparing mechanochemical ablation to radiofrequency ablation: The Multicentre Venefit versus ClariVein(R) for varicose veins trial. *Phlebology.* Feb 2016;31(1):61-65. PMID 25193822
23. Lane T, Bootun R, Dharmarajah B, et al. A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins - Final results of the Venefit versus Clarivein for varicose veins trial. *Phlebology.* Mar 2017;32(2):89-98. PMID 27221810
24. Lam YL, Toonder IM, Wittens CH. Clarivein(R) mechano-chemical ablation an interim analysis of a randomized controlled trial dose-finding study. *Phlebology.* Apr 2016;31(3):170-176. PMID 26249150
25. Sun JJ, Chowdhury MM, Sadat U, et al. Mechanochemical ablation for treatment of truncal venous insufficiency: a review of the current literature. *J Vasc Interv Radiol.* Oct 2017;28(10):1422-1431. PMID 28811080
26. Witte ME, Zeebregts CJ, de Borst GJ, et al. Mechanochemical endovenous ablation of saphenous veins using the ClariVein: A systematic review. *Phlebology.* Dec 2017;32(10):649-657. PMID 28403687
27. Witte ME, Holewijn S, van Eekeren RR, et al. Midterm outcome of mechanochemical endovenous ablation for the treatment of great saphenous vein insufficiency. *J Endovasc Ther.* Feb 2017;24(1):149-155. PMID 27742900
28. U.S. Food and Drug Administration. VenaSeal Closure System. PMA P140018. 2015; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140018. Accessed April 27, 2018.
29. Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg.* Apr 2015;61(4):985-994. PMID 25650040
30. Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). *Vascular.* Apr 2017;25(2):149-156. PMID 27206470
31. Eroglu E, Yasim A, Ari M, et al. Mid-term results in the treatment of varicose veins with N-butyl cyanoacrylate. *Phlebology.* Dec 2017;32(10):665-669. PMID 28669248
32. Zierau UT. Sealing veins with the VenaSeal Sapheon Closure System: results for 795 treated truncal veins after 1000 days. *Vasomed.* 2015;27:124-127. PMID
33. Klem TM, Schnater JM, Schutte PR, et al. A randomized trial of cryo stripping versus conventional stripping of the great saphenous vein. *J Vasc Surg.* Feb 2009;49(2):403-409. PMID 19028042
34. Disselhoff BC, der Kinderen DJ, Kelder JC, et al. Randomized clinical trial comparing endovenous laser with cryostripping for great saphenous varicose veins. *Br J Surg.* Oct 2008;95(10):1232-1238. PMID 18763255
35. Disselhoff BC, der Kinderen DJ, Kelder JC, et al. Five-year results of a randomized clinical trial comparing endovenous laser ablation with cryostripping for great saphenous varicose veins. *Br J Surg.* Aug 2011;98(8):1107-1111. PMID 21633948
36. Tisi PV, Beverley C, Rees A. Injection sclerotherapy for varicose veins. *Cochrane Database Syst Rev.* Oct 18 2006(4):CD001732. PMID 17054141
37. Leopardi D, Hoggan BL, Fitridge RA, et al. Systematic review of treatments for varicose veins. *Ann Vasc Surg.* Mar 2009;23(2):264-276. PMID 19059756

38. El-Sheikha J, Nandhra S, Carradice D, et al. Clinical outcomes and quality of life 5 years after a randomized trial of concomitant or sequential phlebectomy following endovenous laser ablation for varicose veins. *Br J Surg.* Aug 2014;101(9):1093-1097. PMID 24916467
39. Yamaki T, Hamahata A, Soejima K, et al. Prospective randomised comparative study of visual foam sclerotherapy alone or in combination with ultrasound-guided foam sclerotherapy for treatment of superficial venous insufficiency: preliminary report. *Eur J Vasc Endovasc Surg.* Mar 2012;43(3):343-347. PMID 22230599
40. Michaels JA, Campbell WB, Brazier JE, et al. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). *Health Technol Assess.* Apr 2006;10(13):1-196, iii-iv. PMID 16707070
41. Luebke T, Brunkwall J. Meta-analysis of transilluminated powered phlebectomy for superficial varicosities. *J Cardiovasc Surg (Torino).* Dec 2008;49(6):757-764. PMID 19043390
42. Chetter IC, Mylankal KJ, Hughes H, et al. Randomized clinical trial comparing multiple stab incision phlebectomy and transilluminated powered phlebectomy for varicose veins. *Br J Surg.* Feb 2006;93(2):169-174. PMID 16432820
43. Barwell JR, Davies CE, Deacon J, et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet.* Jun 5 2004;363(9424):1854-1859. PMID 15183623
44. Gohel MS, Barwell JR, Taylor M, et al. Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial. *BMJ.* Jul 14 2007;335(7610):83. PMID 17545185
45. Nelzen O, Fransson I. Early results from a randomized trial of saphenous surgery with or without subfascial endoscopic perforator surgery in patients with a venous ulcer. *Br J Surg.* Apr 2011;98(4):495-500. PMID 21656715
46. Blomgren L, Johansson G, Dahlberg-Akerman A, et al. Changes in superficial and perforating vein reflux after varicose vein surgery. *J Vasc Surg.* Aug 2005;42(2):315-320. PMID 16102633
47. Tenbrook JA, Jr., Iafrati MD, O'Donnell T F, Jr., et al. Systematic review of outcomes after surgical management of venous disease incorporating subfascial endoscopic perforator surgery. *J Vasc Surg.* Mar 2004;39(3):583-589. PMID 14981453
48. van Gent WB, Catarinella FS, Lam YL, et al. Conservative versus surgical treatment of venous leg ulcers: 10-year follow up of a randomized, multicenter trial. *Phlebology.* Mar 2015;30(1 Suppl):35-41. PMID 25729066
49. Luebke T, Brunkwall J. Meta-analysis of subfascial endoscopic perforator vein surgery (SEPS) for chronic venous insufficiency. *Phlebology.* Feb 2009;24(1):8-16. PMID 19155335
50. Hirsch SA, Dillavou E. Options in the management of varicose veins, 2008. *J Cardiovasc Surg (Torino).* Feb 2008;49(1):19-26. PMID 18212684
51. Hissink RJ, Bruins RM, Erkens R, et al. Innovative treatments in chronic venous insufficiency: endovenous laser ablation of perforating veins: a prospective short-term analysis of 58 cases. *Eur J Vasc Endovasc Surg.* Sep 2010;40(3):403-406. PMID 20547462
52. Myers KA, Jolley D. Factors affecting the risk of deep venous occlusion after ultrasound-guided sclerotherapy for varicose veins. *Eur J Vasc Endovasc Surg.* Nov 2008;36(5):602-605. PMID 18718772
53. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* May 2011;53(5 Suppl):2S-48S. PMID 21536172
54. Society of Interventional Radiology. Position Statement on Endovenous Ablation. 2003; https://www.sirweb.org/globalassets/aasociety-of-interventional-radiology-home-page/practice-resources/standards_pdfs/sir_venous_ablation_statement_final2015.pdf. Accessed April 27, 2018.
55. Kundu S, Lurie F, Millward SF, et al. Recommended reporting standards for endovenous ablation for the treatment of venous insufficiency: joint statement of the American Venous Forum and the Society of Interventional Radiology. *J Vasc Interv Radiol.* Sep 2007;18(9):1073-1080. PMID 17804767

56. National Institute for Health and Care Excellence (NICE). Ultrasound-guided foam sclerotherapy for varicose veins [IPG440] 2013; https://www.nice.org.uk/guidance/ipg440. Accessed April 27, 2018.
57. National Institute for Health and Care Excellence (NICE). Endovenous mechanochemical ablation for varicose veins [IPG557]. 2016; https://www.nice.org.uk/guidance/ipg557. Accessed April 27, 2018.
58. National Institute for Health and Care Excellence (NICE). Varicose veins: diagnosis and management [CG168]. 2013; https://www.nice.org.uk/guidance/cg168. Accessed April 27, 2018.
59. Brittenden J, Cotton SC, Elders A, et al. Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial. *Health Technol Assess.* Apr 2015;19(27):1-342. PMID 25858333

Other References:

1. Blue Cross and Blue Shield of Kansas National Medical Consultant (ID 1073-3390), February 5, 2007.
2. Blue Cross and Blue Shield of Kansas board certified vascular surgeon medical consultant (481), January 2009.
3. AMR consultant board certified in general surgery, vascular surgery, and critical care surgery (#48325), September 4, 2012.