7.01.124 Treatment of Varicose Veins/Venous Insufficiency

Original Policy Date: October 11, 2000  Effective Date: February 1, 2018
Section: 7.0 Surgery  Page: Page 1 of 27

Policy Statement

Great or Small Saphenous Veins
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 both the following criteria have been met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater
- There is documentation of one or more of the following indications:
  - Ulceration secondary to venous stasis
  - Recurrent superficial thrombophlebitis
  - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
  - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux and both of the following:
    - The symptoms significantly interfere with activities of daily living
    - Conservative management including compression therapy for at least 3 months has not improved the symptoms

Treatment of great or small 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.

Accessory Saphenous Veins
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:

- One of the following:
  - Incompetence of the accessory saphenous vein is isolated
  - The great or small saphenous veins had been previously eliminated (at least 3 months)
- There is demonstrated accessory saphenous reflux
- There is documentation of one or more of the following indications:
  - Ulceration secondary to venous stasis
  - Recurrent superficial thrombophlebitis
  - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
  - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, and both of the following:
    - The symptoms significantly interfere with activities of daily living
    - Conservative management including compression therapy for at least 3 months has not improved the symptoms

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.

Symptomatic Varicose Tributaries
Any of the following treatments may be 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):
7.01.124  Treatment of Varicose Veins/Venous Insufficiency
Page 2 of 27

- Stab avulsion
- Hook phlebectomy
- Sclerotherapy, other than microfoam sclerotherapy
- Transilluminated powered phlebectomy

The use of microfoam sclerotherapy for the treatment of tributary veins is considered not medically necessary.

Treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment of saphenous veins using any other techniques than those noted above is considered investigational.

**Perforator Veins**

Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when all of the following conditions have been met:

- There is demonstrated perforator reflux
- The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated
- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months
- The venous insufficiency is not secondary to deep venous thromboembolism.

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

**Telangiectasia**

Treatment of telangiectasia such as spider veins, angiомаtes, and hemangiomata that are less than 3 millimeters in diameter is considered not medically necessary.

**Other Veins**

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

- Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins
- Sclerotherapy of perforator veins
- Sclerotherapy, other than microfoam sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins
- Endovenous radiofrequency or laser ablation of tributary veins
- Endovenous cryoablation of any vein
- Mechanochemical ablation of any vein
- Cyanoacrylate adhesive of any vein

**Policy Guidelines**

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**

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>C1</td>
<td>Telangiectasies or reticular veins</td>
</tr>
<tr>
<td>C2</td>
<td>Varicose veins</td>
</tr>
</tbody>
</table>
### Treatment of Varicose Veins/Venous Insufficiency

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3</td>
<td>Edema</td>
</tr>
<tr>
<td>C4a</td>
<td>Pigmentation and eczema</td>
</tr>
<tr>
<td>C4b</td>
<td>Lipodermatosclerosis and atrophie blanche</td>
</tr>
<tr>
<td>C5</td>
<td>Healed venous ulcer</td>
</tr>
<tr>
<td>C6</td>
<td>Active venous ulcer</td>
</tr>
<tr>
<td>S</td>
<td>Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>A</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>

Adapted from http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf

CEAP: Clinical, Etiologic, Anatomic, Pathophysiologic classification system.

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.

Up to three sclerotherapy (liquid or foam) sessions (dates of service) are allowable per extremity. More than three sessions are subject to medical review.

All of the following are incidental to the primary procedure and not separately reimbursable:
- All imaging guidance and monitoring (Doppler or Duplex ultrasound, or fluoroscopy) performed during the procedure (surgery, sclerotherapy, ablation, etc.) or for the purpose of mapping
- Injection procedures with or without automatic power injection
- Introduction of needles or catheters
- Local anesthesia
- Sedation
- Use of optical magnifying glasses (loupes)
- Vascular access including venipuncture

### Coding

There is no specific CPT code for transilluminated powered phlebectomy (TIPP). Providers may bill the following CPT codes for TIPP:

**Stab Phlebectomy:**
- 37765: Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
- 37766: Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions

**Unlisted Vascular Procedure:**
- 37799: Unlisted procedure, vascular surgery

Before 2017, the mechanochemical ablation procedures were reported with the unlisted vascular surgery procedure code 37799.

**Effective January 1, 2018,** the following CPT codes are specific to non-compounded microfoam sclerotherapy:
- 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 (e.g., 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 (e.g., great saphenous vein, accessory saphenous vein), same leg

Providers may bill the unlisted vascular surgery procedure code 37799 or the following CPT codes describing sclerotherapy:
- 36468: Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
7.01.124 Treatment of Varicose Veins/Venous Insufficiency
Page 4 of 27

- **36470**: Injection of sclerosant; single incompetent vein (other than telangiectasia)
- **36471**: Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg

The following CPT codes would be used for radiofrequency ablation and endovenous laser ablation:
- **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; subsequent vein(s) 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; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Each code is specific for the requested vein. For example, if 36475 is requested for treatment of the GSV, this would include treatment both above and below the knee; if 36475 was requested for treatment above the knee, and 36476 for below the knee, only 36475 would be allowed. The same applies to 36478 and 36479.

There are CPT codes specific to mechanochemical ablation:
- **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)

**Effective January 1, 2018**, the following CPT codes are specific to endovenous ablation using chemical adhesive such as cyanoacrylate:
- **36482**: Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., 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 (e.g., 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)

### 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) treatment.

### Related Policies

- N/A
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

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 (PMA P140018) process for the permanent closure of clinically significant venous reflux through endovenous embolization with coaptation. The VenaSeal® Closure System seals the vein using a cyanoacrylate adhesive agent. FDA product code: PJQ.

In 2013, Varithena™ (formerly known as Varisolve®; BTG, London), a sclerosant microfoam made with a proprietary gas mix, was approved by the FDA under a new drug application (NDA 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 the 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 the 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 the FDA for “use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins.” In 2008, the modified VNUS® ClosureFast™ Intravascular Catheter was cleared by the 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 the 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 the 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 the 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 the FDA through the 510(k) process (K071468) for mechanoochemical ablation. The 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.
Rationale

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).

Treatment
Treatment of venous reflux/venous insufficiency is aimed at reducing abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of elevation of the extremities, graded compression, and wound care when indicated.

Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or in the deep venous system. The competence of any single valve is not static and may be pressure-dependent. For example, accessory saphenous veins may have independent saphenofemoral or saphenopopliteal junctions that become incompetent when the great or small saphenous veins are eliminated and blood flow is diverted through the accessory veins.

Saphenous Veins and Tributaries
Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux typically includes the following:
1. Identification by preoperative Doppler ultrasonography of the valvular incompetence
2. Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
3. Removal of the superficial vein from circulation (e.g., 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.

Sclerotherapy
The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately resulting in the occlusion of the vessel. The success of the treatment depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam
sclerosants are commonly produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). 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 3500 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 thermal endovenous ablation techniques (radiofrequency ablation [RFA], endovenous laser ablation).

**Thermal 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 to cause injury to the vessel. 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.

**Cyanoacrylate Adhesive**
Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (i.e., 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**
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 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 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.

**Literature Review**

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 for 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 (i.e., ligation and stripping) compared to compression therapy.

**Conventional Treatment of Saphenous Reflux**

**Compression Therapy**

A 2009 Cochrane review on compression for venous leg ulcers included 39 randomized controlled trials (RCTs) with 47 different comparisons. The review was updated in 2012, and included 48 RCTs with 59 different comparisons. Most of the RCTs were small. Objective measures of healing were the time to complete healing, the proportion of ulcers healed within the trial period (typically 12 weeks), the change in ulcer size, and the rate of change in ulcer size. Evidence from 8 trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. In addition, multicomponent systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses did not include time to healing, studies included in the review reported that the mean time to ulcer healing was approximately 2 months, while the median time to healing in other reports was 3 to 5 months.

A Cochrane review on compression stockings for the initial treatment of varicose veins in patients without venous ulceration was published in 2011. Selected for the review were 7 studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2-C4). Six of the studies compared different types or pressures of stockings. Subjectively, participants' symptoms improved, but results were not compared with a control arm. Due primarily to inadequate reporting, the methodologic quality of the 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.\textsuperscript{4,5} In general, recurrence rates after ligation and stripping are estimated at 20\% in short-term follow-up.\textsuperscript{4} Jones et al (1996) reported on the results of a trial that randomized 100 patients with varicose veins to ligation alone or to ligation plus stripping.\textsuperscript{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.\textsuperscript{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 from 2014 compared endovenous ablation (radiofrequency and laser) plus foam sclerotherapy with ligation and stripping for saphenous vein varices.\textsuperscript{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; \textit{p}=0.06) or for symptomatic recurrence (OR=1.28). For endovenous laser ablation versus 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, \textit{p}<0.001; OR=0.29, \textit{p}<0.001, respectively). For endovenous radiofrequency ablation (RFA) versus 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 2016 Cochrane review compared endovenous laser ablation or RFA to surgical repair for short saphenous veins with reflux at the saphenopopliteal junction.\textsuperscript{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 randomized controlled trial (RCT) is a 2014 trial by Brittenden et al that compared foam sclerotherapy, endovenous laser ablation, and surgical treatment in 798 patients.\textsuperscript{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 was performed in 38\% of patients in the foam group and in 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.\textsuperscript{11} At 2-year follow-up, there were no significant differences between the groups for clinically recurrent varicose veins, medical condition 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\%.\textsuperscript{12} Same-site recurrences were more frequent in the endovenous laser ablation group (18\% with endovenous laser ablation vs 5\% with surgery, \textit{p}=0.002), but different-site recurrences were more frequent in the surgically treated group (50\% with surgery vs 31\% with endovenous laser ablation, \textit{p}=0.002). Overall, there was no significant difference in recurrence rates between the
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). 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. At 1-year follow-up, the anatomic success rates were similar between endovenous laser ablation (88.5%) and stripping (88.2%), which were 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. 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.

Literature on isolated treatment of the anterior accessory saphenous vein is limited. In a 2009 study, outcomes from a cohort of 33 patients who underwent endovenous laser ablation of the anterior accessory saphenous vein were compared with 33 matched controls undergoing endovenous laser ablation of the great saphenous vein. In 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 the 2 groups. 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 on endovenous ablation with 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.

**Sclerotherapy**

**Physician-Compounded Sclerotherapy**

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). 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. 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 2012 study was a noninferiority trial comparing foam sclerotherapy with ligation and stripping in 430 patients. Analysis was per protocol. Forty (17%) patients had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in the 2 groups (11.3% sclerotherapy vs 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. There were 2 serious
adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within 1 week of treatment.

**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. 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 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 in 2014. At the 8-week assessment, there was elimination of reflux and/or occlusion of the previously incompetent vein in 85.6% of the combined 0.5% and 1.0% groups, 59.6% of patients in the 0.125% 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 (FDA) 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.

**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 FDA-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 have indicated that, once occluded, recurrence rates at 2 years are similar to those of ligation and stripping.

**Mechanochemical Ablation**

Early results of an RCT and several prospective cohort studies have been reported. In 2017, Lane et al reported on results from an RCT of 170 patients that compared ClariVein with RFA. Maximum visual analog scale (VAS) 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 VAS pain scores during the procedure were also significantly 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 the 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.

One prospective multicenter series (2014) evaluated the efficacy of mechanochemical ablation for treating greater saphenous veins in 126 patients in a community setting. Veins selected were greater than 4 mm and less than 12 mm in diameter, with an average diameter of 7.3 mm. Closure rates were 100% at 1 week, 98% at 3 months, and 94% at 6 months. The Venous Clinical Severity Score (VCSS) decreased from 9 pretreatment to 3 at 6 months. In 2012, Elias and Raines reported on an industry-sponsored safety and efficacy study of mechanochemical ablation with the ClariVein system. Thirty greater saphenous veins in 29 patients were treated with this device. Great saphenous veins with diameters greater than 12 mm were excluded. At 6-month follow-
up, 1 vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events was reported. Another prospective series (2013) evaluated mechanochemical ablation of the small saphenous vein in 50 consecutive patients. Only patients with a vein diameter of 2.5 to 11 mm were included. The dose of sclerosant was increased after the first 15 patients. At the 6-week assessment, all treated veins were occluded; at the 1-year follow-up, 94% remained occluded. The median VAS score for pain during the procedure was 2 out of 10. There were no major complications.

**Section Summary: Mechanochemical Ablation**

The evidence on mechanochemical ablation includes an RCT with short-term results and case series. Mechanochemical ablation is a combination of liquid sclerotherapy plus mechanical abrasion. One RCT with short-term follow-up has been published. These short-term results suggest that intra-procedural 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 is needed to evaluate the efficacy and durability of this procedure compared to 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. 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 VCSS improved to a similar extent in the 2 groups.

Twenty-four-month follow-up was reported for 24 of 38 patients enrolled in a study by Almeida et al (2015). Thirty-three-month follow-up (2015) was reported for 467 (58.7%) of 795 veins treated at 1 institution in Germany. 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 on 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 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. Forty-four percent of patients had residual great saphenous vein remaining in the cryoablation group while 15% had residual vein remaining in the conventional stripping group. AVVQ scores also showed better results for conventional stripping (score, 11.7) compared with cryoablation (score, 8.0). There were no differences between the groups in 36-Item Short-Form Health Survey summary scores, and neural damage was the same (12%) in both groups.

Disselhoff et al (2008, 2011) reported 2- and 5-year outcomes from a randomized trial that compared cryoablation with endovenous laser ablation. 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 was no significant difference between groups in VCSS or AVVQ scores at either 2 or 5 endovenous laser ablation.

**Section Summary: Cryoablation**

Two RCTs have suggested that cryotherapy is not as effective as 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 2006 Cochrane review, based primarily on RCTs from the 1980s, concluded that: “The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins.” Scampini. Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system (e.g., post-operative treatment or other procedures such as surgery). In 2014, El-Sheikha et al reported on a small randomized trial of concomitant or sequential (if needed) phlebectomy following endovenous laser ablation for varicose veins. 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. In 2012, Yamaki et al 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. Fifty-one limbs in 48 patients were treated with ultrasound-guided 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-visual guidance 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 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, of 1009 patients recruited for a 2006 RCT, 64 patients had minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. 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 in 28% of the group treated with conservative therapy.

**Transilluminated Powered Phlebectomy**

A 2008 meta-analysis included 5 studies that compared transilluminated powered phlebectomy (TIPP) with conventional surgery. 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). A single surgeon performed all but 2 of the procedures, and there was no difference in operating time. Patients treated with TIPP had an average of 5 incisions, compared with 20 for the multiple stab procedure. However, blinded evaluation revealed that bruising or discoloration was higher for the TIPP group at 1 and 6 weeks postsurgery. At 6 weeks after surgery, patients in the TIPP group showed no improvement in pain (-2 points on the Burford Pain Scale), while patients in the multiple stab incision group had a significant improvement in pain score compared with presurgical baseline (-20 points). Six weeks postsurgery, QOL measures had improved in the multiple stab incision group but not in the TIPP group. Thus, although TIPP had the advantage of fewer surgical incisions, in this single-center study, it was associated with longer recovery due to more extensive bruising, prolonged pain, and reduced early postoperative QOL.

Section Summary: Tributary Varicosities
The evidence 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 published in 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. These conclusions were based on 4 RCTs published since 2000 that compared superficial vein surgery with conservative therapy in 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 of the trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other 2 treated the 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. A 2011 community hospital-based multicenter, double-blind, randomized trial 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.

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, 1 study (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. O’Donnell (2008) discussed additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

Subfascial Endoscopic Perforator Surgery
In 2004, Tenbrook et al published a review of the literature of subfascial endoscopic perforator surgery, which included 19 case series and 1 randomized trial. In total, the selected studies included 1031 patients with 1140 treated limbs. Reviewers concluded that subfascial endoscopic perforator surgery was associated with excellent results in terms of 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. In 2015, Van Gent et al reported on 10-year follow-up from a randomized trial that compared conservative treatment to subfascial endoscopic perforator surgery for venous leg ulcers. Patients (196 legs) returned to the clinic on an annual basis 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/no stripping of the superficial veins at the time of subfascial endoscopic perforator surgery.

A 2009 meta-analysis of subfascial endoscopic perforator surgery for chronic venous insufficiency 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.” 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**

A 2008 review of procedures for management of varicose veins recommended duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short RFA catheter for the treatment of symptomatic residual perforator vein incompetence. Ablation of incompetent perforator veins with laser or RFA had been shown to be technically feasible, although no studies have been identified that showed an improvement in clinical outcomes (e.g., ulcer healing or recurrence). The 2010 literature update identified 1 study of endovenous laser ablation for perforating veins in 33 patients with a CEAP classification of C4 (skin changes), C5 (healed ulcer), or C6 (active ulcer). 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 regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion.

**Section Summary: Perforator Reflux**

The literature has shown that the routine ligation and ablation of incompetent perforator veins is not necessary for the treatment of varicose veins and venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (i.e., ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (e.g., deep vein valve replacement). 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**

**Saphenous Veins**

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive thermal endovenous ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation
and stripping at 2- to 5-year follow-up has supported use of both radiofrequency ablation (RFA) and endovenous laser ablation. Evidence has suggested that ligation and stripping leads to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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 a faster recovery. One RCT with high loss to follow-up has been published and a larger RCT comparing mechanochemical ablation with RFA has reported early results. These short-term results have suggested that intraoperative pain is lower with mechanochemical ablation than with RFA. However, mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up is needed to evaluate its efficacy and durability compared to 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 of tributary veins (stab avulsion sclerosis or phlebectomy), the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of
tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Perforator Veins**

For individuals who have perforator vein reflux who receive ablation of perforator veins (e.g., subfascial endoscopic perforator surgery), the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (i.e., ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (e.g., deep vein valve replacement). 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.

**Supplemental Information**

**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.

**2015 Input**

In response to requests from Blue Cross Blue Shield Association, input was received from 4 physician specialty societies 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 (AVF) published joint clinical practice guidelines in 2011. Table 1 provides the recommendations.

| Table 1: Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases |
|----------------------------------|------------|-------|-------|
| **Recommendation**               | **Grade** | **SOR** | **QOE** |
| Compression therapy for venous ulcerations and varicose veins | 1B | Strong | Moderate |
| Compression therapy is recommended as the primary treatment to aid healing of venous ulceration | 1A | Strong | High |
| To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended | 2C | Weak | Low |
| Use of compression therapy for patients with symptomatic varicose veins is recommended | 1B | Strong | Moderate |
| 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 | 1B | Strong | Moderate |
| Endovenous thermal ablation (radiofrequency or laser) is recommended over | 1B | Strong | Moderate |
| • chemical ablation with foam or | 1B | Strong | Moderate |
Recommendation | Gradea SOR QOE
---|---
**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.

**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 (SIR) 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:

“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)

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.

3. The patient's anatomy is amenable to endovenous ablation.”

In a joint statement published in 2007, AVF and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency. They recommended that reporting in clinical studies should include the symptoms of venous disease, history of disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation may include patients with reflux in an incompetent great saphenous vein or smaller saphenous vein or in 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. 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 provided that standard arrangements are in place for consent, audit and clinical governance.”

In 2013, NICE published a practice guideline on the diagnosis and management of varicose veins in the leg. NICE recommended a study of the clinical and cost effectiveness of:

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

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. Cost-effectiveness was based on a large multicenter randomized trial comparing treatments for varicose veins (described previously). Five-year trial results are currently being evaluated.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

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

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01459263</td>
<td>Mechanooehemical Endovenous Ablation of Great Saphenous Vein Incompetence Using the Clarivein™ Device: a Prospective Study</td>
<td>100</td>
<td>Apr 2017 (ongoing)</td>
</tr>
<tr>
<td>NTR4613a</td>
<td>Mechanooehemical endovenous ablation versus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial)</td>
<td>160</td>
<td>Apr 2020</td>
</tr>
<tr>
<td>NCT02627846</td>
<td>A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanooehemical Ablation (Clarivein™) in the Management of Superficial Venous Insufficiency (LAMA)</td>
<td>140</td>
<td>Sep 2030</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01807585a</td>
<td>Randomized Control Trial Comparing VenaSeal Saphenous Closure System With Radiofrequency Ablation (Pivotal Study)</td>
<td>244</td>
<td>Sep 2016 (unknown)</td>
</tr>
</tbody>
</table>

NCT: National Clinical Trial. NTR: Nederland’s Trial Registry.
a Denotes industry-sponsored or cosponsored trial.
References


19. 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


7.01.124 Treatment of Varicose Veins/Venous Insufficiency


Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - All prior varicose vein treatments to date and response (including conservative management)
  - Leg and vein to be treated
  - Reason for varicose vein treatment
  - Type of treatment/procedure requested
  - Copy of all Doppler and/or Duplex ultrasounds documenting reflux within the last three months

Post Service

- Varicose vein treatment operative/procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
<th>CPT®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36465</td>
<td>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 (e.g., great saphenous vein, accessory saphenous vein)</td>
<td><strong>Code effective 1/1/2018</strong></td>
</tr>
<tr>
<td></td>
<td>36466</td>
<td>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 (e.g., great saphenous vein, accessory saphenous vein), same leg</td>
<td><strong>Code effective 1/1/2018</strong></td>
</tr>
<tr>
<td></td>
<td>36468</td>
<td>Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk</td>
<td><strong>Code revision effective 1/1/2018</strong></td>
</tr>
<tr>
<td></td>
<td>36470</td>
<td>Injection of sclerosant; single incompetent vein (other than telangiectasia)</td>
<td><strong>Code revision effective 1/1/2018</strong></td>
</tr>
<tr>
<td></td>
<td>36471</td>
<td>Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg</td>
<td><strong>Code revision effective 1/1/2018</strong></td>
</tr>
<tr>
<td></td>
<td>36473</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Code</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>36474</td>
<td><strong>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)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36475</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36476</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36478</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36479</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36482</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated</strong> <em>(Code effective 1/1/2018)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36483</td>
<td><strong>Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., 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)</strong> <em>(Code effective 1/1/2018)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37500</td>
<td><strong>Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37700</td>
<td><strong>Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37718</td>
<td><strong>Ligation, division, and stripping, short saphenous vein</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37722</td>
<td><strong>Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37735</td>
<td><strong>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</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37760</td>
<td><strong>Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37761</td>
<td><strong>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37765</td>
<td><strong>Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37766</td>
<td><strong>Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37780</td>
<td><strong>Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37785</td>
<td><strong>Ligation, division, and/or excision of varicose vein cluster(s), 1 leg</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37799</td>
<td><strong>Unlisted procedure, vascular surgery</strong></td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Code</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-----------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>93970</td>
<td>Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study</td>
<td></td>
</tr>
<tr>
<td></td>
<td>93971</td>
<td>Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study</td>
<td></td>
</tr>
<tr>
<td>HCPCS</td>
<td>S2202</td>
<td>Echosclerotherapy</td>
<td></td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>06DM0ZZ</td>
<td>Extraction of Right Femoral Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DM3ZZ</td>
<td>Extraction of Right Femoral Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DM4ZZ</td>
<td>Extraction of Right Femoral Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DN0ZZ</td>
<td>Extraction of Left Femoral Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DN3ZZ</td>
<td>Extraction of Left Femoral Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DN4ZZ</td>
<td>Extraction of Left Femoral Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DP0ZZ</td>
<td>Extraction of Right Greater Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DP3ZZ</td>
<td>Extraction of Right Greater Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DP4ZZ</td>
<td>Extraction of Right Greater Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DQ0ZZ</td>
<td>Extraction of Left Greater Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DQ3ZZ</td>
<td>Extraction of Left Greater Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DQ4ZZ</td>
<td>Extraction of Left Greater Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DR0ZZ</td>
<td>Extraction of Right Lesser Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DR3ZZ</td>
<td>Extraction of Right Lesser Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DR4ZZ</td>
<td>Extraction of Right Lesser Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DS0ZZ</td>
<td>Extraction of Left Lesser Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DS3ZZ</td>
<td>Extraction of Left Lesser Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DS4ZZ</td>
<td>Extraction of Left Lesser Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DY0ZZ</td>
<td>Extraction of Lower Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DY3ZZ</td>
<td>Extraction of Lower Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06DY4ZZ</td>
<td>Extraction of Lower Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LM0ZZ</td>
<td>Occlusion of Right Femoral Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LM3ZZ</td>
<td>Occlusion of Right Femoral Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LM4ZZ</td>
<td>Occlusion of Right Femoral Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LN0ZZ</td>
<td>Occlusion of Left Femoral Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LN3ZZ</td>
<td>Occlusion of Left Femoral Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LN4ZZ</td>
<td>Occlusion of Left Femoral Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LP0ZZ</td>
<td>Occlusion of Right Greater Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LP3ZZ</td>
<td>Occlusion of Right Greater Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LP4ZZ</td>
<td>Occlusion of Right Greater Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LQ0ZZ</td>
<td>Occlusion of Left Greater Saphenous Vein, Open Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LQ3ZZ</td>
<td>Occlusion of Left Greater Saphenous Vein, Percutaneous Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LQ4ZZ</td>
<td>Occlusion of Left Greater Saphenous Vein, Percutaneous Endoscopic Approach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>06LR0ZZ</td>
<td>Occlusion of Right Lesser Saphenous Vein, Open Approach</td>
<td></td>
</tr>
</tbody>
</table>
### Treatment of Varicose Veins/Venous Insufficiency

#### Type | Code | Description
--- | --- | ---
Occlusion of Right Lesser Saphenous Vein, Percutaneous Approach | 06LR3ZZ
Occlusion of Right Lesser Saphenous Vein, Percutaneous Endoscopic Approach | 06LR4ZZ
Occlusion of Left Lesser Saphenous Vein, Open Approach | 06LS0ZZ
Occlusion of Left Lesser Saphenous Vein, Percutaneous Approach | 06LS3ZZ
Occlusion of Left Lesser Saphenous Vein, Percutaneous Endoscopic Approach | 06LS4ZZ
Occlusion of Lower Vein, Open Approach | 06LY0ZZ
Occlusion of Lower Vein, Percutaneous Approach | 06LY3ZZ
Occlusion of Lower Vein, Percutaneous Endoscopic Approach | 06LY4ZZ

#### ICD-10 Diagnosis
All Diagnoses

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/11/2000</td>
<td>New Policy Adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>02/26/2002</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/29/2002</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>09/01/2003</td>
<td>Policy Revision</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>05/01/2006</td>
<td>Policy Revision</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>08/01/2006</td>
<td>Policy Revision</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>06/28/2007</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>12/10/2008</td>
<td>Policy Title Revision, criteria revised, BCBSA Medical Policy Adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>09/03/2009</td>
<td>Administrative Review</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>07/01/2011</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/30/2015</td>
<td>Policy title change from Varicose Vein Treatments</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td></td>
<td>Policy revision with position change effective 03/30/2015</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>03/30/2015</td>
<td>Policy revision with position change Coding update</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>09/01/2016</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>02/01/2017</td>
<td>Policy revision without position change Coding update</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>07/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>02/01/2018</td>
<td>Coding update</td>
<td>Administrative Review</td>
</tr>
</tbody>
</table>

### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition. **Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.
Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.