Treatment of Varicose Veins/Venous Insufficiency

Policy Number: 7.01.124
Origination: 7/2010
Last Review: 6/2017
Next Review: 6/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for the treatment of varicose veins and venous insufficiency when it is determined to be medically necessary because the criteria shown below are met.

Policy Statements
Greater or Small Saphenous Veins
Treatment of the greater 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 the following criteria have been met:

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

Treatment of greater or 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 the following criteria have been met:

Incompetence of the accessory saphenous vein is isolated, OR the greater or small saphenous veins had been previously eliminated (at least 3 months); AND
There is demonstrated accessory saphenous reflux; AND
There is documentation of one or more of the following indications:

- Ulceration secondary to venous stasis; OR
- Recurrent superficial thrombophlebitis; OR
- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
- Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least 3 months has not improved the symptoms. *

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

**Symptomatic Varicose Tributaries**
The following treatments are considered **medically necessary** as a component of the treatment of symptomatic *varicose tributaries* when performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins (none of these techniques has been shown to be superior to another):

- Stab avulsion
- Hook phlebectomy
- Sclerotherapy
- Transilluminated powered phlebectomy

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

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

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

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

**Telangiectasia**
Treatment of telangiectasia such as spider veins, angiomata, and hemangiomata is considered **cosmetic**.

**Other**
Techniques for conditions not specifically listed above are **investigational**, including, but not limited to:
- Sclerotherapy techniques, other than microfoam sclerotherapy, of greater, small, or accessory saphenous veins
- Sclerotherapy of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, greater or 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

**Considerations**
The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. The following is the Clinical portion of the CEAP.

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The Etiologic, Anatomic, And Pathophysiologic portions of the classifications are online (http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf).

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 (CPT code 76942) is used to guide sclerotherapy of the varicose tributaries, it would be considered inclusive to the injection procedure.

The practice expense for CPT codes for sclerotherapy contains reimbursement for the sclerosing solution. Charges for the sclerosing solution will be considered inclusive to the injection procedure.

There is no specific CPT code for transilluminated powered phlebectomy. Providers might elect to use CPT codes describing stab phlebectomy (37765 or 37766) or unlisted vascular surgery procedure (37799).

Treatment of some varicose veins may be considered cosmetic in nature if not associated with significant clinical symptoms and documented reflux at the saphenofemoral or saphenopopliteal junction, and thus contract exclusions for cosmetic therapies may apply to coverage eligibility. Photographs or chart notes in conjunction with the results of duplex ultrasound scanning demonstrating incompetent veins may be required to establish medical necessity. Note that the term "varicose veins" does not apply to the telangiectatic dermal veins, which may be described as "spider veins" or "broken blood vessels" or veins measuring less than 3 mm in diameter. While abnormal in appearance, these veins typically are not associated with any other symptoms (such as pain or heaviness), and their treatment is considered cosmetic.

*The requirement for compression stockings may be waived if the requested veins measure greater than 8mm in diameter. If the member has had prior medically necessary vein treatment (i.e. failed compression therapy) the requirement for compression stockings attempt may be waived for subsequent vein treatments (ipsilateral or contralateral).

### Description of Procedure or Service

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

| Individuals:  
  - With varicose | Interventions of interest are: | Comparators of interest are: | Relevant outcomes include: |
|----------------|-----------------|-----------------|---------------------|
| Veins/Venous Insufficiency and Saphenous Vein Reflux | Microfoam Sclerotherapy | Conservative Therapy  
- Ligation and Stripping  
- Endovenous Radiofrequency or Laser Ablation | Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
|-----------------------------------------------------|-------------------------|--------------------------------------------------|
| Individuals:  
- With Varicose Veins/Venous Insufficiency and Saphenous Vein Reflux | Interventions of Interest Are:  
- Mechanochemical Ablation | Comparators of Interest Are:  
- Conservative Therapy  
- Ligation and Stripping  
- Endovenous Radiofrequency or Laser Ablation  
- Microfoam Sclerotherapy | Relevant Outcomes Include:  
- Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
|-----------------------------------------------------|-------------------------|--------------------------------------------------|
| Individuals:  
- With Varicose Veins/Venous Insufficiency and Saphenous Vein Reflux | Interventions of Interest Are:  
- Cyanoacrylate Adhesive | Comparators of Interest Are:  
- Conservative Therapy  
- Ligation and Stripping  
- Endovenous Radiofrequency or Laser Ablation | Relevant Outcomes Include:  
- Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
|-----------------------------------------------------|-------------------------|--------------------------------------------------|
| Individuals:  
- With Varicose Veins/Venous Insufficiency and Saphenous Vein Reflux | Interventions of Interest Are:  
- Cryoablation | Comparators of Interest Are:  
- Conservative Therapy  
- Ligation and Stripping  
- Endovenous Radiofrequency or Laser Ablation | Relevant Outcomes Include:  
- Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
|-----------------------------------------------------|-------------------------|--------------------------------------------------|
| Individuals:  
- With Varicose Tributary Veins | Interventions of Interest Are:  
- Ablation of Tributary Veins (Stab Avulsion, Sclerotherapy or Phlebectomy) | Comparators of Interest Are:  
- Conservative Therapy | Relevant Outcomes Include:  
- Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
|-----------------------------------------------------|-------------------------|--------------------------------------------------|
| Individuals:  
- With Perforator Vein Reflux | Interventions of Interest Are:  
- Ablation of Perforator Veins (eg, Subfascial Endoscopic Perforator Surgery) | Comparators of Interest Are:  
- Conservative Therapy | Relevant Outcomes Include:  
- Symptoms  
- Change in Disease Status  
- Morbid Events  
- Quality of Life  
- Treatment-Related Morbidity |
A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgical approaches, thermal ablation, and sclerotherapy. The application of each of these treatment options is influenced by the severity of the symptoms, the type of vein, the source of venous reflux, and the use of other (prior or concurrent) treatments.

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 randomized controlled trials (RCTs) and systematic reviews of RCTs on 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 (EVLA). 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 the procedure and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (1% polidocanol) approved by the Food and Drug Administration are similar to those reported for EVLA 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 that are 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 (MOCA), 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. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation techniques are that it 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 MOCA with radiofrequency ablation (RFA) has reported early results. These short-term results have suggested that intraprocedural pain is lower than RFA. However, the MOCA procedure 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. 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. Short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RFA in a multicenter noninferiority trial at 3 months. Longer follow-up in a larger number of patients is needed to determine 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.

For individuals who have varicose tributary veins who receive ablation of tributary veins (stab avulsion sclerotherapy 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 the treatment of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified that have compared 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 with 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.

For individuals who have perforator vein reflux who receive ablation of perforator veins (eg, subfascial endoscopic perforator surgery [SEPS]), 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/ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. SEPS has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only 1 case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or RF probes has been shown to effectively ablate incompetent
perforator veins with a potential decrease in morbidity in comparison with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Based on the available evidence, clinical input and clinical practice guidelines, the use of endovenous RFA, EVLA, and microfoam sclerotherapy are considered to improve outcomes when used in the saphenous veins. For treatment of saphenous tributaries at the same time or following treatment of the saphenous vein, stab avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy improve outcomes.

**Background**

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

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

**Saphenous Veins and Tributaries**

Saphenous veins include the greater and lesser saphenous, and accessory saphenous veins that travel in parallel with the greater or lesser saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux typically includes the following:
1. Identification by preoperative Doppler ultrasonography of the valvular incompetence
2. Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
3. Removal of the superficial vein from circulation, for example by stripping of the greater and/or lesser saphenous veins
4. Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. These include sclerotherapy, transilluminated powered phlebotomy, and thermal ablation using cryotherapy, high frequency radiowaves (200–300 kHz), or laser energy.

**Sclerotherapy**
The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately resulting in the occlusion of the vessel. The success of the treatment depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered to be good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment. Varithena™ (previously known as Varisolve, BTG Plc, London) is a proprietary microfoam sclerosant that is dispersed from a canister with a controlled density and more consistent bubble size.

**Endovenous Mechanochemical Ablation**
Endovenous mechanochemical ablation (MOCA™) utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3,500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in radiofrequency (RF) ablation or endovenous laser ablation (EVLT).

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

**Cyanoacrylate Adhesive**
Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material upon 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 to seal surgical incisions or other skin wounds.

**Transilluminated Powered Phlebectomy**
Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or hook phlebectomy. This procedure uses 2 instruments: an illuminator which also provides irrigation, and a resector, which has an oscillating tip and can perform suction. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of the varicosity. The resector is then inserted under the skin from the opposite direction, and the oscillating tip is placed directly beneath the illuminated veins to fragment and loosen the veins from the supporting tissue. Irrigation from the illuminator is used to clear the vein fragments and blood through aspiration and additional drainage holes. The illuminator and resector tips may then be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or hook phlebectomy. It has been proposed that TIPP might result in decreased operative time, decreased complications such as bruising, and faster recovery compared to the established procedures.

**Treatment of Perforator Veins**
Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally addressed with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may be occasionally utilized for the closure of incompetent perforator veins that can not be reached by less invasive procedures.
Subfascial endoscopic perforator surgery (SEPS) is a less-invasive surgical procedure for treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin and the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and radiofrequency has also been reported.

**Regulatory Status**

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

In 2013, Varithena™ (formerly known as Varisolve®; BTG Plc, London), a sclerosant microfoam made with a proprietary gas mix, was approved by FDA under a new drug application 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 have received specific U.S. Food and Drug Administration (FDA) marketing clearance for the endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ system (a radiofrequency device) received FDA clearance through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." The VNUS RFS and RFSFlex devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins. The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008.

- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit received FDA clearance through the 510(k) process, "...for use in the endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux."

- A modified Erbe Erbokryo® cryosurgical unit (Erbe USA) received FDA clearance for marketing in 2005. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.

- The Trivex system is a device for transilluminated powered phlebectomy that received FDA clearance through the 510(k) process in October 2003. According to the label, the intended use is for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.”

- The ClariVein® Infusion Catheter (Vascular Insights) received marketing clearance through the 510(k) process in 2008 (K071468). It is used for mechanochemical ablation. Predicate devices were listed as the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature.
Rationale
This evidence review was originally created in March 2010 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through March 23, 2017.

Outcomes of interest for venous interventions include healing and recurrence, recannulation 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 durability for endovenous and surgical procedures are complicated by these different mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

The following section addresses the efficacy of the conventional treatments, specifically regarding the appropriate length of a trial of compression therapy and evaluation of recurrence rates for surgical treatment (ie, 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 a total of 39 randomized controlled trials (RCTs), with 47 different comparisons.(1) The review was updated in 2012, and included 48 RCTs with 59 different comparisons.(2) Most of the RCTs were small. Objective measures of healing were the time to complete healing, the proportion of ulcers healed within the trial period (typically 12 weeks), the change in ulcer size, and the rate of change in ulcer size. Evidence from 8 trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. In addition, multicomponent systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses did not include time to healing, studies included in the review reported that the mean time to ulcer healing was approximately 2 months, while the median time to healing in other reports was 3 to 5 months.

A Cochrane review on compression stockings for the initial treatment of varicose veins in patients without venous ulceration was published in 2011.(3) Included in the review were 7 studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] classification C2 to C4). Six of the studies compared different types or pressures of stockings. Subjectively, participants’ symptoms improved, but results were not compared with a control arm. Due primarily to inadequate
reporting, the methodologic quality of the included trials was unclear. Meta-analyses were not performed due to inadequate reporting and suspected heterogeneity. Reviewers concluded that there is insufficient high-quality evidence to determine whether or not compression stockings are effective as the sole and initial treatment of varicose veins in patients without venous ulceration, or whether any type of stocking is superior to any other type.

**Ligation and Stripping**
Systematic literature reviews indicate a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery.(4,5) In general, recurrence rates after ligation and stripping are estimated at around 20% in short-term follow-up. Jones et al (1996) reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping.(6) At 1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar (1994) reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy.(7) At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

**ENDOVENOUS THERMAL ABLATION (LASER OR RADIOFREQUENCY)**
**Systematic Reviews**
An updated Cochrane review from 2014 compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus ligation/stripping for saphenous vein varices.(8) Included in the review were 13 randomized studies with a combined total of 3081 patients. The overall quality of the evidence was moderate. There was no significant difference between sclerotherapy and surgery in the rate of recurrence as rated by clinicians (odds ratio [OR], 1.74; p=0.06) or for symptomatic recurrence (OR=1.28). For endovenous laser ablation (EVLA) versus surgery, there were no significant differences between the treatment groups for clinician noted or symptomatic recurrence, or for recanalization. Neovascularization and technical failure were reduced in the laser group (OR=0.05, p<0.001; OR=0.29, p<0.001, respectively). For endovenous radiofrequency ablation (RFA) versus surgery, there were no significant differences between the groups in clinician noted recurrence, recanalization, neovascularization, or technical failure. The authors concluded that sclerotherapy, EVLA, and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins.

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

The largest RCT is a 2014 trial by Brittenden et al that compared foam sclerotherapy, EVLA, and surgical treatment in 798 patients. The study was funded by U.K.'s Health Technology Assessment Programme of the National Institute for Health Research. Veins greater than 15 mm were excluded from the study. At the 6-week follow-up visit, patients who were 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 31% of patients in the EVLA group. Disease-specific 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 in the laser group (1%).

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

Christenson et al (2010) compared EVLA 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 EVLA group had 2 veins completely reopened and 5 partially reopened, which was significantly greater than in the ligation and stripping group. In the 2013 MAGNA trial, 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or foam sclerotherapy. At 1-year follow-up, the anatomic success rates were similar between EVLA and stripping (88.5% and 88.2%, respectively), which were superior to foam sclerotherapy (72.2%). Ten percent of the stripping group showed neovascularization. Health-related QOL and the CEAP classification improved in all groups with no significant difference between the groups. Grade I neovascularization was higher in the conventional surgery group (27% vs 3%, p<0.001), while grade II neovascularization was similar in the 2 groups (17% vs 13%).

Literature on isolated treatment of the anterior accessory saphenous vein is limited. In a 2009 study, outcomes from a cohort of 33 patients who underwent EVLA of the anterior accessory saphenous vein were compared with 33 matched controls undergoing EVLA of the great saphenous vein. In 21 of the patients (64%) 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. The Aberdeen Varicose Veins Questionnaire (AVVQ) 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 of the saphenous veins with RFA and EVLA. 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 EVLA, ligation and stripping, or physician compounded foam sclerotherapy (1 cc aethoxysclerol 3%: 3 cc air).(14) At 1-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both EVLA (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 EVLA.(15) Thirty-two percent of legs treated initially with sclerotherapy required 1 or more reinterventions during follow-up compared with 10% in the conventional surgery and EVLA groups. However, clinically relevant grade II neovascularization was higher in the conventional surgery (17%) and EVLA (13%) groups than the sclerotherapy group (4%). EuroQol-5D scores improved equally in all groups. A 2012 study was a noninferiority trial of foam sclerotherapy versus ligation and stripping in 430 patients.(17) Analysis was per protocol. Forty patients (17%) had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in the 2 groups (11.3% sclerotherapy vs 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. There were 2 serious adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within 1 week of treatment.

Microfoam Sclerotherapy
In 2013, Varithena microfoam was approved under a new drug application for the treatment of varicose veins. Efficacy data were from 2 randomized, blinded, multicenter studies.(18) One evaluated Varithena at 0.5%, 1.0%, and 2.0% polidocanol and the second evaluated Varithena at 0.5% and 1.0% polidocanol compared 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 Varithena 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 Varithena groups compared with controls. This second
study, called VANISH-2, was published in 2014.(19) 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 1.0% dose of Varithena 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 Varithena-
treated patients with 1% of patients having proximal symptomatic thrombi; these
were treated with anticoagulants. There was no signal of an increase in
neurological adverse events, and there were no adverse cardiac or
cardiopulmonary effects following treatment with Varithena injectable foam. Rates
of occlusion with Varithena are similar to those reported for EVLA or stripping. A
randomized trial comparing EVLA 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. In comparison, rates
of occlusion with the FDA-approved microfoam sclerotherapy (polidocanol 1%) are
similar to those reported for EVLA or stripping. Results of a non-inferiority trial of
physician-compounded sclerotherapy indicate that once occluded, recurrence rates
at 2 years are similar to those of ligation and stripping.

**MECHANOCHEMICAL ABLATION**
Early results of 2 RCTs and several prospective series and cohort studies have
been reported.

In 2017, Lane et al reported results of a multicenter RCT that evaluated efficacy
and adverse effects of mechanochemical ablation (MOCA) compared to RFA of
varicose veins.(20) A total of 170 patients were randomized to MOCA or to RFA.
Maximum visual analog scale (VAS) pain scores during the procedure were
significantly lower in the MOCA group (median, 15 mm out of 100) compared to
RFA (median, 34 mm; p=0.003). Average VAS pain scores during the procedure
were also significantly lower in the MOCA group (median, 10 mm) compared to the
RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores,
disease-specific, and generic QOL scores were similar between the groups at 1 and
6 months. 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 MOCA of the
great saphenous vein in 126 patients in a community setting.(21) Veins were
selected that were greater than 4 mm and less than 12 mm in diameter, with an average diameter of 7.3 mm. Closure rates were 100% at 1 week, 98% at 3 months, and 94% at 6 months. The Venous Clinical Severity Score (VCSS) decreased from a score of approximately 9 pretreatment to about 3 at 6 months. In 2012, Elias and Raines reported an industry-sponsored safety and efficacy study of MOCA with the ClariVein system.(22) Thirty great 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 MOCA of the small saphenous vein in 50 consecutive patients.(23) Only patients with a vein diameter of 2.5 to 11 mm were included. The dose of sclerosant was increased after the first 15 patients. At the 6-week assessment, all treated veins were occluded and at 1-year follow-up, 94% remained occluded. The median visual analog scale score for pain during the procedure was 2 of 10. There were no major complications. Controlled studies with a greater number of subjects and longer follow-up are needed.

A 2013 review of MOCA notes that a 5-year 840 patient randomized trial comparing ClariVein with RFA began in 2012 in Europe.(24) This trial will provide needed data on the comparative effectiveness of MOCA, measured at a longer duration and in a larger population. Early results from this trial (Bootun et al, 2016) with 119 patients indicate that intraprocedural pain is slightly lower with MOCA (13.4 mm on a 100-mm scale) compared with RFA (24.4 mm; p=0.001).(25)

Section Summary: Mechanochemical Ablation
The evidence on MOCA includes 2 RCTs with short-term results and case series. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. One RCT with short-term follow-up has been published and a larger RCT comparing MOCA to RFA has reported early results. These short-term results have suggested that intraprocedural pain is slightly lower than RFA. However, the MOCA procedure 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 ADHESION
The VenaSeal pivotal study (VeClose) was a multicenter noninferiority trial with 222 patients that compared VenaSeal versus RFA for the treatment of venous reflux.(26,27) 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 of intraoperative pain was similar for the 2 groups (2.2 on a 10-point scale for VenaSeal and 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. Longer term follow-up is needed to permit conclusions on the durability of this procedure.

Twenty-four-month follow-up was reported for 24 of 38 patients enrolled in a study by Almeida et al (2015).(28) Thirty-three-month follow-up (2015) was reported in 467 veins out of a series of 795 veins (58.7%) treated at 1 institution in Germany.(29) An inflammatory reddening of the skin was observed at approximately 1 week after treatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins reexamined, the sealing rate was 97.7%. This series is limited by the high loss to follow-up.

**Section Summary: Cyanoacrylate Adhesion**
Evidence on cyanoacrylate adhesion for the treatment of varicose veins/venous insufficiency includes a multicenter noninferiority trial with 3-month follow-up and case series with longer follow-up. Short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RFA at 3 months. Longer follow-up in a larger number of patients is needed to determine durability of this treatment.

**Endovenous Cryoablation**
Klem et al (2009) reported a randomized trial in 2009 that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins.(30) The percentage of patients with great saphenous vein remaining was 44% in the endovenous cryoablation group and 15% in the conventional stripping group. AVVQ scores also showed better results for conventional stripping (score, 11.7) in comparison with cryoablation (score, 8.0). There were no differences between the groups in 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 EVLA.(31,32) Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP C2) with saphenofemoral incompetence and great saphenous vein reflux. At 10 days after treatment, EVLA had better results than cryoablation with respect to pain score over the first 10 days (2.9 vs 4.4), resumption of normal activity (75% vs 45%) and induration (15% vs 52%). At 2-year follow-up, freedom from recurrent incompetence was observed in 77% of patients after EVLA and 66% of patients after cryoablation (not significantly different). At 5 years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization was found in 62% of patients treated with EVLA and 51% of patients treated with cryoablation (not significantly different). Neovascularization was more common after cryoablation, but incompetent tributaries were more common after EVLA. There was no significant difference between groups in VCSS or AVVQ scores at either 2 or 5 years.

**Section Summary: Endovenous Cryoablation**
Two RCTs suggest that cryotherapy is not as effective as available alternatives.
TREATMENT OF TRIBUTARY VARICOSITIES

Sclerotherapy and Phlebectomy

Early studies established ligation and stripping as the criterion standard for the treatment of saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A 2006 Cochrane Review, based primarily on RCTs from the 1980s, concluded that: "The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins." (33) Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system, eg, post- or adjunctive treatment to other procedures such as surgery. (34) In 2014, El-Sheikha et al reported a small randomized trial of concomitant or sequential (if needed) phlebectomy following EVLA for varicose veins. (35) QOL and clinical severity scores were similar between the groups by 1 year, with 16 of 24 patients (67%) in the sequential phlebectomy group receiving a secondary intervention.

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 were found to have minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. (36) At baseline, 92% had symptoms of heaviness, 69% had cosmetic concerns, 53% reported itching, and 30% reported relief of symptoms through the use of compression hosiery. At 1-year follow-up, there was an improvement in clinicians’ assessment of the anatomic extent of varicose veins, with 85% of patients in the sclerotherapy group improved compared with 29% of patients in the conservative-therapy group. Symptoms of aching were better or eliminated in 69% of the sclerotherapy group and 28% of the group treated with conservative therapy. Cosmetic concerns were improved in 85% of the sclerotherapy patients and 14% of controls.

The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. In 2012, Yamaki et al reported a prospective RCT that compared visual foam sclerotherapy with ultrasound-guided foam sclerotherapy of the great saphenous vein together with visual foam sclerotherapy for varicose tributary veins. (37) A total of 51 limbs in 48 patients were treated with ultrasound-guided foam sclerotherapy plus visual foam sclerotherapy of the varicose tributaries, and 52 limbs in 49 patients were treated with foam sclerotherapy alone. At 6-month follow-up, complete occlusion was found in 23 (45.1%) limbs treated with ultrasound-guided and visual-guided foam sclerotherapy and in 22 (42.3%) limbs treated with visual sclerotherapy alone. Reflux was absent in 30 (58.8%) limbs treated with ultrasound and visual guidance and in 37 (71.2%) treated with visual guidance alone (not significantly different). The authors note that for the treatment of tributary veins in clinical practice, most patients receive direct injection of foam without ultrasound guidance.
Transilluminated Powered Phlebectomy
A 2008 meta-analysis included 5 studies that compared transilluminated powered phlebectomy (TIPP) with conventional surgery. Results showed a significant advantage of TIPP over the conventional treatment for number of incisions, mean cosmetic score, and duration of the procedure. However, TIPP also increased the incidence of hematoma and resulted in worse mean pain scores. Included in the meta-analysis was an RCT by Chetter et al (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 both 1 and 6 weeks after surgery. At 6 weeks after surgery, patients in the TIPP group showed no improvement in pain (-2 points on the Burford Pain Scale), while patients in the multiple stab incision group had a significant improvement in pain score compared with presurgical baseline (-20 points). Six weeks after surgery, 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 a more prolonged recovery due to more extensive bruising, prolonged pain, and reduced early postoperative QOL.

Section Summary: Treatment of Tributary Varicosities
The evidence includes RCTs and systematic reviews of RCTs. The literature indicates that sclerotherapy is effective for the treatment of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified that compare 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.

TREATMENT OF PERFORATOR REFLUX
A systematic literature review published in 2008 indicates insufficient evidence for 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 C5 to 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 in comparison 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.
SEPS to saphenous surgery in 75 patients with varicose ulcers (CEAP C5 or C6) and incompetent perforators. (42)

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 (41% of 68 previously incompetent perforators) was more common than new perforator vein incompetence (22% of 183 previously competent perforators) following superficial vein surgery. (43) O'Donnell (2008) discussed additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. (5) Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

**Subfascial Endoscopic Perforator Surgery**

In 2004, Tenbrook et al published a review of the literature of subfascial endoscopic perforator surgery (SEPS), which included 19 case series and 1 randomized trial. (44) In total, the reviewed studies included 1031 patients with 1140 treated limbs. The authors concluded that SEPS was associated with excellent results in terms of ulcer healing and prevention of recurrence. However, the authors also noted that randomized trials are required to define the relative contributions of compression therapy, superficial venous surgery, and SEPS in the management of severe venous disease. In 2015, Van Gent et al reported 10-year follow-up of a randomized trial that compared conservative treatment versus SEPS for venous leg ulcers. (45) 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 of the surgically treated group may be due to limited/no stripping of the superficial veins at the time of SEPS.

A 2009 meta-analysis of SEPS for chronic venous insufficiency concluded that “Its [SEPS] use should not be employed routinely and could only be justified in patients with persistent ulceration thought to be of venous origin, and in whom any superficial reflux has already been ablated and postthrombotic changes excluded.” (46) Reviewers also stated that “introduction of less invasive techniques for perforator vein ablation, such as ultrasound-guided sclerotherapy or radiofrequency ablation, may diminish the role of SEPS in the future.”

**Other Treatments**

A 2008 review of procedures for management of varicose veins recommends duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short RFA catheter for the treatment of symptomatic residual perforator vein incompetence. (47) Ablation of incompetent perforator veins with laser or RFA had been shown to be technically feasible, although no studies had been identified that showed an improvement in clinical outcomes (eg, ulcer healing
or recurrence). The 2011 literature update identified 1 study of EVLA for perforating veins in 33 patients with a CEAP classification of 4 (skin changes), 5 (healed ulcer), or 6 (active ulcer).\(^{(48)}\) All incompetent saphenous trunks were treated simultaneously (63% of limbs). At 3-month follow-up, occlusion was achieved in 78% of the perforating veins. Five patients (15%) had active ulcers at baseline; 4 of the 5 ulcers had healed by 6 weeks after EVLA. Evidence regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion.\(^{(49)}\)

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

Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. SEPS has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only 1 case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or RF probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity in comparison with surgical interventions.

**SUMMARY OF EVIDENCE**
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 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 randomized controlled trials (RCTs) and systematic reviews of RCTs on endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at 2- to 5-year follow-up supports use of both radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). Evidence suggests 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 randomized controlled trials. 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 the procedure and some reports of serious adverse events. In comparison, rates of occlusion with the FDA-approved microfoam sclerotherapy (1% polidocanol) are
similar to those reported for EVLA or stripping. Results of a non-inferiority trial of physician-compounded sclerotherapy indicate 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 that are 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 (MOCA), 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. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation techniques are that it 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 MOCA with radiofrequency (RF) ablation has reported early results. These short-term results suggest that intraprocedural pain is lower than RFA. However, the MOCA procedure 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. 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. Short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RFA in a multicenter noninferiority trial at 3 months. Longer follow-up in a larger number of patients is needed to determine 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 randomized controlled trials (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 indicate 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.

For individuals who have varicose tributary veins who receive ablation of tributary veins (stab avulsion sclerotherapy 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 indicates that sclerotherapy is effective for the treatment of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified that compare RFA or laser
ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy (TIPP) is effective at removing varicosities; outcomes are comparable with 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.

For individuals who have perforator vein reflux who receive ablation of perforator veins (eg, subfascial endoscopic perforator surgery [SEPS]), 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 indicates that the routine ligation/ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. SEPS has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only 1 case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or RF probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity in comparison 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, input was received from 4 physician specialty societies while this policy was under review in 2015. There was no agreement on the need to treat varicose tributaries to improve functional outcomes in the absence of saphenous vein disease. Input was also mixed on the use of mechanochemical ablation or use of 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 clinical practice guidelines in 2011.(50) The recommendations were rated as
strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C, and include the following (see Table 1).

**Table 1: Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compression therapy for venous ulcerations and varicose veins</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression therapy is recommended as the primary treatment to aid healing of venous ulceration</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended</td>
<td>1A</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>Use of compression therapy for patients with symptomatic varicose veins is recommended</td>
<td>2C</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

| **Treatment of the incompetent great saphenous vein**                          |       |      |         |
| Endovenous thermal ablation (radiofrequency or laser) is recommended over     | 1B    | Strong | Moderate |
| ▪ chemical ablation with foam or                                              | 1B    | Strong | Moderate |
| ▪ 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.

**Society of Interventional Radiography**

In 2003, the Society of Interventional Radiography (SIR) published a position statement(51) that considered endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins under the following conditions:

1. The endovenous treatment of varicose veins may be medically necessary when one of the following indications (A–E) is present:
   a. Persistent symptoms interfering with activities of daily living in spite of conservative/nonsurgical management. Symptoms include aching,
cramping, burning, itching, and/or swelling during activity or after prolonged standing.
b. Significant recurrent attacks of superficial phlebitis
c. Hemorrhage from a ruptured varix
d. Ulceration from venous stasis where incompetent varices are a contributing factor
e. Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above)

and;

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

and;

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

In a joint statement published in 2007, AVF and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency.(52) The document recommended that reporting in clinical studies should include the symptoms of venous disease, history of disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation may include patients with reflux in an incompetent 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.(53) 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 is adequate to support the use of this procedure provided that standard arrangements are in place for consent, audit, and clinical governance.(54)

In 2013, NICE published a practice guideline on the diagnosis and management of varicose veins in the leg.(55) NICE recommends a study of the clinical and cost effectiveness of

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

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.(56) Cost-effectiveness was based on a large multicenter randomized trial comparing treatments for varicose veins (described previously).(10) 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 2. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01459263</td>
<td>Mechanochemical 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>Mechanochemical 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 Mechanochemical Ablation (ClariVein®) in the Management of Superficial Venous Insufficiency (LAMA)</td>
<td>140</td>
<td>Sep 2030</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01807585a</td>
<td>Randomized Control Trial Comparing</td>
<td>244</td>
<td>Sep 2016</td>
</tr>
<tr>
<td>VenaSeal Sapheon Closure System With Radiofrequency Ablation (Pivotal Study)</td>
<td>(unknown)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial. NTR: Nederlands Trial Registry.

a Denotes industry-sponsored or cosponsored trial.

References:


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ablation for the treatment of venous insufficiency: joint statement of the American Venous
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sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the
Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial.

**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36468</td>
<td>Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk</td>
</tr>
<tr>
<td>36470</td>
<td>Injection of sclerosing solution; single vein</td>
</tr>
<tr>
<td>36471</td>
<td>Injection of sclerosing solution; multiple veins, same leg</td>
</tr>
<tr>
<td>36473</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated (new code 1/1/2017)</td>
</tr>
<tr>
<td>36474</td>
<td>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) (new code 1/1/2017)</td>
</tr>
<tr>
<td>36475</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated</td>
</tr>
<tr>
<td>36476</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>36478</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated</td>
</tr>
<tr>
<td>36479</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>37500</td>
<td>Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)</td>
</tr>
<tr>
<td>37700</td>
<td>Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions</td>
</tr>
<tr>
<td>37718</td>
<td>Ligation, division, and stripping, short saphenous vein</td>
</tr>
<tr>
<td>37722</td>
<td>Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below</td>
</tr>
<tr>
<td>37735</td>
<td>Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia</td>
</tr>
<tr>
<td>37760</td>
<td>Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg</td>
</tr>
<tr>
<td>37761</td>
<td>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg</td>
</tr>
<tr>
<td>37765</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions</td>
</tr>
</tbody>
</table>
Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
Unlisted procedure, vascular surgery
Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study
Echoclerotherapy

ICD-10 Codes
I183.001-I83.899 Varicose veins of lower extremities, code range
I187.2 Venous, insufficiency (chronic, peripheral)

CPT 36469 deleted code as of 1/1/2015

There is no specific CPT code for transilluminated powered phlebectomy. Providers might elect to use CPT codes describing stab phlebectomy (37765 or 37766) or unlisted vascular surgery procedure (37799).

There are CPT codes specific to mechanochemical ablation:
36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical, first vein treated
36474; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

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

There is no specific CPT for microfoam sclerotherapy. Providers might elect to use CPT codes describing sclerotherapy (36468-36471) or the unlisted vascular surgery procedure code 37799. Use of codes 36475-36476 would be inappropriate as the procedure is not ablation therapy.

Additional Policy Key Words
N/A

Policy Implementation/Update Information
7/1/10 Policies on treatments for varicose veins/venous insufficiency combined (Sclerotherapy, 7.01.55; Endoluminal ablation, 7.01.76; Perforator
Veins, 7.01.90; TIPP, 7.01.97; Stripping and Ligation, 7.01.504) – these individual policies are now archived. For consistency, the term “endoluminal” was replaced by “endovenous,” including in the policy statements; however, the intent of the policy statements is unchanged. Policy statement for accessory saphenous vein treatment when the greater or lesser saphenous veins are not treated.

3/1/11 Policy statements regarding treatment of greater or lesser saphenous veins by surgery or endovenous radiofrequency or laser ablation that do not meet the criteria and treatment of accessory saphenous veins by surgery or endovenous radiofrequency or laser ablation that do not meet the criteria changed from cosmetic to not medically necessary. The policy statement regarding treatment of telangiectasia corrected to remove the “not medically necessary” statement. This would be considered cosmetic.

7/1/11 No policy statement changes.
7/1/12 No policy statement changes.
7/1/13 A policy statement on accessory saphenous veins was modified to include isolated incompetence of the accessory saphenous vein as medically necessary. Endovenous mechanochemical ablation for varicose veins was added to the policy as investigational.

2/1/14 Added a clarification to the considerations section regarding conservative treatment with compression stockings.
7/1/14 No policy statement changes.
7/1/15 Added “or microfoam sclerotherapy” to the policy statements.
1/1/16 Cyanoacrylate adhesive considered medically necessary for lower saphenous veins. The requirement of failure of compression therapy was removed from the policy statements on ulceration secondary to venous stasis and recurrent superficial thrombophlebitis. CEAP classification criteria were added to the medically necessary policy statement on great and small saphenous veins.

7/1/16 Terminology was changed from greater and lesser to great and small saphenous veins. Removed cyanoacrylate adhesive from medically necessary and not medically necessary statement for Greater or Small Saphenous Veins and added to investigational statement for any vein.
11/1/16 Considerations section updated to include editing information regarding sclerosing agents.
6/1/17 Revised the Considerations section regarding minimum size of veins treated.

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