Treatment of Varicose Veins/Venous Insufficiency

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Next Review: 6/2020

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

The Etiologic, Anatomic, And Pathophysiologic portions of the classifications are online ([http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf](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 is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental 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.

The sclerosing agent (ie: Sotradecol) is included in the sclerotherapy code.

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

Note: If ultrasound guidance (CPT code 76942) is used to guide sclerotherapy of the varicose tributaries, it would be considered incidental to the injection procedure.

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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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.

### Saphenous Veins

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

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. For physician-compounded sclerotherapy, there is high variability in success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that once occluded, recurrence rates at two 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.

Based on the available evidence, clinical input obtained in 2015, and clinical practice guidelines, the use of endovenous RFA, endovenous laser ablation, 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.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation, the evidence includes two RCTs and case series. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that mechanochemical ablation does not require multiple needle sticks with tumescent anesthesia and may result in less pain during the procedure. One RCT with high loss to follow-up has been published, and a larger RCT is comparing mechanochemical ablation with RFA has reported early results. These short-term results have suggested that intraprocedural pain is lower with mechanochemical ablation than with RFA. However, liquid sclerotherapy is not as effective as thermal ablation techniques for saphenous veins, and mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in larger RCTs is needed to evaluate its efficacy and durability compared with established procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes an RCT and a prospective cohort. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. Evidence assessing cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with initial 3 months of follow-up and subsequent reports with follow-up through 24 months. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at three months; the loss to follow-up in the further follow-up studies limits the confidence in this outcome. A prospective cohort reported high closure rates at 30 months but also had a high loss to follow-up. Adequately powered trials with adequate follow-up are 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. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Varicose Tributary Veins**
For individuals who have varicose tributary veins who receive ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 (e.g., subfascial endoscopic perforator surgery) of perforator veins, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 an 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 one 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.

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 the 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 of venous disease 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
Treatment of venous reflux/venous insufficiency seeks to reduce abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of elevation of the extremities, graded compression, and wound care when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or 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.

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

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

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

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

**Endovenous Mechanochemical Ablation**
Endovenous mechanochemical ablation uses both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 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 the need for the tumescent anesthesia used with endovenous thermal ablation techniques (radiofrequency ablation, endovenous laser ablation).

**Cyanoacrylate Adhesive**

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

**Transilluminated Powered Phlebectomy**

Transilluminated powered phlebectomy 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 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 transilluminated powered phlebectomy might decrease surgical time, decrease complications such as bruising and lead to a faster recovery than established procedures.

**Treatment of Perforator Veins**

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally treated with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may occasionally be used to close incompetent perforator veins that cannot be reached by less invasive procedures.

Subfascial endoscopic perforator surgery is a less invasive surgical procedure for the 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 radiofrequency ablation has also been reported.

**Regulatory Status**

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

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

The following devices were cleared for marketing by 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 (ie, 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 were 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 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 mechanochemical ablation. FDA determined that this device was substantially equivalent to the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system
includes an infusion catheter, motor drive, stopcock, and syringe, and is intended for the infusion of physician-specified agents in the peripheral vasculature. FDA product code: KRA

This evidence review was created in March 2010 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through November 15, 2018.

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

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

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

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

**Conventional Treatment of Saphenous Reflux**
Compression Therapy
A Cochrane review by O’Meara et al (2009) evaluated compression for venous leg ulcers included 39 RCTs with 47 different comparisons. This review was updated in 2012 and included 48 RCTs with 59 different comparisons. Most RCTs were small.

Rationale
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 eight trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. Also, multicomponent systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses did not include time to healing, studies included in the review reported the mean time to ulcer healing was approximately two months, while the median time to healing in other reports was three to five months.

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

Ligation and Stripping
Systematic literature reviews have indicated a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery. In general, recurrence rates after ligation and stripping are estimated at 20% in short-term follow-up. Jones et al (1996) reported on the results of a trial that randomized 100 patients with varicose veins to ligation alone or ligation plus stripping. 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. At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

Treatment of Saphenous Veins
Clinical Context and Therapy Purpose
The purpose of endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy, mechanochemical ablation, cyanoacrylate adhesive, or cryoablation in patients who have varicose veins/venous insufficiency and saphenous vein reflux is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy, mechanochemical ablation, cyanoacrylate adhesive, or cryoablation improve the net health outcome in individuals who have varicose veins/venous insufficiency and saphenous vein reflux?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are those who have varicose veins/venous insufficiency and saphenous vein reflux.

Interventions
The therapies being considered are endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy, mechanochemical ablation, cyanoacrylate adhesive, or cryoablation.

Comparators
The following therapies and practices are currently being used to treat veins/venous insufficiency and saphenous vein reflux: conservative therapy, ligation and stripping, endovenous radiofrequency or laser ablation, and microfoam sclerotherapy.

Outcomes
The general outcomes of interest for all five interventions are reductions in symptoms and morbid events, change in disease status, and improvements in QOL.

Timing
Follow-up at one and two years is of interest for endovenous thermal ablation (radiofrequency or laser) to monitor relevant outcomes.

Setting
Patients with varicose veins/venous insufficiency and saphenous vein reflux are actively managed by general surgeons and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
To assess efficacy outcomes, comparative controlled prospective trials were sought, with preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with preference for prospective studies.

To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Treatment of Saphenous Veins: Endovenous Thermal Ablation (laser or Radiofrequency)

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

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

Randomized Controlled Trials
The largest RCT was reported by Brittenden et al (2014) and compared foam sclerotherapy, endovenous laser ablation, and surgical treatment in 798 patients. The trial was funded by the U.K.’s National Institute for Health Research. Veins greater than 15 mm in diameter were excluded from the trial. At the 6-week follow-up visit, patients assigned to treatment with foam or laser had the option of treatment with foam for any residual varicosities; this optional treatment was performed in 38% of patients in the foam group and 31% of patients in the endovenous laser ablation group. Disease-specific 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. At two-year follow-up, there were no significant differences between groups for clinically recurrent varicose veins, medical condition measured on the Homburg Varicose Vein Severity Score, or disease-related QOL. Saphenofemoral reflux was detected by ultrasonography more frequently after endovenous laser treatment (17.8% vs 1.3%). The follow-up rate at five years was 81%. Same-site recurrences were more frequent in the endovenous laser ablation group (18% with endovenous laser ablation vs 5% with surgery, p=0.002), but different-site recurrences were more frequent in the surgically treated group (50% with surgery vs 31% with endovenous laser ablation, p=0.002). Overall, there was no significant difference in recurrence rates between groups. There were also no significant differences between groups in disease severity or QOL at 5 years.

Christenson et al (2010) compared endovenous laser ablation with ligation and stripping in 200 limbs (100 in each group). At 1-year follow-up, 98% of the limbs were reported to be free of symptoms. At two-year follow-up, the endovenous laser ablation group had two veins completely reopened and five 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 one-year follow-up, the anatomic success rates were similar for endovenous laser ablation (88.5%) and stripping (88.2%), which were both superior to foam sclerotherapy (72.2%). Ten percent of the stripping group showed neovascularization. At five 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.

Wallace et al (2018) published the five-year outcomes of an RCT (HELP-1 trial) comparing surgery and endovenous laser ablation (EVLA) as treatments for symptomatic great saphenous varicose veins. Data from 218 patients were available at 5-year follow-up. The clinical recurrence rate was 34.4% for the surgery group and 20.9% for EVLA (p=0.010). Patients’ QOL, assessed using EuroQol Five Dimensions (EQ-5D) and AVVQ, was significantly improved from baseline for both surgery (EQ-5D: 0.859 to 1.0, p=0.002; AVVQ: 13.69 to 4.59, p<0.001) and EVLA (EQ-5D: 0.808 to 1.0, p=0.002; AVVQ: 12.73 to 3.35, p<0.001). Technical success assessed by duplex ultrasound examination was 85.4% for surgery and 93.2% for EVLA (p=0.074).
### Table 1. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions Active</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brittenden (2014)</td>
<td>UK</td>
<td>11</td>
<td>2008-2012</td>
<td>Individuals with primary varicose veins</td>
<td>Foam sclerotherapy (n=286) or laser ablation (n=210)</td>
<td>Surgical treatment (n=289)</td>
</tr>
<tr>
<td>Rass (2012); RELACS</td>
<td>US</td>
<td>2</td>
<td>2004-2007</td>
<td>Individuals with GSV insufficiency</td>
<td>EVLT (n=185)</td>
<td>HLS (n=161)</td>
</tr>
<tr>
<td>Wallace (2018)</td>
<td>UK</td>
<td>1</td>
<td>2004-2009</td>
<td>Individuals with GSV insufficiency</td>
<td>Endovenous laser ablation (n=108)</td>
<td>Surgery (n=110)</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; GSV: great saphenous vein; EVLT: endovenous laser treatment; HLS: high ligation and stripping; NR: not reported.

1 Date of original intervention study

### Table 2. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>AVVQ Score&lt;sup&gt;1&lt;/sup&gt; at Baseline;6 Months</th>
<th>Frequency of Procedural Complications</th>
<th>Rate of Same-Site Recurrence</th>
<th>Clinically Recurrent Varicose Veins</th>
<th>AVVQ Score at Baseline;5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foam</td>
<td>17.6±9.9; 9.1±7.9</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laser</td>
<td>17.8±9.1; 7.9±8.4</td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>18.2±9.1; 7.8±7.5</td>
<td>7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rass (2012) RELACS</td>
<td>Laser</td>
<td>18%</td>
<td>16.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>5%</td>
<td>23.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>0.002</td>
<td>0.15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wallace (2018)</td>
<td>Laser</td>
<td>20.9%</td>
<td>13.69; 4.59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>34.3%</td>
<td>12.73; 3.35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>0.010</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CI: confidence interval; AVVQ: Aberdeen Varicose Veins Questionnaire.

<sup>1</sup> AVVQ scores range from 0 to 100 (worst possible quality of life)

### Table 3. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Intervention&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Comparator&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Outcomes&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Follow-Up&lt;sup&gt;e&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brittenden (2014)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Longer follow-up needed</td>
</tr>
<tr>
<td>RELACS (2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wallace (2018)</td>
<td></td>
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</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.


The literature on the isolated treatment of the anterior accessory saphenous vein is limited. In a study by Theivacumar et al (2009), outcomes from a cohort of 33 patients who underwent endovenous laser ablation of the anterior accessory saphenous vein were compared with 33 matched controls undergoing endovenous laser ablation of the great saphenous vein. For 21 (64%) of the patients in the accessory saphenous vein group, there had been no previous treatment of the great saphenous vein. At 12-month follow-up, there was no evidence of reflux in these patients, and the treated accessory saphenous vein was not visible with ultrasound. Aberdeen Varicose Veins Questionnaire (AVVQ) scores had improved in both groups, with no significant difference between them. Patient satisfaction scores were also similar.

**Section Summary: Endovenous Thermal Ablation (Laser or Radiofrequency)**

There are multiple large RCTs and systematic reviews of RCTs assessing endovenous ablation using radiofrequency or laser energy of the saphenous veins. Comparison with ligation and stripping at 2- to 5-year follow-up has indicated similar recurrence rates for the different treatments. Evidence has suggested that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization, resulting in similar outcomes for endovenous thermal ablation and surgery. Laser ablation and RFA have similar success rates.
Treatment of Saphenous Veins: Sclerotherapy

Physician-Compounded Sclerotherapy

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

In the 2013 MAGNA trial (previously described), 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to endovenous laser ablation, ligation and stripping, or physician-compounded foam sclerotherapy (1 mL aethoxysclerol 3%: 3 cc air). 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 one 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%). EQ-5D scores improved equally in all groups.

Vahaahao et al (2018) published a study looking at the 5-year follow-up of patients with symptomatic great saphenous vein (GSV) insufficiency. Between 2008 and 2010, 166 individuals were randomized to receive open surgery, EVLA, or ultrasound-guided foam sclerotherapy (UGFS). The GSV occlusion rate was 96% (95% CI: 91-100%) for open surgery, 89% (95% CI: 82-98%) for EVLA, and 51% (95% CI: 38-64%) for UGFS (p<0.001). For patients with no additional treatment during follow-up, occlusion rates for open surgery, EVLA, and UGFS were 96%, 89%, and 41%, respectively. The study was limited by the lack of blinding and by non-standardized foam application.

A noninferiority trial by Shadid et al (2012) compared foam sclerotherapy with ligation and stripping in 430 patients. The analysis was per protocol. Forty (17%) patients had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in both groups (11.3% sclerotherapy vs 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. Two serious adverse events in the sclerotherapy group (deep venous thrombosis, pulmonary emboli) occurred within one 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 two 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 an improvement in symptoms at week eight, as measured by the Varicose Vein Symptoms Questionnaire. The improvement in symptoms was greater in the pooled polidocanol treatment group (p<0.001) and in each of the individual dose-concentration groups compared with vehicle alone. Secondary and tertiary end points (appearance, duplex ultrasound response, QOL) were also significantly better for the polidocanol groups compared with controls. This second study, called VANISH-2, was published by Todd et al (2014). 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 approval. Safety analysis found deep vein thrombosis detected by ultrasound in 2.8% of polidocanol-treated patients, with 1% of patients having proximal symptomatic thrombi; these patients were treated with anticoagulants. There was no sign of an increase in neurologic adverse events, and there were no adverse cardiac or cardiopulmonary effects following treatment with polidocanol injectable foam. Rates of occlusion with Varithena are similar to those reported for endovenous laser ablation or stripping. A randomized trial comparing endovenous laser ablation and stripping with this new preparation of foam sclerotherapy is needed to evaluate its comparative effectiveness. Evaluation out to 5 years is continuing.

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

Section Summary: Sclerotherapy
For physician-compounded sclerotherapy, there is high variability in success rates of the procedure and some reports of serious adverse events. Results of a noninferiority trial of physician-compounded sclerotherapy indicated that once occluded, recurrence rates at two years are similar to those of ligation and
stripping. By comparison, rates of occlusion with the Food and Drug Administration-approved microfoam sclerotherapy (polidocanol 1%) are similar to those reported for endovenous laser ablation or stripping.

**Treatment of Saphenous Veins: Mechanochemical Ablation**

**Randomized Trials**

Two publications (Bootun et al [2016], Lane et al [2017]) reported on early results from an RCT of 170 patients that compared ClariVein with RFA (see Table 5). Maximum visual analog scale pain scores (out of 100) during the procedure were significantly lower in the mechanochemical ablation group (median, 15 mm) than in the RFA group (median, 34 mm; \( p=0.003 \)). Average visual analog scale pain scores during the procedure were also modestly lower in the mechanochemical ablation group (median, 10 mm) than in the RFA group (median, 19.5 mm; \( p=0.003 \)). Occlusion rates, clinical severity scores, disease-specific QOL, and generic QOL scores were similar between groups at one and six months. However, only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point (see Table 6). The second randomized trial (Lam et al [2016]) reported interim results of a dose-finding study, finding greater closure with use of polidocanol 2% or 3% (liquid) than with polidocanol 1% (microfoam).

**Table 5. Relevance Gaps**

<table>
<thead>
<tr>
<th>Study</th>
<th>Populationa</th>
<th>Interventionb</th>
<th>Comparatorc</th>
<th>Outcomesd</th>
<th>Follow-Up²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bootun et al (2016)²⁴; Lane et al (2017)²⁵</td>
<td></td>
<td></td>
<td></td>
<td>1. Primary outcome was pain during the procedure</td>
<td>1. Outcomes only out to 6 mo</td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

² Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 6. Study Design and Conduct Gaps**

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation²⁴</th>
<th>Blindingb</th>
<th>Selective Reporting²⁶</th>
<th>Follow-Up²⁷</th>
<th>Power²⁸</th>
<th>Statistical²⁹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bootun et al (2016)²⁴; Lane et al (2017)²⁵</td>
<td>1. Patients not blinded to treatment (assessors of duplex ultrasound were blinded)</td>
<td></td>
<td></td>
<td>1. 76% follow-up at 1 mo and 71% follow-up at 6 mo</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

**Systematic Reviews**

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

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

**Section Summary: Mechanochemical Ablation**

Mechanochemical ablation is a combination of liquid sclerotherapy and mechanical abrasion. The evidence on mechanochemical ablation includes an RCT with short-term results that compared mechanochemical ablation with RFA and case series with follow-up out to three years. The short-term results of the RCT suggested that intraprocedural pain is slightly lower with mechanochemical ablation than with RFA. However, mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in RCTs with a larger number of patients is needed to evaluate the efficacy and durability of this procedure compared with established procedures.
Treatment of Saphenous Veins: Cyanoacrylate Adhesive
The VenaSeal pivotal study (VeClose), a multicenter noninferiority trial with 222 patients, compared VenaSeal with RFA for the treatment of venous reflux.30,31 The pivotal registration study for the VeClose study and follow-up through 24 months have been published.30,31,33,34 These studies are summarized in Tables 7 and 8. The primary end point (the proportion of patients with complete closure of the target GSV at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs 2.4 for RFA, p=0.11). Ecchymosis at day 3 was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA (p<0.01). Scores on the AVVQ and Venous Clinical Severity Score improved to a similar extent in both groups. The mean time to return to work in a prospective cohort of 50 patients reported by Gibson and Ferris (2017) was 0.2 days.32

For the cyanoacrylate and RFA groups, the complete occlusion rates were 97.2% and 97.0%, respectively, although subsequent treatments were allowed. Freedom from recanalization, which may be more representative of treatment success, was also similar between the two groups (p=0.08).33 Twenty-four month results were reported by Gibson et al (2018), which included 171 patients (87 from CAC and 84 from RFA).34 The complete closure rates for cyanoacrylate and RFA were 95.3% and 94.0% (p=0.0034), respectively. Recanalization-free survival at 24 months was non-inferior in the cyanoacrylate group compared to the RFA group (94.6% vs 97.8%, p< 0.001 for non-inferiority). No significant device- or procedure-related adverse events were reported for either group.

Table 7. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions1</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA SSED (2015), Morrison et al (2015, 2017); Gibson et al (2018); VeClose</td>
<td>US</td>
<td>10</td>
<td>2013-2014</td>
<td>Age ≥21 and ≤ 70 years with symptomatic3 GSV reflux and CEAP C2- C4b GSV diameter while standing of 3-12 mm4</td>
<td>VenaSeal CAE (108)6 RFA5 6</td>
</tr>
</tbody>
</table>

CAE: cyanoacrylate embolization; CEAP: Clinical Etiology Anatomy Pathophysiology; GSV: great saphenous vein; RCT: randomized controlled trial; SSED: Summary of Safety and Effectiveness Data;

1 A total of 242 participants were enrolled: (20 in roll-in training/2 per site and 222 in clinical trial)
2 One or more of the following symptoms related to the target vein: aching, throbbing, heaviness, fatigue, pruritus, night cramps, restlessness, generalized pain or discomfort, swelling.
3 Throughout the target vein as measured by Duplex ultrasound
4 Covidien ClosureFast
5 Protocol mandated use of compression stockings for 7 days post-procedure
### Table 8. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Vein Closure</th>
<th>Vein Closure</th>
<th>Vein Closure</th>
<th>Procedure Related Event</th>
<th>Device Related Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 months n (%)</td>
<td>12 months n (%)</td>
<td>24 months n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>222</td>
<td>189</td>
<td>171</td>
<td>222</td>
<td>222</td>
</tr>
<tr>
<td>VenaSeal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>107 (99.1%)²</td>
<td>92 (96.7%)</td>
<td>82/86 (95.3%)</td>
<td>27 (25%)</td>
<td>31 (27%)</td>
<td></td>
</tr>
<tr>
<td>RFA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>109 (95.6%)²</td>
<td>91 (96.8%)</td>
<td>79/84 (94.0%)</td>
<td>13 (12%)</td>
<td>7 (6%)</td>
<td></td>
</tr>
</tbody>
</table>

CI: confidence interval; Diff: difference; HR: hazard ratio; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

1 Complete closure defined as Doppler ultrasound showing vein closure along entire treated vein segment with no discrete segments of patency exceeding 5 cm. Central laboratory reading.

2 Used prespecified data imputation method (Last Observation Carried Forward)

The purpose of gaps tables (see Tables 9 and 10) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

### Table 9. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Populationa</th>
<th>Interventionb</th>
<th>Comparatorc</th>
<th>Outcomesd</th>
<th>Follow-Upé</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Follow-up scheduled to continue to 3 years</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

### Table 10. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocationa</th>
<th>Blindingb</th>
<th>Selective Reportingg</th>
<th>Follow-Upé</th>
<th>Powerd</th>
<th>Statisticalf</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morrison (2015), 31, Morrison (2017), 33, Gibson (2018) 34</td>
<td>1, 2, 3. The outcome was assessed by the treating</td>
<td></td>
<td>1. &gt;20% loss to follow-up 2. multiple approaches to</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. variable reporting of CI and p values</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

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

Eroglu et al (2017) reported closure rates of 94.1% at 30 months in a prospective cohort of 159 patients. Thirty-three-month follow-up was reported by Zierau (2015) 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 assessing cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with follow-up through 24 months. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at three months; the loss to follow-up in the subsequent follow-up studies limits the confidence in this outcome. Prospective cohorts reported high closure rates at 30 months but also had high loss to follow-up. Adequately powered trials with long-term follow-up are needed to determine the durability of this treatment. The evidence is insufficient to determine an improvement in the net health outcome.

Treatment of Saphenous Veins: 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 GSV remaining with cryoablation while 15% had residual vein remaining with conventional stripping. AVVQ scores also showed better results for conventional stripping (score, 11.7) than cryoablation (score, 8.0). There were no differences between groups in 36-Item Short-Form Health Survey summary scores or neural damage (12% in both groups).

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

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

Tributary Varicosities

Clinical Context and Therapy Purpose
The purpose of ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins in patients who have varicose tributary veins is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins improve the net health outcome in individuals who have varicose tributary veins?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals who have varicose tributary veins.

Interventions
The therapy being considered is ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins.

Comparators
The following therapy is currently being used to treat varicose tributary veins: conservative therapy.

Outcomes
The general outcomes of interest are reductions in symptoms and morbid events, change in disease status, and improvements in QOL.
**Timing**
Follow-up at 6- and 12- months is of interest for ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins to monitor relevant outcomes.

**Setting**
Patients with varicose tributary veins are actively managed by general surgeons and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**
Methodologically credible studies were selected using the principles outlined for indications 1 through 5.

**Sclerotherapy and Phlebectomy**
Early studies established ligation and stripping as the criterion standard for treating saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A Cochrane review by Tisi et al (2006), based primarily on RCTs from the 1980s, concluded that: “The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins.” 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). El-Sheikha et al (2014) reported on a small randomized trial of concomitant or sequential (if needed) phlebectomy following endovenous laser ablation for varicose veins. QOL and clinical severity scores were similar between the groups by 1 year, with 16 (67%) of 24 patients in the sequential phlebectomy group receiving a secondary intervention.

The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. For example, Yamaki et al (2012) reported on a prospective RCT that compared visual foam sclerotherapy plus ultrasound-guided foam sclerotherapy of the GSV with visual foam sclerotherapy for varicose tributary veins. Fifty-one limbs in 48 patients were treated with ultrasound-guided foam sclerotherapy plus visual foam sclerotherapy of the varicose tributaries, and 52 limbs in 49 patients were treated with foam sclerotherapy alone. At 6-month follow-up, complete occlusion was found in 23 (45.1%) limbs treated with ultrasound plus visually guided foam sclerotherapy and in 22 (42.3%) limbs treated with visual sclerotherapy alone. Reflux was absent in 30 (58.8%) limbs treated with ultrasound plus visual guidance and in 37 (71.2%) treated with visual guidance alone (p=NS). The authors noted that, for the treatment of tributary veins in clinical practice, most patients receive a direct injection of foam without ultrasound guidance.

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

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

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

**Perforator Reflux**

**Clinical Context and Therapy Purpose**
The purpose of ablation (eg, subfascial endoscopic perforator surgery) of perforator veins in patients who have perforator vein reflux is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is: Does the use of ablation (eg, subfascial endoscopic perforator surgery) of perforator veins improve the net health outcome in individuals who have perforator vein reflux?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals who have perforator vein reflux.

**Interventions**
The therapy being considered is ablation (eg, subfascial endoscopic perforator surgery) of perforator veins.

**Comparators**
The following therapy is currently being used to treat perforator vein reflux: conservative therapy.

**Outcomes**
The general outcomes of interest are reductions in symptoms and morbid events, change in disease status, and improvements in QOL.

**Timing**
Follow-up at ten-years is of interest for ablation (eg, subfascial endoscopic perforator surgery) of perforator veins to monitor relevant outcomes.

**Setting**
Patients with perforator vein reflux are actively managed by general surgeons and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**
Methodologically credible studies were selected using the principles outlined for indications 1 through 5.

A systematic literature review by O'Donnell (2008) indicated 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 for advanced chronic venous insufficiency (CEAP classes C5-C6). The four trials included two level I (large subject population) and two level II (small subject population) studies. Two trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other two treated the GSV alone. The 2 randomized studies (2004, 2007) in which the GSV alone was treated (including the ESCHAR trial) showed a significant reduction in ulcer recurrence compared with conservative therapy. A community hospital-based multicenter, double-blind, randomized trial reported by Nelzen and Fransson (2011) found no clinical benefit (self-reported symptoms) from adding subfascial endoscopic perforator surgery to...
saphenous surgery in 75 patients with varicose ulcers (CEAP classes C5-C6) and incompetent perforators.49.

Treatment of the GSV alone has been reported to improve perforator function. For example, Blomgren et al (2005) showed that reversal of perforator vein incompetence (28 [41%] of 68 previously incompetent perforators) was more common than new perforator vein incompetence (41 [22%] of 183 previously competent perforators) following superficial vein surgery.50, O'Donnell (2008) discussed additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency.5 Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

**Subfascial Endoscopic Perforator Surgery**

Tenbrook et al (2004) reviewed the literature on subfascial endoscopic perforator surgery, which included 19 case series and 1 randomized trial.51, In total, the selected studies included 1031 patients with 1140 treated limbs. Reviewers concluded that subfascial endoscopic perforator surgery was associated with excellent results regarding ulcer healing and prevention of recurrence. However, they also noted that randomized trials are required to define the relative contributions of compression therapy, superficial venous surgery, and subfascial endoscopic perforator surgery in the management of severe venous disease. Van Gent et al (2015) reported on 10-year follow-up from a randomized trial that compared conservative treatment with subfascial endoscopic perforator surgery for venous leg ulcers.52, Patients (196 legs) returned to the clinic annually, and analysis was conducted with the last-observation carried forward. The primary outcome (incidence ulcer-free) was significantly higher in the surgical group (58.9%) than in the conservative treatment group (39.6%; p=0.007). The number of incompetent perforator veins at follow-up was a risk factor for not being ulcer-free (OR=18.5, p<0.001). The relatively high rate of recurrence in the surgically treated group might have been due to limited or no stripping of the superficial veins at the time of subfascial endoscopic perforator surgery.

In a meta-analysis of subfascial endoscopic perforator surgery for chronic venous insufficiency, Luebke and Brunkwall (2009) concluded that “Its use should not be employed routinely and could only be justified in patients with persistent ulceration thought to be of venous origin, and in whom any superficial reflux has already been ablated and postthrombotic changes excluded.”53, Reviewers also stated that the “introduction of less invasive techniques for perforator vein ablation, such as ultrasound-guided sclerotherapy or radiofrequency ablation, may diminish the role of subfascial endoscopic perforator surgery in the future.”

**Other Treatments**

In a review of procedures for management of varicose veins, Hirsch and Dillavou (2008) recommended duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a short RFA catheter for the treatment of symptomatic residual perforator vein incompetence.54, Ablation of incompetent
perforator veins with laser or RFA has been shown to be technically feasible, although no studies have been identified that showed improvements in clinical outcomes (eg, ulcer healing or recurrence). A literature update by Hissink et al(2010) identified 1 study of endovenous laser ablation for perforating veins assessing 33 patients with CEAP classifications of C4 (skin changes), C5 (healed ulcer), or C6 (active ulcer). All incompetent saphenous trunks were treated simultaneously (63% of limbs). At 3-month follow-up, occlusion was achieved in 78% of the perforating veins. Five (15%) patients had active ulcers at baseline; 4 of the 5 ulcers had healed by 6 weeks after endovenous laser ablation. Evidence on the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion.

Section Summary: Perforator Reflux
The literature has shown that the routine ligation and ablation of incompetent perforator veins is not necessary for treating varicose veins and venous insufficiency concurrent with superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating and ablating incompetent perforator veins. Subfascial endoscopic perforator surgery has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only one 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 endovenous thermal ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity (TRM). There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at 2- to 5-year follow-up has supported the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. For physician-compounded sclerotherapy, there is high variability in
success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that once occluded, recurrence rates at two 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.

Based on the available evidence, clinical input obtained in 2015, and clinical practice guidelines, the use of endovenous RFA, endovenous laser ablation, 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.

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

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes an RCT and a prospective cohort. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. Evidence assessing cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with initial 3 months of follow-up and subsequent reports with follow-up through 24 months. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at three months; the loss to follow-up in the further follow-up studies limits the confidence in this outcome. A prospective cohort reported high closure rates at 30 months but also had a high loss to follow-up. Adequately powered trials with adequate follow-up are 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. The relevant outcomes are symptoms, change in disease status, morbid
events, QOL, and TRM. Results from a recent RCT of cryoablation have indicated
that this therapy is inferior to conventional stripping. Studies showing a benefit on
health outcomes are needed. The evidence is insufficient to determine the effects
of the technology on health outcomes.

**Varicose Tributary Veins**
For individuals who have varicose tributary veins who receive ablation (stab
avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes
RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms,
change in disease status, morbid events, QOL, and TRM. The literature has shown
that sclerotherapy is effective for treating tributary veins following occlusion of the
saphenofemoral or saphenopopliteal junction and saphenous veins. No studies
have been identified comparing RFA or laser ablation of tributary veins with
standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated
powered phlebectomy is effective at removing varicosities; outcomes are
comparable to available alternatives such as stab avulsion and hook phlebectomy.
The evidence is sufficient to determine that the technology results in a meaningful
improvement in the net health outcome.

**Perforator Veins**
For individuals who have perforator vein reflux who receive ablation (eg, subfascial
endoscopic perforator surgery) of perforator veins, the evidence includes RCTs and
systematic reviews of RCTs. The relevant outcomes are symptoms, change in
disease status, morbid events, QOL, and TRM. The literature has indicated that the
routine ligation or ablation of incompetent perforator veins is not necessary for the
treatment of varicose veins/venous insufficiency at the time of superficial vein
procedures. However, when combined superficial vein procedures and compression
therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein
reflux may be as beneficial as an alternative (eg, deep vein valve replacement).
Comparative studies are needed to determine the most effective method of
ligating or ablating incompetent perforator veins. Subfascial endoscopic perforator
surgery has been shown to be as effective as the Linton procedure with a
reduction in adverse events. Although only one 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.

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

Practice Guidelines and Position Statements

Society for Vascular Surgery and American Venous Forum


Table 11. 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>Compression therapy for venous ulcerations and varicose veins</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</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>
<tr>
<td>Treatment of the incompetent great saphenous vein</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Endovenous thermal ablation (radiofrequency or laser) is recommended</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>• chemical ablation with foam or</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>• 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.</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Varicose tributaries</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Phlebectomy or sclerotherapy are recommended to treat varicose tributaries</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy</td>
<td>2C</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>Perforating vein incompetence</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>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</td>
<td>2B</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
QOE: quality of evidence; SOR: strength of recommendation.

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
The Society of Interventional Radiography (2003) 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)

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, American Venous Forum and Society of Interventional Radiography (2007) 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 the disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation might include patients with reflux in an incompetent great saphenous vein or smaller saphenous vein or a major tributary branch of the great or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory great saphenous vein. The presence of reflux in these veins is important to document using duplex ultrasound imaging,
and the ultrasound criteria used to define reflux should be indicated. It was also stated that, in current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 to 1.0 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

**National Institute for Health and Care Excellence**
The NICE (2013) updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins.\(^{60}\) 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.”

The NICE (2016) revised its guidance on endovenous mechanochemical ablation, 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....”\(^{61}\).

The NICE (2013) published guidance on the diagnosis and management of varicose veins in the leg.\(^{62}\) The NICE (2015) published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation, and surgery for varicose veins.\(^{63}\) 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. In the absence of a national coverage determination, 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 12.
Table 12. 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>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03392753</td>
<td>Randomised Controlled Trial of Mechanoclysis Ablation Versus Cyanoacrylate Adhesive for the Treatment of Varicose Veins</td>
<td>180</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NTR4613</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>NCT01936168</td>
<td>Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA)</td>
<td>460</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT02627846</td>
<td>A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanoclysis Ablation (ClariVein®) in the Management of Superficial Venous Insufficiency (LAMA)</td>
<td>140</td>
<td>Sep 2030</td>
</tr>
</tbody>
</table>

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

a Denotes industry-sponsored or cosponsored trial.

REFERENCES


22. 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


**Billing Coding/Physician Documentation Information**

**0524T** Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring (New code 1/1/2019)

**36465** Injection of non-compounded foam sclerosant with ultrasound
compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)

36466 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg

36482 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated

36483 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36468 Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk

36470 Injection of sclerosant; single incompetent vein (other than telangiectasia)

36471 Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg

36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated (new code 1/1/2017)

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) (new code 1/1/2017)

36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated

36476 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

36479 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>37766</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions</td>
</tr>
<tr>
<td>37780</td>
<td>Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)</td>
</tr>
<tr>
<td>37785</td>
<td>Ligation, division, and/or excision of varicose vein cluster(s), 1 leg</td>
</tr>
<tr>
<td>37799</td>
<td>Unlisted procedure, vascular surgery</td>
</tr>
<tr>
<td>93970</td>
<td>Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study</td>
</tr>
<tr>
<td>93971</td>
<td>Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study</td>
</tr>
<tr>
<td>S2202</td>
<td>Echosclerotherapy</td>
</tr>
</tbody>
</table>

**ICD-10 Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I83.001-</td>
<td>Varicose veins of lower extremities, code range</td>
</tr>
<tr>
<td>I83.899</td>
<td></td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous, insufficiency (chronic, peripheral)</td>
</tr>
</tbody>
</table>

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.

**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.
6/1/18  No policy statement changes.
6/1/19  No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.