Healthy Blue

Medical Policy

Subject:	Treatment of Varicose Veins (Lower Extremities)		
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Description/Scope

This document addresses various modalities (listed below) for the treatment of valvular incompetence (reflux) of the great saphenous vein (GSV), anterior accessory great saphenous vein (AAGSV), or small saphenous vein (SSV) (also known as greater saphenous vein or lesser saphenous vein, respectively) and associated varicose tributaries as well as telangiectatic dermal veins.

The following modalities are included in this document:

- Coil embolization;
- Cyanoacrylate adhesion (VenaSeal® Closure System);
- Echosclerotherapy (also known as ultrasound-guided sclerotherapy or ultrasound guided foam sclerotherapy [UGFS] [for example, Varithena], or microfoam sclerotherapy);
- Endoluminal cryoablation;
- Endoluminal laser ablation (also known as EVLT® or ELAS);
- Endoluminal radiofrequency ablation (also known as VNUS Closure® System or Venefit™ Procedure);
- Endovenous thermal ablation (EVTA) which includes radiofrequency and laser ablation (EVLA);
- Mechanochemical ablation (for example: ClariVein®);
- Sclerotherapy (including catheter-assisted balloon sclerotherapy [for example, KAVS procedure]).

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Position Statement

Medically Necessary:

I. Endoluminal radiofrequency ablation or endoluminal laser ablation, of the great saphenous vein (GSV), anterior accessory great saphenous vein (AAGSV), **or** small saphenous veins (SSV) is considered **medically necessary** when the following criteria are met:
   A. Truncal vein incompetence (that is, reflux with retrograde flow of 0.5 second duration or greater in the GSV, AAGSV, or SSV) based on vein anatomy is confirmed by Doppler or duplex ultrasound evaluation and report; **and**
   B. Previous endoluminal radiofrequency ablation or endoluminal laser ablation for refluxing varicosities of the same named vein, on the same extremity, has not been performed within the previous 6 weeks *nor* more than 3 times in the previous 12 months; **and**

C. One or more of the following criteria (1, 2, or 3) are met:
   1. Symptoms of venous insufficiency or recurrent thrombophlebitis (including but not limited to: aching, burning, itching, cramping, or swelling during activity or after prolonged sitting) which:
      a. are causing discomfort to the degree that employment or activities of daily living are compromised; **and**
      b. persist despite appropriate conservative therapy, for no less than 6 weeks, such as leg elevation, weight loss and exercise; **and**
      c. persist despite a trial of properly fitted gradient compression stockings for at least 6 weeks; **or**
   2. There is ulceration secondary to stasis dermatitis; **or**
   3. There is hemorrhage from a superficial varicosity.

II. Sclerotherapy or echosclerotherapy, including ultrasound guided foam sclerotherapy (UGFS), of varicose tributary or extension (for example, anterolateral thigh vein, anterior accessory saphenous vein, or intersaphenous vein[s]) or perforator veins is considered **medically necessary** when the following criteria are met (A and B, or A and C):
   A. Vein being treated is greater than 3.0 mm in diameter with reflux confirmed by Doppler or duplex ultrasound evaluation and report; **and**
   B. When performed during the same operative session as an endoluminal radiofrequency ablation procedure or endoluminal laser ablation procedure which meets the criteria above; **or**
   C. When performed for the treatment of residual or recurrent symptoms which meet the following criteria:
      1. Surgical ligation and stripping, endoluminal radiofrequency ablation, or endoluminal laser ablation of the AAGSV, GSV or SSV was previously performed; **and**
      2. Prior sclerotherapy or echosclerotherapy treatments for refluxing varicosities of the same extremity have not been performed within the previous 6 weeks; **and**
      3. One or more of the following criteria (a, b, or c) are met:
         a. Symptoms of venous insufficiency or recurrent thrombophlebitis (including but not limited to: aching, burning, itching, cramping, or swelling during activity or after prolonged sitting) which:
            i. are causing discomfort to the degree that employment or activities of daily living are compromised; **and**
            ii. persist despite appropriate conservative therapy for 6 weeks (such as leg elevation, weight loss and exercise), excluding similar management prior to the required treatment of the great or small saphenous vein; **and**
            iii. persist despite a trial of properly fitted gradient compression stockings for at least 6 weeks, excluding similar management prior to the required treatment of the great or small saphenous vein; **or**
         b. There is ulceration secondary to stasis dermatitis; **or**
         c. There is hemorrhage from a superficial varicosity.

Not Medically Necessary:

I. Endoluminal radiofrequency ablation and endoluminal laser ablation, are each considered **not medically necessary** when the above criteria are not met, and for all other uses in the lower extremities including, but not limited to:
   1. As an alternative to perforator vein ligation;

2. As treatment of saphenous vein tributaries or extensions not considered medically necessary above, (for example, anterolateral thigh and intersaphenous veins);
3. As an alternative to adjunctive sclerotherapy or echosclerotherapy of symptomatic varicose tributaries.

II. Sclerotherapy or echosclerotherapy (including UGFS) is considered **not medically necessary** when the above criteria are not met, and for all other uses including, but not limited to**:**
1. As the sole***** treatment of symptomatic varicose tributary or extension or perforator veins in the presence of valvular incompetence of the great or small saphenous veins (by Doppler or duplex ultrasound scanning);
2. As the sole treatment of symptomatic varicose tributary or perforator veins in the absence of saphenous vein reflux or major saphenous vein tributary reflux;
3. For the treatment of secondary varicose veins resulting from deep-vein thrombosis or arteriovenous fistulae when used to treat valvular incompetence (that is, reflux) of the great or small saphenous veins with or without associated ligation of the saphenofemoral junction;
4. When performed as part of other protocols for sclerotherapy, including, but not limited to the COMPASS protocol, for the treatment of valvular incompetence (that is, reflux) of the great or small saphenous veins.
5. When used in conjunction with a balloon catheter (for example, KAVS procedure).

III. Endoluminal cryoablation is considered **not medically necessary**.

IV. Mechanochemical ablation of any vein is considered **not medically necessary**.

V. Coil embolization is considered **not medically necessary** as treatment of lower extremity veins.

Note: COMPASS is an acronym for Comprehensive Objective Mapping, Precise Image-guided Injection, Antireflux Positioning and Sequential Sclerotherapy.

***** Sole refers to sclerotherapy without concomitant or prior ligation (with or without vein stripping), or endoluminal radiofrequency ablation, or endoluminal laser ablation for valvular incompetence of the great or small saphenous veins.

Investigational and Not Medically Necessary:

Cyanoacrylate adhesion (for example, VenaSeal Closure System) is considered **investigational and not medically necessary** as treatment of venous reflux.

Cosmetic and Not Medically Necessary:

Treatment using sclerotherapy or various laser treatments (including tunable dye or pulsed dye laser, for example, PhotoDerm®, VeinLase™, Vasculite™) of the telangiectatic dermal veins (for example, reticular, capillary, venule), which may be described as "spider veins" or "broken blood vessels" is considered **cosmetic and not medically necessary.**

Rationale

Endovenous Thermal Ablation (EVTA) (includes radiofrequency and laser ablation)

Goode and colleagues (2009) evaluated the suitability of radiofrequency ablation, endovenous laser ablation, and foam sclerotherapy for treatment of symptomatic varicose veins. Information was collected at a single facility for 1 year (2006) on 577 legs from 403 consecutive persons with symptomatic varicose veins. Duplex ultrasonography was used to select individuals for each procedure. GSV reflux occurred in 77% (446 of 577) of legs. A total of 328 (73%) of the legs were considered suitable for at least one of the endovenous procedures. Of the 114 legs with recurrent GSV reflux disease, 83 (73%) were considered suitable to receive endovenous therapy. Overall, a majority of individuals in this study with primary and recurrent varicose veins with GSV incompetence were deemed suitable for endovenous treatment. Of note, the authors reported that GSVs with diameters 3-12 mm were considered suitable for radiofrequency ablation and those with diameters less than 1 cm (10 mm) were considered suitable for foam sclerotherapy. Diameters larger than 1 cm (10 mm) were considered unsuitable for foam sclerotherapy due to an increased risk of staining and phlebitis. Further noted, was:

> For RFA and EVLA a straight segment of GSV of approximately 15-20 cm immediately distal to the saphenofemoral junction, as well as a GSV diameter larger than 3 mm at the intended cannulation site (at the knee), were needed to ensure suitability.

Khilnani and colleagues (2010) addressed the use of EVTA for perforator and surface varicose veins in guidelines from a multi-society consensus:

> The use of EVTA to close incompetent perforating veins has been described. At this point, the indications and contraindications for use as well as the success rates and safety of this approach have only recently begun to be evaluated. The use of EVTA to close surface varicose veins is not encouraged. These veins are usually too tortuous for current generation devices to pass through. Also, these veins are very superficial; EVTA of such veins carries a high risk of thermal skin injury.

Gloviczki and colleagues (2011) addressed endovenous thermal ablation (laser and radiofrequency) as a safe and effective procedure for the treatment of saphenous incompetence. These ablative procedures are associated with less pain and morbidity than open surgery. Endovenous thermal ablation is recommended over sclerotherapy for treatment of an incompetent saphenous vein. Sclerotherapy is recommended for treatment for telangiectasia, reticular veins and varicose veins.

In a large analysis of Medicare utilization data, trends in endovenous ablation practice in the United States were characterized over a 3-year time-period (2012-2015). During this time, 3244 unique providers performed 619,029 procedures with an average of 1.8 ablations per individual. The number of ablations performed nationwide is on the rise, as well as the number of ablations performed per individual. Non-vascular surgeons were reportedly more likely to perform more than the average two ablations on any given individual (Crawford, 2019). Similarly, an analysis of a Medicare fee-for-service claims data published results from a 1-year period of 102,145 beneficiaries who underwent endovenous ablation performed by 2462 unique providers. The median and mean number of ablations performed per beneficiary per year were 1.6 and 1.9, respectively. These averages included physicians whose practice patterns deviated significantly from the mean with 3.3% of beneficiaries undergoing 6 to 10 ablations, and 0.3% undergoing 11 or more ablations (Mann, 2019). Another, significantly smaller study (n=200)

similarly found the average number of ablations performed in an individual with chronic venous disease was 1.3 (Crawford, 2017).

Endoluminal Radiofrequency (RF) Ablation (thermal heating)

The VNUS Closure System (VNUS Medical Technologies, Inc., San Jose, CA) received U.S. Food and Drug Administration (FDA) 510(k) clearance in 1999. VNUS has been evaluated as an alternative to vein ligation and stripping or stripping alone for the treatment of saphenofemoral or saphenopopliteal junction incompetence and saphenous vein reflux. Endoluminal RF ablation of the saphenous vein is based on the principle of treating reflux disease by control of the point of reflux and isolation of the refluxing saphenous vein from circulation. The current evidence suggests that this procedure has success rates similar to those reported for surgical ligation and stripping with less postoperative pain and faster postoperative recovery. The VNUS Closure System is now known as the Venefit Procedure (Covidien, Mansfield, MA).

Proebstle and colleagues (2015) reported 5-year results of a prospective European multicenter cohort study on radiofrequency segmental thermal ablation (RFA) for incompetent GSVs using a catheter with an integrated heating element. A total of 225 subjects had 295 GSVs treated with RFA. At 5 years post-treatment, 177 subjects with 236 treated limbs completed follow-up exams for a study completion rate of 78.7%. Varicose veins were present in 98.6% of legs at baseline with 52.2 originating from the GSV. At 3 months post treatment, only 15.2% of the treated limbs had varicose veins present. The number of legs with varicose veins increased to 40.7% at 5 years. An initial vein occlusion rate of 100% was reported. Kaplan-Meier analyses showed a GSV occlusion rate of 91.9% and a reflux-free rate of 94.9% at 5 years. Among the 15 GSVs noted with reflux at follow-up, only 3 showed full recanalization of the GSV at 1 week, 6 months and 3 years. Of the 12 legs with partial recanalization, reflux originated at the saphenofemoral junction in 10, with a mean length of the patent segment of 5.8 cm; only 6 subjects were symptomatic. A total of 92.4% of the treated limbs were reported to be pain free at the 5-year follow-up visit. Retreatment was required in 15.3% by 5 years. The authors concluded, “comprehensive follow-up for other methods to 5 years is required to establish the optimal treatment for varicose veins.”

Endovenous/Endoluminal Laser Ablation

Venacure EVLT (Angiodynamics, Inc., Latham, NY) received FDA 510(k) clearance in 2002. EVLT of the GSV has been studied in two large-scale case series studies and several smaller case series. These studies demonstrate lower relapse rates when compared with ligation and stripping, as well as comparable symptom relief and complication rates similar to endoluminal radiofrequency ablation. The use of this procedure outside the criteria specified in the position statement is not in alignment with the current standards of practice in the medical community (Brittenden, 2019; Darwood, 2008; Min, 2003; Rasmussen, 2007; Wallace, 2019).

In a meta-analysis, van den Bos and colleagues (2009) reported that the literature supported minimally invasive interventions in the treatment of lower extremity varicosities despite the lack of large controlled studies. Comparing the outcomes of RF and laser ablation of the GSV and LSV/SSV in the literature showed that laser ablation was more effective than RF ablation.

RF or laser ablation for veins other than the saphenous veins (for example, anterolateral thigh, anterior accessory saphenous and interspahenous [Giacomini] veins) has been proposed. Peden and colleagues (2007) and Elias and

colleagues (2007) addressed the feasibility of endoluminal RF and endovenous laser ablation for refluxing perforator veins. They concluded that additional clinical studies are needed to validate these treatment techniques. Van den Bos and colleagues (2009) reported on RF ablation of 14 incompetent perforator veins (IPV) in 12 individuals. At 3 months of follow-up, 9 (64%) of the 14 perforators treated were obliterated on ultrasound examination and the other 5 showed remaining reflux. The authors found that while RF ablation of perforator veins may be a promising procedure, further standardization of the procedure is required, as well as comparative clinical trials between RF ablation and standard therapies. In a small study, Bush and colleagues (2007) reported laser and sclerotherapy ablation of the intersaphenous (Giacomini) vein in 14 individuals. The ablations were successful and without complications. No recanalization occurred during a 2 to 4 year follow-up. In a small comparative clinical trial (n=69), Park and colleagues evaluated the safety and efficacy of endovenous laser ablation for either IPVs or GSVs without evidence of saphenofemoral reflux over a period of 12 months. Endovenous ablation resulted in similar closure rates between the two groups (100% at 3, 6, and 12 months for both vein types). However, technical failure of the procedure was higher in subjects with IPVs compared with GSVs, and study authors determined that endovenous ablation might not be suitable as a primary treatment method for IPVs.

Wallace and colleagues published long-term outcomes from a randomized trial comparing RFA with surgical ligation and stripping as a treatment of incompetent GSV (2019). At study start, 276 individuals were enrolled and randomized to one of the two treatment groups, at 5-year follow-up, 218 (79%) were available for evaluation. Recanalization was more frequent in the surgery group (34.3%) compared to the EVLA group (20.9%) (p=0.01). Satisfaction, as measured by quality of life surveys, were similar between treatment groups.

Endovenous laser ablation has been considered for treatment of refluxing saphenous tributaries. This was addressed in one small study of 18 participants (Bush, 2007) and a case report of 2 individuals (Theivacumar, 2007).

Theivacumar and colleagues (2009) proposed treating sapheno-femoral reflux and preserving the GSV by laser ablation of the anterior accessory great saphenous vein (AAGSV) in those with isolated sapheno-femoral junction (SFJ)/AAGSV reflux. They studied 66 individuals with SFJ reflux treated with EVLT, which included GSV ablation with 33 matched individuals with (SFJ)/AAGSV reflux treated with EVLT of the AAGSV. This feasibility study showed successful laser ablation of the AAGSV when the vein was relatively straight, at least 10 cm long, greater than or equal to 3 mm in diameter, and free of varicosities within the treatment length. Both groups had similar outcomes (sclerotherapy for residual varicosities). Doppler ultrasound (DUS) was performed at 6, 12, and 52 weeks to assess SFJ and tributary competence and ablation of the axial vein. Absence of flow in a noncompressible vein or a non-visible axial (GSV or AAGSV) vein on ultrasound represented successful ablation. The AAGSV was not visible in those treated for SFJ/AAGSV reflux. The authors reported that isolated SFJ/AAGSV reflux occurs in only 10% of those with reflux. In conventional surgery, many surgeons strip a competent GSV because of the risk that neovascularization after SFJ ligation may result in GSV reflux and recurrence. The authors stated that selective ablation of incompetent axial veins preserves a healthy GSV for other coronary or vascular procedures, if needed.

A randomized, 5-year comparative effectiveness study was conducted comparing quality of life outcomes amongst individuals with primary varicosities who underwent EVLA (n=210), sclerotherapy (n=286) or surgery (n=289) of the GSV or SSV. Of the 798 trial participants, 595 (75%) completed the quality of life surveys at year 5 (sample size analysis accounted for 30% loss to follow-up). Scores on the Aberdeen Varicose Vein Questionnaire (AAVQ) were significantly better among recipients of laser ablation or surgery compared to those who received therapy with

foam sclerotherapy (p<0.00 for both comparisons). Overall, 11% of the laser ablation group, 14% in the foam sclerotherapy group, and 7% in the surgery group had further treatment (Brittenden, 2019).

There is ample quality evidence that reflux of the AAGSV contributes to significant discomfort and disability and to support the use of EVLA and RFA as a safe and efficacious therapeutic option, including a 1C recommendation from the American College of Phlebology (2017). Published evidence regarding the efficacy of EVLA and RFA of the posterior accessory of the great saphenous vein (PAGSV) does not show that it is an established approach in the practicing medical community (Aurshina, 2018; Bush, 2014; Proebstle, 2015; Ravi, 2009; Schul, 2016; Theivacumar, 2009).

Endoluminal Cryoablation

In 2009, Klem and colleagues conducted a RCT and reported that endoluminal cryoablation (n=249) was inferior to conventional stripping (n=245) for treating individuals with symptomatic varicose veins. A total of 44% of individuals in the endoluminal cryoablation group and 15% in the conventional stripping group had persistent GSVs. The AVVQ also showed better results for conventional stripping (score of 11.7) in comparison with cryoablation (score of 8.0). There were no differences between the groups in SF-36 subscores, and neural damage was the same (12%) in both groups.

Mechanochemical Ablation

Elias and colleagues (2012) described a small industry-sponsored safety and efficacy study of the ClariVein system. A total of 30 great saphenous veins in 29 subjects were treated with the system. GSVs with diameters greater than 12 mm were excluded. A total of 77% of veins were Comprehensive Classification System for Chronic Venous Disorders (CEAP) Class 2; 7% in Class 3 (varicose veins and edema); and 16% in class 4a (varicose veins with skin changes). At 6 months of follow-up, one vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events were reported.

In a prospective cohort study, Boersma and colleagues (2013) evaluated mechanochemical endovenous ablation (MOCA) of the SSV in 50 consecutive individuals. MOCA is the actual technique that uses the ClariVein catheter. Only veins with a diameter of 2.5 to 11 mm were included. The dose of sclerosant was increased after the first 15 cases. At the 6-week assessment, all treated veins were occluded and at 1 year follow-up, 94% remained occluded. The median visual analog scale score for pain during the procedure was 2 of 10. There were no major complications.

A prospective observational multi-center report (Bishawi, 2013) evaluated the efficacy of MOCA of the GSV in 126 symptomatic individuals from community vein centers. Veins selected were greater than 4 mm and less than 12 mm in diameter. Closure rates were 100% at 1 week, 98% at 3 months, and 94% at 6 months. There was significant improvement reported at all-time intervals in the venous clinical severity score. Study limitations reported by the authors included a lack of control group and historical data from other studies was used as comparison.

A systematic review evaluated the ClariVein's anatomical, technical and clinical success by analyzing pooled data from 13 studies comprising 1521 veins (GSV and SSV). Although anatomical success rates at 2-3 years were 87-92%, authors acknowledge, at the time of analysis no randomized trials had been published comparing efficacy and

safety of MOCA to thermal ablation. Furthermore, although initial improvements were seen in disease-specific quality of life (QOL) measures, these measures began to decline in some study cohorts a year following treatment. In a total of 1464 veins, there were 3 cases of deep vein thrombosis (DVT) (0.2%), 2 cases of pulmonary embolism (0.1%) and transient paresthesia was seen in 1 case (<0.1%) (Whitte, 2017).

A randomized, multicenter, prospective clinical trial compared RFA with MOCA in 209 individuals with unilateral GSV incompetence. Overall, median pain scores during the first 14 days were lower after MOCA (n=105) relative to RFA (n=104) (0.2 vs 0.5, respectively; p=0.010). At 300 days, complication rates and quality of life measures were similar. In the MOCA group, there were 4 complete failures (3.8%) compared with none in the RFA group (P=0.045). Median 30-day Venous Clinical Severity Score (VCSS) was significantly lower at 30 days after MOCA (1.0 vs 2.0). At year 2, differences in failure rates were not significantly different. Study limitations include short follow-up and small sample size (Holewijn, 2019).

In another randomized trial design, 125 individuals with refluxing GSV were enrolled to undergo MOCA (n=65), EVLA (n=34) or RFA (n=33); the primary outcome of interest was occlusion rate of the GSV at 1-year follow-up. At study-end, the GSV was fully occluded in every vein that had been ablated (EVLA and RFA), whereas occlusion in the MOCA group was significantly lower at only 82% (p=0.002). Secondary outcomes of disease-related QOL measures and complication rates at 1 year did not differ significantly between groups (Vahaaho, 2019).

Vahaaho and colleagues (2021) conducted another RCT to compare MOCA with EVLA and RFA in individuals with unilateral GSV insufficiency. In total, 117 individuals were enrolled and treated following randomization (2:1:1 for MOCA, EVLA, and RFA, respectively). Closure of the GSV (evaluated via duplex Doppler ultrasound) and disease-specific QOL measures were assessed at 1 month, 1 year, and 3 years following treatment. The occlusion rate was significantly lower at 3 years following treatment with MOCA than with either EVLA or RFA (82% vs 100%; p=0 .005). QOL measures were similar between the three groups. GSVs greater than 7 mm in diameter at enrollment were associated with recanalization in the MOCA arm by study's end. Authors conclude that the technical success rates of MOCA are inferior to EVLA and RFA.

Mohamed and colleagues (2021) conducted an RCT to evaluate the safety and efficacy of MOCA compared to EVLA in individuals with unilateral GSV insufficiency. A total of 143 individuals were enrolled, randomized 1:1 and received treatment with either modality along with concomitant phlebectomy when indicated. At study end, 12 months, occlusion rates after EVLA were 63/69 (91%) compared to 53/69 (77%) in the MOCA group; p= 0.020. Both groups experienced significant improvement in QOL measures and 1 study participant in the MOCA group experienced a DVT. This study adds to the established evidence that MOCA's efficacy is inferior to established alternatives.

Sclerotherapy

Sufficient evidence exists in the peer-reviewed medical literature to support the procedure of sclerotherapy when used adjunctively for the treatment of symptomatic varicose tributaries, when performed either at the same time as surgical ligation and stripping, RFA, or EVLA of the saphenous vein, or for the treatment of residual or recurrent symptomatic varicose tributaries following the above procedures (Tisi, 2006). A vein may be difficult to puncture

or treat if the diameter is less than 3 mm. Therefore, not only does the treated vein need to demonstrate reflux, the diameter of the vein should be greater than 3.0 mm.

Sclerotherapy as the *sole* treatment of symptomatic varicose tributaries of the GSV is not indicated in the presence of saphenofemoral or saphenopopliteal junctional reflux. Published studies indicate that such treatment, without definitive treatment of valvular incompetence (reflux) of the saphenous veins with stripping and ligation or other surgical treatments (for example, endoluminal RFA, or EVLA), provides minimal long-term benefit and leads to high recurrence rates. Individuals who undergo definitive treatment, as well as adjunctive sclerotherapy of the varicose tributaries, have shown better long-term results, lower rates of recurrence, and better quality of life scores.

The overwhelming majority of varicosities of the saphenous tributaries are related to co-existing valvular incompetence (reflux) of the great or small saphenous veins. However, a small subset of individuals (up to 14%) may be symptomatic in the absence of underlying reflux. Sclerotherapy as a sole therapy has been proposed for these individuals; however, the evidence base is too small to support the use of sclerotherapy as a sole therapy. In a randomized study of 25 individuals, those receiving sclerosant reported a higher obliteration rate compared with those receiving normal saline at 12 weeks follow-up. The study does not address the key issue of long-term symptom resolution (Kahle, 2004).

Sclerotherapy directed at the underlying refluxing saphenous veins (as opposed to the visible varicosities of the tributary veins) requires ultrasound guidance. This procedure may be referred to as echosclerotherapy or ultrasound-guided sclerotherapy. The goal of ultrasound-guided foam sclerotherapy (UGFS) when treating varicose veins is to damage the endothelial surface of the vein to cause scarring and blockage of the treated vein. Under local anesthesia, the sclerosant foam is injected into the affected veins using ultrasound guidance. The foam sclerosant causes an inflammatory reaction in the vein wall, causing vein blockage. Compression bandages are applied after the procedure for a period of time.

Varithena is a drug/device combination product that generates an injectable foam. In 2013, Varithena microfoam (polidocanol injectable foam) was FDA approved under a new drug application as a sclerosing agent indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the GSV system above and below the knee (Varithena prescribing information, 2016). Todd and colleagues (2014) reported results of VANISH-2, a randomized, blinded multicenter pivotal trial designed to evaluate the safety and efficacy of polidocanol endovenous microfoam (Varithena). Participants were randomized to receive polidocanol endovenous microfoam 0.5%, polidocanol endovenous microfoam 1.0% or placebo. In 232 treated participants, polidocanol endovenous microfoam 0.5% and polidocanol endovenous microfoam 1.0% were reported as superior to placebo, with a larger improvement in symptoms and greater improvements in assessments of appearance. Results of duplex ultrasound and other clinical measures supported the findings. Of the subjects treated with polidocanol endovenous microfoam, 60% had an adverse event compared with 39% of placebo. Results of VANISH-2 were confirmed by King and colleagues (2015) in a multi-center parallel study of 284 subjects. The authors reported that treatment with PEM 1% and PEM 2% resulted in similar side effects, was equally effective in improving symptoms and appearance, and had a similar duplex response rate.

More recently, Todd and colleagues (2016) reported safety and efficacy data from the VANISH-2 trial for individuals treated with polidocanol endovenous microfoam 1% at baseline (visit 2/week 0), from visit 5/week 8 through the year 1 visit. A total of 56 of the original 232 baseline subjects had received polidocanol endovenous

microfoam 1% and were subsequently assessed at visit 5/week 8 and year 1. Ongoing symptom and appearance improvement were reported at year 1 with no new venous thrombus adverse events.

Gibson and colleagues (2016) evaluated Varithena in a multi-center study of 77 individuals with symptomatic, visible varicose veins randomized to treatment consisting of either Varithena 1% (n=39) or placebo (n=38). Varithena provided significantly greater symptom and appearance improvement than did placebo at week 8.

Another small 2016 multi-center study (Vasquez and colleagues) was performed in individuals with GSV incompetence and symptomatic visible superficial venous disease. A total of 117 subjects were treated (38 placebo, 39 polidocanol endovenous microfoam 0.5%, 40 polidocanol endovenous microfoam 1%). Self-assessment and physician assessments were similar at week 8 for those treated by microfoam with improvements reported in appearance, need for additional treatment, saphenofemoral junction reflux elimination, symptoms and quality of life. Superficial thrombophlebitis was the most frequent adverse event (35.4%).

Controlled studies have shown that sclerotherapy/echosclerotherapy of the underlying refluxing great or small saphenous veins is associated with a higher rate of recurrence compared to ligation and stripping (Belcaro, 2003). Van den Bos and colleagues (2009) conducted a meta-analysis of 64 studies (12,320 limbs) evaluating treatment of lower extremity varicosities, including GSVs and SSVs. Study authors reported that UGFS was comparable to conventional surgical stripping, but not as effective as EVLA. Comparable results were observed between UGFS and RFA.

Shadid and colleagues (2012) performed a randomized non-inferiority trial comparing foam sclerotherapy with ligation and stripping. A total of 230 subjects were treated with UGFS and 200 underwent stripping of the GSV. Forty subjects (17%) had repeat UGFS. At 2 years, the probability of clinical recurrence was similar in the two groups (11.3% sclerotherapy vs 9.0% ligation and stripping); however, reflux was more common in the sclerotherapy group (35% vs 21%). Thrombophlebitis occurred in 7.4% of subjects after sclerotherapy. There were two serious adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within 1 week of treatment. Study limitations include lack of blinding and limited follow-up of 2 years.

In 2014, Darvall and colleagues reported outcomes 5-8 years after UGFS for varicose veins obtained using health-related quality of life (HRQL), patient-reported outcomes (PROMs), satisfaction and retreatment rates. A total of 391 limbs in 285 subjects were included at a median of 71 months following first UGFS treatment. Originally, 72.1% had symptomatic, uncomplicated varicose veins, 21.9% had undergone surgery previously, 87.2% had GSV treatment and 19.9% had SSV treatment. HRQL scores improved significantly at long-term follow-up. Between 62.7% and 81% of subjects reported improvements in social, work and leisure activities that either met or exceeded their expectations. Overall, 82% were very satisfied with their treatment and 3.3% were dissatisfied. A total of 15.3% of limbs required retreatment by 5 years.

The Comprehensive Objective Mapping, Precise Image-guided Injection (echosclerotherapy), Antireflux Positioning and Sequential Sclerotherapy (COMPASS) procedure represents a distinct sclerotherapy protocol for the treatment of valvular incompetence (reflux) of the great or small saphenous veins. The evidence regarding this techniques, in particular the study published by Belcaro and colleagues (2003), suffers from flaws in study design, including a failure to address specific information in regard to participant selection criteria, no description of the randomization process, and a failure to include appropriate comparator groups, including standard surgical

treatment consisting of vein stripping and ligation. In addition, one of the surgical reference arms was not a part of the randomization process, but was a retrospective historical control group. Additionally, the retreatment that occurred because of ongoing ultrasound monitoring was generally defined as a continuation of the initial therapy in the COMPASS protocol, rather than true recurrences or treatment failures. This aspect of the COMPASS protocol may be responsible for the low "recurrence rate" reported in the published studies. With the COMPASS protocol, individuals are viewed as being in the latter "phases" of therapy for prolonged periods. Some reports indicate that individuals have received therapy in excess of 1year. This is in contrast to alternative treatment methods, including standard surgical techniques, laser ablation or radiofrequency ablation procedures, which are completed within 7 to 10 days.

The KAVS [catheter-assisted vein sclerotherapy] procedure involves an intravascular catheter that is introduced into the vein for short-term therapeutic use. The catheter has a balloon at the distal end that will temporarily block the blood flow to that segment of the vein being targeted for sclerotherapy. Evidence evaluating the safety and efficacy of endovenous catheter-directed chemical ablation in conjunction with balloon isolation as a treatment of varicose veins is not a widely accepted practice approach in the medical community.

PhotoDerm, VeinLase and Vasculite

PhotoDerm, VeinLase and Vasculite are laser devices primarily used in treating telangiectatic and reticular veins and other skin related applications. There is no compelling evidence that these conditions have any significantly negative health impact and fail to meet the criteria for medical necessity. However, there is adequate evidence that these treatment methods do significantly decrease the appearance of these superficial veins. Therefore, these techniques are considered primarily cosmetic in nature.

Comparisons of Ablation and Sclerotherapy to Surgical Ligation and Stripping

Rasmussen and colleagues (2011) reported on a RCT of 500 subjects comparing endovenous laser ablation (EVLA), radiofrequency ablation, foam sclerotherapy and surgical stripping of the GSV. The primary outcome was the failure rate at 1 year. Significantly more GSVs were open and refluxing at 1 year in the ultrasound guided foam sclerotherapy (UGFS) group than in the other groups ($p<0.001$). There were no statistically significant differences among patent GSVs in the 3 other groups ($p=0.543$). In a primary RCT (MAGNA Trial) of 240 individuals conducted by Biemans (2013), UGFS was not as effective as EVLA in the short term (1 year), but comparable to high ligation and stripping. At 5-year follow-up of the MAGNA trial, Kaplan-Meier analysis showed obliteration or absence of the GSV in 85% of individuals who underwent conventional surgery and 77% of those who underwent EVLA (not significantly different) (van der Velden, 2015). Grade I neovascularization was higher in the conventional surgery group (27% vs 3%, $p<0.001$); however, grade II neovascularization was similar both groups (17% vs 13%).

A randomized controlled trial with a 5-year follow-up comparing EVLA with ligation and stripping for GSV incompetence was reported by Rasmussen and colleagues (2013). A total of 121 consecutive participants (137 legs) with symptomatic varicose veins and GSV incompetence were randomized to EVLA or high ligation and stripping. The primary endpoint of the study was open refluxing GSV. Secondary endpoints were recurrent varicose veins, frequency of reoperations, Venous Clinical Severity Score, and quality of life scores. Subjects were examined with duplex scanning before treatment and after 12 days, and after 1, 3, and 6 months, and every year thereafter for up to 5 years. In the EVLA and stripping groups, 9 and 4 of GSVs had open refluxing segments of 5 cm or more during the 5-year follow-up. Recurrent varicose veins were observed in 24 and 25 legs during the 5 years in the laser and

stripping groups, respectively. Reoperations were performed in 17 and 15 legs in the laser and stripping groups, respectively. Venous Clinical Severity Score and AAVQ Score improved significantly in both groups; however, Medical Outcomes Study Short Form-36 quality of life score improved in several domains in both groups with no difference between the groups. The authors reported "both surgery and EVLA are efficient treatments with long-term beneficial effects in patients with GSV varicose veins." Study limitations include a small sample size and lack of blinding.

A Cochrane review (Nesbitt, 2014) compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy to ligation and stripping for GSV varices. A total of 13 randomized studies consisting of a combined 3081 participants were included in the review. Due to variations in reporting of results, the overall quality of the evidence was determined to be moderate. The authors concluded:

> Currently available clinical trial evidence suggests that UGFS, EVLT and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins. Due to large incompatibilities between trials and different time point measurements for outcomes, the evidence is lacking in robustness. Further randomised trials are needed, which should aim to report and analyse results in a congruent manner to facilitate future meta-analysis.

Brittenden and colleagues (2014) performed the Comparison of Laser, Surgery and Foam Sclerotherapy (CLASS) trial, a large multicenter RCT designed to assess quality of life and other outcomes of varicose vein treatments. A total of 798 participants with primary varicose veins at 11 United Kingdom centers were randomized by computer generation. Outcomes were compared for surgical, foam and laser treatments. Surgery consisted of proximal ligation and stripping (of only the GSV) and concurrent phlebectomies. Foam consisted of sodium tetradecyl sulfate used off-label rather than in its liquid manufactured form. Laser ablation of truncal saphenous veins was performed and followed by foam sclerotherapy for residual varicosities if needed at the 6-week follow-up, with the exception of concurrent phlebectomies performed at one center. Outcome assessments occurred at baseline, 6 weeks and 6 months following treatment. The primary outcome measures at 6 months were generic quality of life and disease specific quality of life. Secondary outcomes included measures of clinical success and complications. The mean disease-specific quality of life, after adjustment for covariates including baseline scores, was slightly worse after foam treatment than after surgery ($p=0.006$) but was comparable in the laser and surgery groups. There were no significant differences between the surgery group and the foam or the laser group in generic quality of life measures. The frequency of serious adverse events (3%) was similar in all groups. The frequency of procedure related complications was lower in the laser group (1%) than in the surgery group ($p<0.001$); but similar in the foam group (6%) and the surgery group (7%). Clinical success measures were similar among all groups. However, successful ablation of the main trunks of the saphenous vein was less common in the foam group than in the surgery group ($p<0.001$). The authors concluded: "All treatments had similar clinical efficacy, but there were fewer complications after laser treatment, and ablation rates were lower after treatment with foam."

A single center, prospective, randomized, nonblinded trial (Gauw, 2016) compared long-term results of treatment for GSV incompetence by saphenofemoral ligation and stripping (SVL/S) to EVLA. A total of 130 legs of 121 subjects with GSV insufficiency were randomized to either SFL/S (n=68) or EVLA (n=62). Five subjects were lost to follow-up. After 5 years more recurrent varicose veins caused by neoreflux in incompetent tributaries of the saphenofemoral junction (SFJ) were observed after EVLA (31%; 19/61) compared with SFL/S (7%; 4/60; $p<0.01$). Groin neovascularization identified at 3 and 5 years post-treatment follow-up was observed in the SFL/S group

(n=6) and not in the EVLA group. After 5 years, clinically visible recurrences from the SFJ region after EVLA were observed in 33% (20/61) compared with 17% of subjects (10/60) after SFL/S (p<0.04). Both groups reported improved venous symptoms and a significant cosmetic improvement. There was no difference in the CEAP staging and a standardized, non-disease-specific instrument for describing and valuing health states (EuroQol-5D), between the groups up to 5 years after follow-up. The authors concluded that EVLA had no advantage over high ligations of the SFJ and stripping under tumescent anesthesia for the treatment of FSV reflux for up to 5 years.

Coil Embolization

There is scant published literature addressing coil embolization for treatment of lower extremity veins. An early study by van Dijk and colleagues (1999) investigated percutaneous coil embolization of incompetent perforating veins to treat venous ulcers and recurrent varicosities in the lower leg. A total of 15 individuals with 18 incompetent perforating veins in the lower leg were treated by ultrasound-guided percutaneous placement of embolization coils. Successful vein occlusion with one or more coils occurred in 12 of the 18 veins (technical success rate, 67%). Clinical symptoms improved in only 3 of the 15 individuals (clinical success rate, 20%). During follow-up at 2-12 months, recanalization of coil-embolized veins occurred in 9 of the 12 initially occluded veins. Another small study (Viani, 2014) consisted of 9 individuals and evaluated a "one-shot scleroembolization" technique designed to treat lower extremity varicose veins. The technique combined the use of a coil positioned in the terminal portion of the GSV and a foamed sclerosant drug. At 3 months' follow-up, there were no complications reported and the GSV remained occluded in all cases. Currently, coil embolization is not an approach widely accepted by the practicing medical community for the treatment of varicose veins.

Cyanoacrylate Adhesion

In 2015, the VenaSeal Closure System was approved by the FDA through the PMA process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation (Product Information [PI] Label 2015). The VenaSeal pivotal study (VeClose) was a multicenter noninferiority trial with 222 individuals that compared VenaSeal (n=108) with RFA (n=114) for the treatment of venous reflux. The primary end-point, the proportion of veins with complete closure of the target GSV at 3 months measured by ultrasound, was non-inferior to RFA with a 99% closure rate for VenaSeal compared with 96% for RFA. A secondary endpoint, intraoperative pain, was similar between the two groups (2.2 on a 10-point scale for VenaSeal and 2.4 for RFA; p=0.11). Ecchymosis at day 3 was significantly lower in the VenaSeal group; 67.6% of those treated with cyanoacrylate had no ecchymosis compared with 48.2% of individuals treated with RFA (p<0.01). Scores on the AAVQ and Venous Clinical Severity Score were similar between the groups (Morrison, 2015). The short-term follow-up, lack of primary outcome data in 13% (n=28) of enrollees, and lack of explanation for loss to follow-up are among the weaknesses of this pivotal clinical trial. Subsequently published studies on the safety and efficacy of VenaSeal are small (n<100), non-randomized cohort studies, most with similarly short follow-up (< 6 months) (Almeida, 2017; Gibson, 2017; Gibson, 2019; Park, 2017; Proebstle; 2015). The VenaSeal trial data was published with moderately long-term outcomes (36 months), demonstrating sustained outcomes in non-inferiority of VenaSeal (94.4%) relative to RFA (91.9%). Quality of life outcomes were also similar between treatment groups. There were 5 adverse events in the VenaSeal arm, 3 of which were classified as 'definitely' or 'potentially' related to the procedure, whereas neither of the 2 adverse events in the RFA arm were related to the procedure. Unfortunately, 33% of the VenaSeal arm was lost to follow-up by the 36-month evaluation. The small sample in

conjunction with the high volume of loss to follow-up, preclude definitive conclusions based on the available data (Morrison, 2019).

In 2020, Morrison and colleagues published results from a 5-year extension study of VeClose trial. The primary outcome was complete closure of the target vein. A total of 89 of the original 222 subjects completed the 60-month visit, which included 47 from the VenaSeal group, 33 from the RFA group, and 9 additional nonrandomized VenaSeal recipients. Between 36 and 60 months of follow-up, no new recanalization events occurred in either group. At study-end, freedom from recanalization in the randomized VenaSeal and RFA groups were 91.4% and 85.2%, respectively and both groups demonstrated sustained improvements in quality of life scores. Furthermore, 41.1% of the VenaSeal group and 39.4% of the RFA group were at least two CEAP clinical classes lower than at baseline. No long-term device- or procedure-related serious adverse events occurred in either group between the 36- and 60-month follow-ups. With just 40% of the original study participants remaining, and relatively small numbers within each group for analysis, the outcomes of this trial are promising but limited.

In 2020, Kolluri and colleagues conducted a network meta-analysis of RCTs comparing 6-month outcomes reported in 20 heterogeneous RCTs evaluating cyanoacrylate adhesion, EVLA, RFA, mechanochemical ablation, sclerotherapy and surgery for the management of chronic venous insufficiency. Only 3 of these 20 RCTS (Morrison, 2015, Morrison, 2017, Gibson, 2018, described above) looked at cyanoacrylate adhesion and then only in comparison to RFA. This analysis does not provide direct evidence of the effect of cyanoacrylate adhesion compared to the other included treatments.

Conservative Treatment

Compression therapy is the basic and most frequently used treatment of varicose veins of the lower extremities. However, there has been uncertainty regarding the need for conservative treatment before any intervention for simple varicose veins. While conservative treatments, including compression therapy, will not provide full relief for all individuals, some will receive adequate control of symptoms and thereby avoid the risks of a destructive, irreversible procedure. Michaels and colleagues (2006) reported results of a randomized trial performed at two large UK hospitals that compared surgery with conservative treatment for uncomplicated varicose veins (n=246). Conservative treatment consisted of lifestyle changes (that is, exercise, management of weight and diet, leg elevation), and the use of compression hosiery. In the surgical arm of the study, subjects received the same lifestyle advice but also underwent surgical treatment. The primary outcome of the study was clinical effectiveness at 1 year, as measured by a quality of life questionnaire. There were significant losses to follow-up due to individuals failing to attend or withdrawing from the trial (21 of 122 following conservative treatment and 43 of 124 after surgery). The authors reported a quality of life benefit from surgery at 2 years post treatment and benefits were also reported in symptomatic and anatomical measures. Available data indicated that 3 of 65 subjects (5%) in the surgical group and 53 of 107 (50%) subjects in the conservative treatment group self-reported dissatisfaction of their initial treatment. Limitations of this study included a high dropout rate due to many subjects opting to undergo surgical treatment to cosmetically improve their varicose veins, difficulties in follow-up and the potential difficulty of self-assessing one's own leg symptoms.

Amsler and colleagues (2008) conducted a meta-analysis of randomized controlled trials (RCT) that compared medical compression stockings exerting an ankle pressure of 10-20 mmHg with placebo or no treatment and with stockings exerting a pressure of more than 20 mmHg. All RCT's were independently reviewed and 11 fulfilled the

predefined criteria. Data were collected from 790 healthy subjects exposed to various forms of stress, 552 subjects with a chronic venous disorder or chronic venous insufficiency and 141 subjects after varicose vein surgery. Overall, compression with 10-20 mmHg had a clear effect on edema and symptoms as compared with <10 mmHg pressure, placebo stockings, or no treatment ($p<0.0001$). No study showed a difference between 10-20 and >20 mmHg stockings. There were several limitations of the studies used in the meta-analysis including "often poor" reporting standards of trials and also "much heterogeneity was observed in the assessment techniques."

The Clinical Practice Guidelines for the Society for Vascular Surgery and the American Venous Forum (Gloviczki, 2011) includes the following recommendations for compression therapy:

- We suggest compression therapy using moderate pressure (20-30 mm Hg) for patients with symptomatic varicose veins (GRADE 2C*).
- We recommend against compression therapy as the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation (GRADE 1B*).
- We recommend compression as the primary therapeutic modality for healing venous ulcers (GRADE 1B).
- We recommend compression as an adjuvant treatment to superficial vein ablation for the prevention of ulcer recurrence (GRADE 1A*).

*See first paragraph of "other considerations" section for GRADE and level of evidence explanations.

Chwala and colleagues (2015) reported that therapeutic management of chronic venous disease can be based on conservative (medical) or invasive methods. Conservative methods noted by the authors involved the use of the following:

- Lifestyle changes (weight loss, exercise, periodic limb elevation, rehabilitation of the ankle joint, avoidance of a standing position and a sitting position with lowered limbs).
- Compression therapy – using compression bandaging or graduated compression products, when properly selected, effectively reduces edema and pain. However, their tolerance may be problematic, especially in the summer.
- Pharmacotherapy – phlebotropic drugs, acting primarily by modifying the venous tone, reduce the severity of inflammation and vascular permeability of capillary vessels, which in turn leads to a decrease in pain, symptoms and edema.

In 2021, Shingler and colleagues conducted a Cochrane review of RCTs to assess the effectiveness of compression stockings for the sole, initial treatment of varicose veins in people without healed or active venous ulcers. A total of 13 studies were chosen for inclusion which included 1021 participants. Authors conclude that there was "insufficient high-certainty evidence to determine whether or not compression stockings are effective as the sole and initial treatment of varicose veins in people without healed or active venous ulceration, or whether any type of stocking is superior to any other type."

Duplicate GSV

True duplicate GSV systems have been reported; however, this is an uncommon occurrence. The duplicate GSV system will lie in the same plane, parallel to the skin, and run along the aponeurotic deep fascia. These two GSVs

will also have the same diameter draining a common cutaneous territory. An anterior accessory vein (AASV) is often mistaken for a duplication of the GSV, but the AASV is usually smaller and does not drain the same cutaneous territory as the GSV. A true duplicate GSV is not an accessory vein and should be treated as any other GSV.

Junctional Incompetence

The location of junctional incompetence will vary based on the individual's vein anatomy. The termination of the GSV is the saphenofemoral junction (SFJ). GSV disease develops when there is pathologic reflux at this junction. SSV anatomy is more variable. Approximately 2/3 of the time, the SSV terminates in the popliteal vein, and SSV disease then develops when there is pathologic reflux of the saphenopopliteal junction (SPJ). However, the SSV can terminate in the GSV or in accessory veins. Accordingly, the location of pathologic reflux may vary.

Repeat Therapy

While repeat treatment following initial varicose vein therapy is relatively common, a period to allow healing and the full benefit of initial therapy to be realized is both prudent and advisable prior to undergoing further treatment. In the vast majority of clinical trials, a period of at least 6 weeks elapsed prior to determining success or failure of interventions (Brittenden, 2014; Dijk, 1999; Morrison, 2018; Nandhra; 2015; Paravastu, 2017; Roopram, 2013). As such, 6 weeks is considered an appropriate and conservative amount of time to reevaluate the need for further treatment, at which time continued demonstration of significant disability and discomfort should be established prior to proceeding with additional interventions.

Other Considerations

In 2011, Gloviczki and colleagues released clinical practice guidelines for the Society for Vascular Surgery and the American Venous Forum. The authors summarized available venous research related to the care of individuals with varicose veins and associated chronic venous diseases. The available evidence was graded by quality and relevance of data. Recommendations were based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system as strong (GRADE 1) if the benefits clearly outweighed the risks, burden, and costs and (GRADE 2) if the benefits closely balanced with risks and burden. The level of available evidence to support the evaluation or treatment was stated to be of high (A), medium (B), or low or very low (C) quality. Key recommendations included:

- All patients with varicose veins or more severe chronic venous disease (CVD) being considered for treatment must have a duplex ultrasound scanning of the deep and superficial veins. The GSV, small saphenous vein (SSV) (also known as the lesser saphenous vein [LSV]), anterior accessory of the great saphenous vein (AAGSV) and posterior accessory of the great saphenous vein (PAGSV) incompetence must have a reflux time greater than 500 msec. "Pathologic" perforating veins includes those with outward flow of 500 ms or more, with a diameter of at least 3.5 mm, located beneath a healed or open venous ulcer (GRADE 1B).
- The clinical, etiology, anatomy, pathological (CEAP) classification is to be used for patients with CVD (GRADE 1A) and the revised Venous Clinical Severity Score is to be used to assess treatment outcome (GRADE 1B).

- Compression therapy is to be used for patients with symptomatic varicose veins (GRADE 2C) but compression therapy is not recommended as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B).
- Compression therapy is to be used as the primary treatment to aid healing of venous ulceration (GRADE 1B).
- To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended (GRADE 1A).
- For treatment of the incompetent great saphenous vein (GSV), we recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B).
- Phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C).
- Selective treatment of perforating vein incompetence in patients with simple varicose veins (CEAP class C2; GRADE 1B) is not recommended, but suggest treatment of pathologic perforating veins (outward flow duration >500 ms, vein diameter >3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6; GRADE 2B).
- Suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (GRADE 2B).

O'Donnell and colleagues (2014) published clinical practice guidelines for the management of venous leg ulcers. GRADE Recommendations were based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system as strong (GRADE 1) if the benefits clearly outweighed the risks, burden, and costs and (GRADE 2) if the benefits closely balanced with risks and burden. The level of available evidence to support the evaluation or treatment was stated to be of high (A), medium (B), or low or very low (C) quality. A summary of the operative/endovascular management guidelines includes the following:

- **Superficial Venous Reflux and Active Venous Leg Ulcer-Ulcer Healing**
  In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we suggest ablation of the incompetent veins in addition to standard compressive therapy to improve ulcer healing. [GRADE - 2; LEVEL OF EVIDENCE - C]
- **Superficial Venous Reflux and Active Venous Leg Ulcer-Prevent Recurrence**
  In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE - 1; LEVEL OF EVIDENCE - B]
- **Superficial Venous Reflux and Healed Venous Leg Ulcer**
  In a patient with a healed venous leg ulcer (C5) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE - 1; LEVEL OF EVIDENCE - C]
- **Superficial Venous Reflux With Skin Changes at Risk for Venous Leg Ulcer (C4b)**
  In a patient with skin changes at risk for venous leg ulcer (C4b) and incompetent superficial veins that have axial reflux directed to the bed of the affected skin, we suggest ablation of the incompetent superficial veins in addition to standard compressive therapy to prevent ulceration. [GRADE - 2; LEVEL OF EVIDENCE - C]

- **Combined Superficial and Perforator Venous Reflux With or Without Deep Venous Reflux and Active Venous Leg Ulcer**
  In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the ulcer bed, we suggest ablation of both the incompetent superficial veins and perforator veins in addition to standard compressive therapy to aid in ulcer healing and to prevent recurrence. [GRADE - 2; LEVEL OF EVIDENCE - C]
- **Combined Superficial and Perforator Venous Reflux With or Without Deep Venous Disease and Skin Changes at Risk for Venous Leg Ulcer (C4b) or Healed Venous Ulcer (C5)**
  In a patient with skin changes at risk for venous leg ulcer (C4b) or healed venous ulcer (C5) and incompetent superficial veins that have reflux to the ulcer bed in addition to pathologic perforating veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the healed ulcer bed, we suggest ablation of the incompetent superficial veins to prevent the development or recurrence of a venous leg ulcer. [GRADE - 2; LEVEL OF EVIDENCE - C] Treatment of the incompetent perforating veins can be performed simultaneously with correction of axial reflux or can be staged with re-evaluation of perforator veins for persistent incompetence after correction of axial reflux. [GRADE - 2; LEVEL OF EVIDENCE - C]
- **Pathologic Perforator Venous Reflux in the Absence of Superficial Venous Disease, With or Without Deep Venous Reflux, and a Healed or Active Venous Ulcer**
  In a patient with isolated pathologic perforator veins (outward flow of >500 ms duration, with a diameter of >3.5 mm) located beneath or associated with the healed (C5) or active ulcer (C6) bed regardless of the status of the deep veins, we suggest ablation of the "pathologic" perforating veins in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence. [GRADE - 2; LEVEL OF EVIDENCE - C]
- **Treatment Alternatives for Pathologic Perforator Veins**
  For those patients who would benefit from pathologic perforator vein ablation, we recommend treatment by percutaneous techniques that include ultrasound-guided sclerotherapy or endovenous thermal ablation (radiofrequency or laser) over open venous perforator surgery to eliminate the need for incisions in areas of compromised skin. [GRADE - 1; LEVEL OF EVIDENCE - C]

In 2016, the American Vein and Lymphatic Society issued practice guidelines for the treatment of superficial venous disease of the lower leg. Their document was based on recommendations in the Gloviczki paper, other current studies, and "consensus of experts where the evidence based research is sparse yet the therapy is considered standard of care." Grading recommendations used in the guidelines according to evidence: 1A-Strong recommendation, high-quality evidence; 1B-Strong recommendation, moderate quality evidence; 1C-Strong recommendation, low quality or very low-quality evidence; 2A-Weak recommendation, high-quality evidence; 2B-Weak recommendation, moderate-quality evidence; 2C-Weak recommendation, low-quality or very low-quality evidence. Recommendations/suggestions (2A or better) made by the American Vein and Lymphatic Society consist of the following:

Indications for Treatment

- Compression therapy is an effective method for the management of symptoms related to superficial disease but it does not correct the source of reflux. When patients have a correctable source of reflux definitive treatment should also be offered unless it is contraindicated or unwanted. GRADE 1A

- We recommend against compression therapy as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate. GRADE 1A
- Indications for treatment include pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning), edema, varix hemorrhage, recurrent superficial phlebitis, stasis dermatitis, or ulceration. We recommend patients should be evaluated using the CEAP classification and the Venous Clinical Severity Score (VCSS). We would define medically necessary as a CEAP classification of C2 or higher. GRADE 1A

In addition

- We recommend all patients being considered for treatment must have a duplex ultrasound of the superficial venous system and at a minimum, evaluation of the common femoral vein and popliteal vein for patency and competence. The exam should ideally be done in the standing position. Grade 1A
- We suggest all noninvasive vascular diagnostic studies be performed by a qualified physician or by a qualified technologist under the general supervision of a qualified physician. GRADE 1C
- We recommend that named veins ((Great Saphenous Vein (GSV), Small Saphenous Vein (SSV), Anterior Accessory of the Great Saphenous Vein (AAGSV), Posterior Accessory of the Great Saphenous Vein (PAGSV), Intersaphenous Vein (Vein of Giacomini)) must have a reflux time > 500 msec regardless of the reported vein diameter. GRADE 1A

Treatment of Named Saphenous Veins

- We recommend endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence. GRADE 1B
- We recommend open surgery is appropriate in veins not amenable to endovenous procedures but otherwise is not recommended because of increased pain, convalescent time, and morbidity. GRADE 1B
- We recommend when open surgery of the small saphenous vein is per formed it include high ligation and selective invagination of the proximal portion. GRADE 1B

Treatment of Circumflex Veins and Other Non Truncal Veins

- The treatment of other non-truncal, tributary varicose vein reflux (circumflex veins anterior and posterior thigh) is more complex. The medical record should reflect that these veins are incompetent, and note their size, presence or absence of tortuosity, and depth relationship to the skin, i.e. accessible or not accessible by phlebectomy. We recommend varicose (visible) symptomatic tributary veins can be treated by stab phlebectomy, liquid sclerotherapy or foam chemical ablation. GRADE 1B
- We recommend (non-visible) symptomatic tributary veins be treated by ultrasound guided liquid sclerotherapy or foam chemical ablation. GRADE 1B

Pavlovic and colleagues (2014) published guidelines developed from a 2012 European consensus conference on endovenous thermal ablation for varicose vein disease under auspices of the International Union of Phlebology (IUP). The guidelines reported absolute and relative contraindications (GRADE 1C [strong recommendation, low quality or very low quality evidence]) which included the following:

Absolute contraindications:

- Acute deep vein thrombosis (DVT),

- Acute superficial phlebitis,
- Acute infections at puncture sites (infection should be treated first),
- Deep venous obstruction if the vein to be treated is a functional collateral.

Technical issues, which may be viewed as relative contraindications:

- Tortuous vein difficult to catheterize,
- Diameter of the vein at the accessing segment <3mm (may be difficult to puncture and pass the catheter),
- Partly occluded venous segment (intraluminal webs, thrombosed or hypoplastic),
- Vein segment to be treated shorter than necessary for catheter placement.

Relative contraindications (not an all-inclusive list):
Careful risk/benefits evaluated, and any modifications clinically indicated are considered, and discussed and agreed with the patient.

- Immobile or hardly ambulating patients (a relative contraindication – if low-molecular-weight heparin [LMWH] prophylaxis is given it is a safe procedure even in this setting [the experts'opinion]),
- Pregnancy,
- Uncontrolled severe diseases.

The authors also recommended consideration of the following side effects and complications:

Side effects and minor complications

- Pain
- Bruising (ecchymosis)
- Erythema
- Hematoma
- Hyperpigmentation
- Paresthesias (hypo, hyper)
- Tender (phlebitis) or non-tender palpable treated vessel (most commonly thigh GSV)
- Infection
- Telangiectatic matting

Major complications

- DVT and/or pulmonary embolism
- Arterial damage including arteriovenous fistulas (very rarely reported)
- Severe nerve damage (very rarely reported)
- Skin burns (seen almost exclusively in patients treated without tumescence)
- Infection
- Fiber breakage during EVLA
- Stroke (a single case reported after EVLA)

In 2020, the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology published a joint appropriate use criteria for chronic lower

extremity venous disease based on panel consensus, not a systematic review of the evidence. The criteria are intended "to serve as a guide to patient care, particularly in areas where high quality evidence is lacking to aid clinicians in making day-to-day decisions for common venous interventions." In it, are appropriateness criteria for saphenous vein ablation, management decisions for diseased tributaries associated with saphenous ablation, and for the treatment of perforator veins (Masuda, 2020).

Conclusion

In summary, data suggests that therapeutic management of varicose veins with a variety of treatment modalities is associated with symptomatic improvement under specific circumstances. Treatment of varicose veins normalize venous hemodynamics and remove visible varices in order to relieve symptoms, prevent recurrence and minimize the complications (Pavlović, 2015). However, consideration of the potential procedural risks, contraindications and technical issues, should be taken prior to treatment initiation.

Background/Overview

Veins carry deoxygenated and nutrient depleted blood back to the heart and lungs. The veins located in the legs must work against gravity to move the blood upward toward the heart and lungs. The vascular system in the legs consists of the superficial and deep veins. The superficial veins lie on top of the muscles of the leg and include the GSV and the SSV and their associated tributaries. The deep veins lie deep within the muscle compartments and generally parallel their associated arteries. The deep veins include the tibial, popliteal and femoral veins. The superficial and deep veins run vertically within the leg and are connected by perforator veins in a ladder-like pattern. One-way valves are present in all the leg veins. These valves act against gravity to prevent the blood from flowing backwards (refluxing) to the legs instead of flowing towards the heart and lungs. Reflux of blood back into the vein causes dilation of the vessel, restriction of adequate blood flow to portions of the leg, and in some cases, discomfort or pain. Varicose veins are found most often on the back of the calf or on the inside of the leg between the groin and ankle. The most common valvular failures occur at the saphenofemoral junction (groin) between the GSV and the common femoral vein or at the saphenopopliteal junction (knee) between the SSV and the popliteal vein. Venous anatomy can vary significantly between individuals by the absence or presence of accessory and tributary veins. The following are examples and locations (GSV or SSV) of these veins:

- anterior accessory (GSV): indicates any venous segment ascending parallel to the GSV and located anteriorly, both in the leg and in the thigh;
- posterior accessory (GSV): indicates any venous segment ascending parallel to the GSV and located posteriorly, both in the leg and in the thigh;
- superficial accessory (GSV): indicates any venous segment ascending parallel to the GSV and located more superficially above the saphenous fascia, both in the leg and in the thigh;
- cranial extension (SSV): courses between the biceps femoris and semimembranosus muscles. A cranial extension of the SSV that communicates with the GSV via the posterior thigh circumflex vein is often termed the intersaphenous vein or vein of Giacomini;
- superficial accessory (SSV): ascends parallel to the SSV and is located more superficially, above the saphenous fascia;
- anterior thigh circumflex vein: is a tributary vein of the GSV (or of the anterior accessory GSV) ascending obliquely in the anterior thigh;

- posterior thigh circumflex vein: is a tributary vein of the GSV (or of the posterior accessory GSV), which ascends obliquely in the posterior thigh.

An imaging technique called ultrasound or duplex scanning can be used to identify whether venous reflux is in the superficial, deep or perforating veins. It also can help determine whether reflux is confined to veins above or below the knee. This information is important in diagnosing the cause of this condition and in the planning of treatment.

The venous severity score is used for the assessment of clinical outcomes after therapy for varicose veins and more advanced chronic venous disease. Nine clinical characteristics of chronic venous disease are graded from 0 to 3 (absent, mild, moderate, severe) with specific criteria to avoid overlap or arbitrary scoring.

Some form of venous disorder affects approximately 80 million Americans and varicose veins are present in about 30% of women and 10% to 20% of men. Often, varicose veins present as a cosmetic concern but they may cause symptoms such as cramping, throbbing, burning, swelling, feeling of heaviness or fatigue, and may interfere with activities of daily living. There is frequent confusion between varicose veins and "spider veins," which are small blue or red veins at the surface of the skin. Spider veins, also known as telangiectatic dermal veins, spider nevi, or broken blood vessels, while potentially unattractive, are not associated with any physical symptoms and are a benign condition.

Treatment for symptomatic varicose veins includes conservative measures such as frequent elevation of affected leg(s), walking, weight reduction and avoidance of prolonged sitting, analgesics and the use of compression stockings. The key to treatment of varicose veins is prevention of reflux in the short and long saphenous veins that connect to the major veins in the hip and pelvic area (femoral veins), a condition referred to as saphenofemoral reflux. When this non-invasive approach fails to relieve symptoms, several invasive options exist, as described below.

Standard procedures (*not within the scope of this document*)

Surgical Ligation and Stripping

The traditional therapy for venous reflux in the saphenous vein is surgical ligation and stripping. This begins with an incision in the groin region to expose the saphenous vein. The surgeon then ligates (ties off) the saphenous vein and small veins in the area. A second incision is made either just below the knee or at the ankle for the same purpose. Once both ends of the vein are free, a wire-like instrument is threaded through the vein, from the groin to the second incision, and secured to the vein. The vein is then pulled out (or "stripped") and removed from the leg.

Microphlebectomy

Also known as ambulatory phlebectomy or stab avulsion, microphlebectomy is a technique to remove varicose veins. In this procedure, several tiny incisions are made in the skin through which the varicose vein is removed. This technique is best suited for tortuous varicosities where passage of a probe or catheter cannot be accomplished.

Hook Phlebectomy

Hook phlebectomy, also known as avulsion phlebectomy or small incision avulsion, is a surgical procedure performed alone or together with vein stripping. During avulsion phlebectomy, the surgeon makes a series of tiny

incisions in the leg to remove varicose veins with a hook. Historically, hook phlebectomy has been performed as a blind procedure involving multiple incisions.

Subfascial Endoscopic Perforating Vein Surgery (SEPS):

SEPS is a minimally invasive surgical technique used to treat chronic venous ulcers caused by incompetent perforating veins due to chronic venous insufficiency. Prior to SEPS, the perforator veins were treated via an open surgical technique however, the open surgical approach had significant complication rates, including poor healing of incisions in ulcerated skin. Once the affected perforators are identified by imaging, the target veins are accessed percutaneously by instruments used to separate the connective tissue (fascia) from the incompetent perforator, and ligation is then accomplished by clip or cautery. Due to high quality published evidence supporting the safety and efficacy of even less invasive and more efficacious techniques, SEPS is no longer a choice treatment for varicosities.

Trans-Illuminated Powered Phlebectomy (TIPP):

The TIPP technique uses the TRIVEX™ System. Through a small incision, a fiber optic illuminator is positioned nearby the varicose vein. A resector with a rotating blade is then guided through the skin next to the vein. Suction draws the vein into the tip of the vein resector, and the vein fragments are removed by suction. TIPP is no longer a choice treatment, due to high quality published evidence supporting the safety and efficacy of even less invasive and more effective techniques.

Alternative procedures

Endoluminal Radiofrequency Ablation (VNUS Closure, now known as the Venefit Procedure) System:

Also known as radiofrequency endovenous occlusion, endoluminal RF ablation is typically performed by using a thin catheter inserted into the saphenous vein through a small opening in the skin. Radiofrequency energy is then delivered through the end of the catheter to heat the saphenous vein wall, causing it to collapse, scar and close. However, there is a lack of clinical evidence to sufficiently demonstrate the clinical efficacy for vessels other than the saphenous vein.

Endovenous Laser Treatment (EVLT):

Endovenous laser ablation of the saphenous vein utilizes a small laser fiber that is inserted through a small incision in the skin into the vein. Pulses of laser light are emitted inside the vein, heating the vein wall causing it to collapse, scar and seal shut. A bandage or compression hose is placed on the treated leg following the treatment.

Sclerotherapy:

Sclerotherapy uses injectable sclerosing solutions, both liquid and foam, to treat abnormally dilated or cosmetically unacceptable veins (Weiss, 2015). Sclerotherapy of varicose tributaries may be used adjunctively with stripping and ligation, RF ablation or endovenous laser ablation of the GSV. During this procedure, a chemical known as a sclerosing agent, typically a 0.5%-3% solution of sodium tetradecyl sulfate (STS) is injected into the vein to collapse its walls and eliminate blood flow. Following the procedure, pressure is applied to the vein through padding and compression stockings that are typically worn for 7 to 10 days. This continuous pressure allows a scar

to form between the two walls of the vein preventing the further development of varicosities. Individual response to each injection can vary and it may require more than one injection to obliterate a vessel.

Echosclerotherapy is a term used to describe ultrasound-guided sclerotherapy where the veins are injected under direct ultrasound visualization.

Comprehensive Objective Mapping, Precise Image-guided Injection, Antireflux Positioning and Sequential Sclerotherapy (COMPASS) is a variation of ultrasound-guided sclerotherapy, and has been proposed as a treatment for varicose veins. This therapy uses ultrasound-guided sclerotherapy, followed by multiple diagnostic ultrasound imaging procedures, and sclerotherapy treatments for the treatment of subsequent varicose veins. This therapy may involve several weeks or months of treatment.

Mechanochemical Ablation:

Endovenous mechanochemical ablation utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced until it reaches the saphenofemoral junction. As the catheter is pulled back, a wire rotates within the lumen of the vein. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is hypothesized that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in RF ablation or EVLT.

Coil Embolization

Coil embolization involves catheter placement into a calf or leg vein, followed by insertion of a small coil into the catheter that is guided into the vein. An injection of alcohol or a foamed sclerosant drug is typically used during the procedure resulting in vein occlusion.

Cyanoacrylate Adhesion

Cyanoacrylate adhesion, known in the US as the VenaSeal Closure system, is a medical grade adhesive, which is applied along the target vein via a catheter, usually inserted just below the knee. Approximately 0.1 cc of adhesive is applied approximately every 3cm along the vein, this effectively seals it off to reroute circulate to veins that are not tortuous. The procedure takes less than half an hour on average and is considered a minimally invasive office procedure.

Note: The term "varicose veins" does not apply to telangiectatic (spider) veins or reticular veins. Similar to varicose veins, these veins are created when the valves that control the blood flow in the veins weaken. This causes the formerly small veins located just below the skin to become engorged with blood. As a result, these veins widen, becoming visible beneath the skin, but are generally not associated with pain, bleeding, ulceration, or other medical problems, and therefore their treatment is considered purely cosmetic.

Definitions

Anterior accessory saphenous vein (AASV): A major truncal superficial vein lateral to the great saphenous vein that is above the saphenous fascia.

Anti-embolism hose (also called elastic stockings or compression stockings)**:** A type of stocking worn to prevent the formation of blood clots in the legs (thromboses); assisting in the return flow of the blood to the heart, and prevention of pooling in the veins; there are three support grades of prescription hose; mild to severe support (15-20, 20-30, 30-40 mmHg) which are generally used to assist with a medical condition and light support (8-15 mmHg) that may be used as a preventive measure.

Arteriovenous fistulae: A condition where a vein and artery are directly connected without the usual intervening small vessels.

Catheter ablation: A technique involving the application of either radiofrequency or laser energy through an endovenous catheter for the purpose of ablating varicose vein tissue of the GSV or SSV; this does not include the "closure" or ablation of a vein using the injection of a sclerosing agent through a hollow catheter.

CEAP (clinical, etiology, anatomy, pathological) classification: A descriptive classification for chronic venous disorders. Used for the classification of varicose veins.

CEAP Description	
1. Clinical classification	
C0	No visible or palpable signs of venous disease
C1	Telangiectases or reticular veins
C2	Varicose veins
C3	Edema
C4	Changes in skin and subcutaneous tissue secondary to CVD
$C4_a$	Pigmentation or eczema
C_b	Lipodermatosclerosis and/or atrophie blanche
$C4_c$	Corona phlebectatica
C5	Healed venous ulcer
C6	Active venous ulcer
$C6_r$	Recurrent active venous ulcer
C_S	Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
C_A	Asymptomatic
2. Etiologic classification	
Ec	Congenital
Ep	Primary
Es	Secondary \
Es	Secondary - intravenous
Es	Secondary – extravenous
En	No venous etiology identified
3. Anatomic classification	
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins

An No venous location identified

4. Pathophysiologic classification

Pr Reflux
Po Obstruction
Pr,o Reflux and obstruction
Pn No venous pathophysiology identifiable

Adapted from Lurie, 2020.

Coaptation: Joining or fitting together, as of the ends of a broken bone or the edges of a wound.

Junctional reflux: Reflux at either the saphenofemoral junction (SFJ [confluence of the Great Saphenous Vein and the femoral vein] or the saphenopopliteal junction (SPJ [confluence of the Small Saphenous Vein and the popliteal vein]).Perforator veins: Connect the superficial veins to the deep veins.

PhotoDerm: A pulsed laser light treatment to aesthetically treat a specific area of leg telangiectasis.

Reticular vein: Dilated bluish subdermal vein, generally 1 mm to less than 3 mm in diameter and usually tortuous. Synonyms include blue veins, subdermal varices and telangiectasia.

Saphenofemoral reflux: A backflow of blood in the veins causing varicose vein symptoms and bulging.

Saphenous vein: A vein that serves as the principal blood vessel returning blood from the surface of the leg back to the trunk.

Sclerotherapy: A treatment for varicose veins in which a chemical is injected into the vein causing the vein to shrink and close.

Stasis dermatitis: A condition caused by too little circulation in the legs; it begins with swelling of the ankles and progresses to tan-colored skin, patchy reddening, tiny, round, purplish-red spots, and hardening of the skin.

Subfascial: Below the fascia; fascia is a strong connective tissue that performs a number of functions, including surrounding and providing structural support within the body.

Telangiectasia: Dilated superficial blood vessels, especially of the upper reticular dermal plexus.

Thrombophlebitis: Inflammation of a vein, along with the formation of a clot; this occurs most commonly as the result of injury to the vessel wall, abnormal increased clotting capacity of the blood (hypercoagulability), infection, or a chemical irritation.

Tributary vein: A superficial vein branch that flows into larger veins.

Truncal veins: Major veins within the superficial venous system which include the great saphenous vein (GSV), small saphenous vein, anterior accessory saphenous vein (AASV) and the Giacomini vein.

Truncal vein incompetence: Reflux with retrograde flow of 0.5 second duration or greater in the GSV, AAGSV, or SSV.

Varicose vein or varicosity: Veins that are abnormally swollen or enlarged due to weakening in the vein's wall. Measured in an upright position they are 3 mm in diameter or greater.

Venous insufficiency: An abnormal circulatory condition marked by decreased return of venous blood from the legs to the trunk of the body.

Venous reflux: Malfunctioning venous valves lead to reversal of blood flow through the valves during standing or sitting.

Venous severity score: A score used for the assessment of clinical outcomes after therapy for varicose veins and more advanced chronic venous disease.

Coding

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

When services may be Medically Necessary when criteria are met:

CPT	
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
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
37799	Unlisted procedure, vascular surgery [when specified as echosclerotherapy or ultrasound-guided sclerotherapy of other than truncal veins]

HCPCS

S2202	Echosclerotherapy

ICD-10 Procedure

065P3ZZ-065Q4ZZ	Destruction of saphenous vein [right or left, by percutaneous or percutaneous endoscopic approach; includes codes 065P3ZZ, 065P4ZZ, 065Q3ZZ, 065Q4ZZ]
06LP0ZZ-06LQ4ZZ	Occlusion of saphenous vein [right or left, by approach; includes codes 06LP0ZZ, 06LP3ZZ, 06LP4ZZ, 06LQ0ZZ, 06LQ3ZZ, 06LQ4ZZ]
3E030TZ	Introduction of destructive agent into peripheral vein, open approach
3E033TZ	Introduction of destructive agent into peripheral vein, percutaneous approach

ICD-10 Diagnosis

I78.0	Hereditary hemorrhagic telangiectasia
I80.00-I80.9	Phlebitis and thrombophlebitis
I82.501-I82.599	Chronic embolism and thrombosis of deep veins of lower extremity
I82.5Y1-I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity
I82.5Z1-I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity
I82.811-I82.819	Embolism and thrombosis of superficial veins of lower extremities
I83.001-I83.899	Varicose veins of lower extremities [with complications]
I87.011-I87.099	Postthrombotic syndrome [with complications]
I87.2	Venous insufficiency (chronic) (peripheral)
I87.8	Other specified disorders of veins (phlebosclerosis)
I96	Gangrene, not elsewhere classified
L97.101-L97.929	Non-pressure chronic ulcer of lower limb, not elsewhere classified
M79.604-M79.606	Pain in leg
M79.661-M79.669	Pain in lower leg
Q27.32	Arteriovenous malformation of vessel of lower limb
Q27.8	Other specified congenital malformations of peripheral vascular system
R22.40-R22.43	Localized swelling, mass and lump, lower limb
R60.0	Localized edema
Z86.718	Personal history of other venous thrombosis and embolism
Z86.72	Personal history of thrombophlebitis

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met (including for asymptomatic varicose veins diagnosis codes listed below), for all other diagnoses except as listed below as cosmetic and not medically necessary, or for the situations indicated in the Position Statement section as not medically necessary.

ICD-10 Diagnosis

I83.90-I83.93	Asymptomatic varicose veins of lower extremities

When services are Cosmetic and Not Medically Necessary:
For the procedure codes listed above, for the following diagnosis, or when the code describes a procedure indicated in the Position Statement section as cosmetic and not medically necessary.

ICD-10 Diagnosis

I78.1	Nevus non-neoplastic (spider veins)

When services are also Not Medically Necessary:

CPT

36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) [when specified as coil embolization for varicose vein diagnoses]
37799	Unlisted procedure, vascular surgery [when specified as COMPASS protocol, endoluminal cryoablation, or coil embolization of varicose veins]
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 [KAVS procedure]

ICD-10 Procedure

06LP0DZ	Occlusion of right saphenous vein with intraluminal device, open approach [when specified as coil embolization for varicose vein diagnoses]
06LP3DZ	Occlusion of right saphenous vein with intraluminal device, percutaneous approach [when specified as coil embolization for varicose vein diagnoses]
06LP4DZ	Occlusion of right saphenous vein with intraluminal device, percutaneous endoscopic approach [when specified as coil embolization for varicose vein diagnoses]
06LQ0DZ	Occlusion of left saphenous vein with intraluminal device, open approach [when specified as coil embolization for varicose vein diagnoses]
06LQ3DZ	Occlusion of left saphenous vein with intraluminal device, percutaneous approach [when specified as coil embolization for varicose vein diagnoses]
06LQ4DZ	Occlusion of left saphenous vein with intraluminal device, percutaneous endoscopic approach [when specified as coil embolization for varicose vein diagnoses]

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:

CPT

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

ICD-10 Diagnosis

All diagnoses

When services are Cosmetic and Not Medically Necessary:

CPT

36468	Injections of sclerosant for spider veins (telangiectasia); limb or trunk
96999	Unlisted special dermatological service or procedure [when specified as tunable dye or pulsed dye laser treatment for varicose veins]

ICD-10 Diagnosis

All diagnoses

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	07/11/2022	Corrected the Coding section formatting to indicate the appropriate NMN headings based on the Position Statement.
Revised	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised INV/NMN indications to NMN indications for endoluminal ablation, endoluminal cryoablation, mechanochemical ablation, sclerotherapy and coil embolization. Updated Rationale, Coding and References sections.
Revised	11/11/2021	MPTAC review. Revised MN criteria to state 'truncal' vein incompetence instead of 'junctional' incompetence. Updated Rationale, Background/Overview, Definitions and References sections.

	12/29/2020	Updated Rationale and References sections.
Reviewed	11/05/2020	MPTAC review. Updated punctuation in the MN criteria. Updated Description/Scope, Rationale, Background/Overview, Definitions and References sections.
Revised	11/07/2019	MPTAC review. Added AAGSV and clarifications to the MN criteria for ablation and limits to retreatment to the MN criteria for all procedures. Updated Scope, Rationale, Background/Overview and References sections.
Reviewed	08/22/2019	MPTAC review. Updated Scope, Rationale and References sections.
Revised	01/24/2019	MPTAC review. Added 'conservative therapy' to the MN criteria in place of 'non-surgical management'. Added balloon sclerotherapy to the INV/NMN criteria. Updated Scope, Rationale and References sections. Updated Coding section; added code 0524T.
Revised	03/22/2018	MPTAC review. Reformatted Clinical Indications section and added NMN statement for cyanoacrylate adhesion. Updated Scope, Rationale, Background/Overview, and References sections. Coding section updated; added 36482, 36483, 06LP0DZ, 06LP3DZ, 06LP4DZ, 06LQ0DZ, 06LQ3DZ, 06LQ4DZ.
	12/27/2017	The document header wording updated from "Current Effective Date" to "Publish Date." Updated Coding section with 01/01/2018 CPT changes; added codes 36465 and 36466 and descriptor changes for codes 36468, 36470, 36471.
	10/01/2017	Updated Coding section with ICD-10-PCS procedure code changes; removed 065R3ZZ, 065R4ZZ, 065S3ZZ, 065S4ZZ, 06LR0ZZ, 06LR3ZZ, 06LR4ZZ, 06LS0ZZ, 06LS3ZZ, 06LS4ZZ deleted 09/30/17. Clarified CPT unlisted code 37799 when used for foam sclerotherapy.
Revised	05/04/2017	MPTAC review. Formatting updated in position statement section. Updated medically necessary statement for sclerotherapy or echosclerotherapy to clarify that "greater than 3.0 mm in diameter" refers to all of the veins being treated. Replaced the term "Giacomini vein" with "intersaphenous vein" in the medically necessary and investigational and not medically necessary statements. Updated Rationale and References sections.
	01/01/2017	Updated Coding section with 01/01/2017 CPT changes.
Revised	05/05/2016	MPTAC review. Investigational and Not medically necessary statement added for coil embolization of lower extremity veins. Description, Rationale, Background, Reference and Index sections updated. Updated Coding section, including removal of ICD-9 codes.
Revised	08/06/2015	MPTAC review. Clarified the term "junctional incompetence" in the medically necessary statement from" reflux with retrograde flow of 0.5 second duration" to "0.5 second duration or greater." Rationale, Background and Reference sections updated.
Revised	05/07/2015	MPTAC review. Replaced the terms greater saphenous vein (GSV) and lesser saphenous vein (LSV) with great saphenous vein (GSV) and small saphenous vein (SSV). Revised language addressing symptoms of venous insufficiency or recurrent thrombophlebitis to include "causing discomfort to the degree that

		employment or activities of daily living are compromised." Removed requirement for medication from medically necessary criteria. Updated Description, Rationale and Reference sections.
Revised	11/13/2014	MPTAC review. Updated Description, Rationale and Reference sections.
Revised	11/14/2013	MPTAC review. Clarified medically necessary statement for junctional (saphenofemoral or saphenopopliteal as appropriate based on vein anatomy) incompetence. Rationale, Background and Reference sections updated.
Revised	08/08/2013	MPTAC review. Mechanochemical ablation of any vein added as an investigational and not medically necessary statement. Rationale, Coding, Reference and Index sections updated.
Revised	02/14/2013	MPTAC review. Position statement reformatted. Description, Rationale, Reference, and Index sections updated.
Revised	05/10/2012	MPTAC review. Medically Necessary criteria reorganized. Rationale and References updated.
Revised	05/19/2011	MPTAC review. Addition of reticular vein to position statement. Description, Rationale and References updated.
Revised	05/13/2010	MPTAC review. Medically necessary and investigational and not medically necessary criteria revised to address saphenofemoral and saphenopopliteal junction incompetence and endoluminal cryoablation. Rationale, Background, Coding and References updated.
	10/01/2009	Updated Coding section with 10/01/2009 ICD-9 changes; removed ICD-9 diagnosis code 453.8 (no longer applicable).
Revised	05/21/2009	MPTAC review. Vein anatomy clarified in position statement. Background updated to address standard therapies. References updated.
Revised	11/20/2008	MPTAC review. Criteria updated to address saphenous vein tributaries and extensions. Rationale, Background, Coding and References updated.
Revised	11/29/2007	MPTAC review. Criteria for perforator ligation clarified. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary" and the phrase "cosmetic/not medically necessary" was clarified to read "cosmetic and not medically necessary." References updated.
Revised	12/07/2006	MPTAC review. Minimal pressure criteria (30mmHg) for compression stockings deleted. Coding updated; removed HCPCS S2130, S2131 deleted 12/31/2004.
Revised	03/23/2006	MPTAC review.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**

Anthem, Inc.	10/28/2004	SURG.00037	Treatment of Varicose Veins (lower extremities)
WellPoint Health Networks, Inc.	03/11/2004	3.01.23	Endosaphenous Radiofrequency or Laser Ablation for Treatment of Primary Venous Insufficiency
	09/23/2004	Clinical Guideline	Sclerotherapy-Varicose Veins
	12/02/2004	Clinical Guideline	Treatment of Refluxing Saphenous Vein in Patients with Varicose Veins