This document addresses various modalities (listed below) for the treatment of valvular incompetence (reflux) of the great saphenous vein (GSV) 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.

- Endoluminal radiofrequency ablation (also known as VNUS Closure™ System or Venefit™ Procedure);
- Endoluminal laser ablation (also known as EVLT™ or ELAS);
- Endovenous thermal ablation (EVTA) which includes radiofrequency and laser ablation;
- Endoluminal cryoablation;
- Sclerotherapy;
- Echosclerotherapy (also known as ultrasound-guided sclerotherapy or ultrasound guided foam sclerotherapy [UGFS]);
- Mechnochemical ablation (for example: ClariVein®).

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.

Medically Necessary:

Endoluminal radiofrequency ablation or endoluminal laser ablation, of the great saphenous vein (GSV) or small saphenous veins (SSV) is medically necessary when the following criteria are met:

1. Junctional (saphenofemoral for GSV; saphenopopliteal for SSV) incompetence (that is, reflux with retrograde flow of 0.5 second duration or greater) based on vein anatomy is demonstrated by Doppler or duplex ultrasound scanning; and
2. 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:
      - are causing discomfort to the degree that employment or activities of daily living are compromised; and
      - persist despite appropriate non-surgical management, for no less than 6 weeks, such as leg elevation and exercise; and
      - persist despite a trial of properly fitted gradient compression stockings for at least 6 weeks; or
   b. There is ulceration secondary to stasis dermatitis; or
   c. There is hemorrhage from a superficial varicosity.

Sclerotherapy or echosclerotherapy, including ultrasound guided foam sclerotherapy (UGFS), of varicose tributary or extension (for example, anterolateral thigh vein, anterior accessory saphenous vein, or Giacomini vein[s]) or perforator veins greater than 3.0 mm in diameter with demonstrated reflux is medically necessary when the following criteria are met:

A. When performed at the same time as an endoluminal radiofrequency ablation procedure or endoluminal laser ablation procedure which meets the criteria above; or
B. 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 great or small saphenous veins was previously performed; and
   2. 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:
         - are causing discomfort to the degree that employment or activities of daily living are compromised; and
         - persist despite appropriate non-surgical management for 6 weeks, excluding similar management prior to the required treatment of the great or small saphenous vein; and
         - 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:

Endoluminal radiofrequency ablation, endoluminal laser ablation, sclerotherapy and echosclerotherapy (including UGFS) are each considered not medically necessary when the above criteria are not met.

Investigational and Not Medically Necessary:

Endoluminal radiofrequency ablation and endoluminal laser ablation, are each considered investigational and not medically necessary for all other uses in the lower extremities including, but not limited to:

a. As an alternative to perforator vein ligation; or
b. As treatment of saphenous vein tributaries or extensions (for example, anterolateral thigh, anterior accessory saphenous and Giacomini veins); or
c. As an alternative to adjunctive sclerotherapy or echosclerotherapy of symptomatic varicose tributaries.

Endoluminal cryoablation is considered investigational and not medically necessary.

Mechanochemical ablation of any vein is considered investigational and not medically necessary.

Sclerotherapy or echosclerotherapy (including UGFS) is considered investigational and not medically necessary:

a. 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); or
b. As the sole treatment of symptomatic varicose tributary or perforator veins in the absence of saphenous vein reflux or major saphenous vein tributary reflux; or
a. 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; or
b. 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.

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.

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.

**Endovenous radiofrequency (RF) ablation (thermal heating)**

The VNUS Closure System (VNUS Medical Technologies, Inc., San Jose, CA) received U.S. Food and Drug Administration (FDA) 510k 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 limbs 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 limbs 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 192.4 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 that "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 510k 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. With respect to long-term outcomes and head-to-head comparison with other therapies, including ligation and stripping or RF ablation, the data is not adequate to make sufficient comparisons. The use of this procedure outside the criteria specified in the position statement has not been adequately evaluated to allow conclusions regarding efficacy (Darwood, 2008; Min, 2003; Rasmussen, 2007).

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. They also stated that larger controlled studies are necessary to validate the clinical efficacy of RF and laser procedures.

RF or laser ablation for veins other than the saphenous veins (for example, anterolateral thigh, anterior accessory saphenous and Giacomini veins) has been proposed. Peden and colleagues (2007) and Eliash 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 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 2 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.

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 (e.g., 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. In summary, they concluded that this procedure requires randomized controlled studies (RCTs) and long-term follow-up to properly assess health outcomes.

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 Aberdeen Varicose Vein Questionnaire (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 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 (MOCATM) 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. Large controlled studies with longer follow-up are needed.

A prospective observational multi-center report (Bishawi, 2013) evaluated the efficacy of mechanochemical ablation of the GSV in 126 symptomatic individuals from community vein centers. 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. Large controlled studies with longer follow-up are needed.

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, endoluminal radiofrequency ablation, or endoluminal laser ablation 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 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 RF ablation, or endoluminal laser ablation), 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 (QOL) 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 reflexing 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.

In 2013, Varithena™ microfoam was FDA approved under a new drug application for the treatment of varicose veins. 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.

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 well-designed 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 2 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 (i.e., 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 of time. Some reports indicate that individuals have received therapy in excess of 1 year. This is in contrast to alternative treatment methods, including standard surgical techniques, laser ablation or radiofrequency ablation procedures, that are completed within 7 to 10 days.

**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, 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 re-fluxing 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 conducted by Biemans (2013), UGFS was not as effective as EVLA in the short term, but comparable to high ligation and stripping.

A randomized controlled trial with a 5-year follow-up comparing endovenous laser ablation (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 Aberdeen Varicose Vein Symptoms Severity 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 that "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.

An updated 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."

**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. 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 QOL 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 QOL 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:
Historical recommendations included: evidence to support the evaluation or treatment was stated to be of high (A), medium (B), or low or very low (C) quality. Key *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) outweighed the risks, burden, and costs and (GRADE 2) if the benefits closely balanced with risks and burden. The level of available Recommendations Assessment, Development, and Evaluation (GRADE) system as strong (GRADE 1) if the benefits clearly be treated as any other GSV.

Duplicate great saphenous vein (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.

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).
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 2014, The American College of Phlebology 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 College of Phlebology 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. 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 performed 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's 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)

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 (International Angiology, 2015). However, there are potential procedural risks, contraindications and technical issues to be taken into consideration prior to treatment initiation.

<table>
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<th>Background/Overview</th>
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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 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**

**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.

**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.

**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.

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.

<table>
<thead>
<tr>
<th>Definitions</th>
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<tbody>
<tr>
<td>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.</td>
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<tr>
<td>Arteriovenous fistulae: A condition where a vein and artery are directly connected without the usual intervening small vessels.</td>
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<td>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 &quot;closure&quot; or ablation of a vein using the injection of a sclerosing agent through a hollow catheter.</td>
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<tr>
<td>CEAP (clinical, etiology, anatomy, pathological) classification: A descriptive classification for chronic venous disorders. Used for the classification of varicose veins.</td>
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**CEAP Description**

1. **Clinical classification**
   - C0 No visible or palpable signs of venous disease
   - C1 Telangiectases or reticular veins
   - C2 Varicose veins
   - C3 Edema
   - C4a Pigmentation and/or eczema
   - C4b Lipodermatosclerosis and/or atrophie blanche
   - C5 Healed venous ulcer
   - C6 Active venous ulcer
   - CS Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
   - CA Asymptomatic

2. **Etiologic classification**
   - Ec Congenital
   - Ep Primary
   - Es Secondary (postthrombotic)
   - 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 Eklöf, 2004.

Perforator veins: Connect the superficial veins to the deep veins.

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

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 tanned-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.

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 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**

36470    Injection of sclerosing solution; single vein
36471    Injection of sclerosing solution; multiple veins, 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; second and subsequent veins 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; second and subsequent veins treated in a single extremity, each through
HCPCS
S2202 Echosclerotherapy

ICD-10 Procedure [For dates of service on or after 10/01/2015]
065P3ZZ-065Q4ZZ Destruction of greater saphenous vein [right or left, by percutaneous or percutaneous endoscopic approach; includes codes 065P3ZZ, 065P4ZZ, 065Q3ZZ, 065Q4ZZ]
065R3ZZ-065S4ZZ Destruction of lesser saphenous vein [right or left, by percutaneous or percutaneous endoscopic approach; includes codes 065R3ZZ, 065R4ZZ, 065S3ZZ, 065S4ZZ]
06LP0ZZ-06LQ4ZZ Occlusion of greater saphenous vein [right or left, by approach; includes codes 06LP0ZZ, 06LP3ZZ, 06LP4ZZ, 06LQ0ZZ, 06LQ3ZZ, 06LQ4ZZ]
06LR0ZZ-06LS4ZZ Occlusion of lesser saphenous vein [right or left, by approach; includes codes 06LR0ZZ, 06LR3ZZ, 06RP4ZZ, 06LS0ZZ, 06LS3ZZ, 06LS4ZZ]
3E030TZ Introduction of destructive agent into peripheral vein, open approach
3E033TZ Introduction of destructive agent into peripheral vein, percutaneous approach

ICD-10 Diagnosis [For dates of service on or after 10/01/2015]
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
Z86.71 Personal history of venous thrombosis and embolism
Z86.72 Personal history of thrombophlebitis

ICD-9 Procedure [For dates of service prior to 10/01/2015]
39.92 Injection of sclerosing agent into vein

ICD-9 Diagnosis [For dates of service prior to 10/01/2015]
448.0 Hereditary hemorrhagic telangiectasia
451.0-451.2 Phlebitis and thrombophlebitis of vessels of lower extremities
453.6 Venous embolism and thrombosis of superficial vessels of lower extremity
454.0-454.8 Varicose veins of lower extremities [with complications]
459.11-459.19 Postthrombotic syndrome [with complications]
459.81 Venous (peripheral) insufficiency, unspecified
459.89 Other specified disorders of circulatory system (phlebosclerosis)
707.10-707.19 Ulcer of lower limbs, except decubitus
729.5 Pain in limb
729.81 Swelling of limb
747.64 Other anomalies of peripheral vascular system, lower limb vessel anomaly
782.3 Edema
785.4 Gangrene
V12.51 Personal history of venous thrombosis and embolism
V12.52 Personal history of thrombophlebitis

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above, when criteria are not met, and for the following diagnosis

ICD-10 Diagnosis [For dates of service on or after 10/01/2015]
183.90-183.93 Asymptomatic varicose veins of lower extremities

ICD-9 Diagnosis [For dates of service prior to 10/01/2015]
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 [For dates of service on or after 10/01/2015]
178.1 Nevus non-neoplastic (spider veins)

ICD-9 Diagnosis [For dates of service prior to 10/01/2015]
448.1 Nevus non-neoplastic (spider veins)

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above, for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT 37799 Unlisted procedure, vascular surgery [when specified as COMPASS protocol, endoluminal cryoablation or mechanochemical ablation of varicose veins]

ICD-10 Diagnosis [For dates of service on or after 10/01/2015]
All diagnoses

ICD-9 Diagnosis [For dates of service prior to 10/01/2015]
All diagnoses

When services are Cosmetic and Not Medically Necessary:

CPT 36468 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
96999 Unlisted special dermatological service or procedure [when specified as tunable dye or pulsed dye laser treatment]

ICD-10 Diagnosis [For dates of service on or after 10/01/2015]
All diagnoses

ICD-9 Diagnosis [For dates of service prior to 10/01/2015]
All diagnoses

References


46. Todd KL 3rd, Wright DJ; VANISH-2 Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. Phlebology. 2014; 29(9):608-618.


Government Agency, Medical Society and Other Authoritative Publications:


Websites for Additional Information

Index

ClariVein
Closure Procedure
COMPASS
Endoluminal Cryoablation
Endosaphenous Radiofrequency or Laser Ablation for Primary Venous Insufficiency
eVLT
Laser Ablation for Primary Venous Insufficiency
Mechanochemical Ablation
MOCA
PhotoDerm
Photothermal sclerosis
Primary Venous Insufficiency
Radiofrequency Ablation for Primary Venous Insufficiency
Spider Veins
Subfascial endoscopic perforating vein surgery (SEPS)
Telangiectatic Dermal Veins
Trans-Illuminated Powered Phlebectomy (TIPP)
TRIVEX System
Varicose Veins
Vasculite
VeinLase
Venefit
Varithena
VNUS Closure Catheter Systems

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

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>Revised</td>
<td>08/06/2015</td>
<td>Medical Policy &amp; Technology Assessment Committee (MPTAC) review. Clarified the term &quot;junctional incompetence&quot; in the medically necessary statement from &quot;reflux with retrograde flow of 0.5 second duration&quot; to &quot;0.5 second duration or greater.&quot; Rationale, Background and Reference sections updated.</td>
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<tr>
<td>Revised</td>
<td>05/07/2015</td>
<td>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 &quot;causing discomfort to the degree that employment or activities of daily living are compromised.&quot; Removed requirement for medication from medically necessary criteria. Updated Description, Rationale and Reference sections.</td>
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<tr>
<td>Revised</td>
<td>11/13/2014</td>
<td>MPTAC review. Updated Description, Rationale and Reference sections.</td>
</tr>
<tr>
<td>Revised</td>
<td>11/14/2013</td>
<td>MPTAC review. Clarified medically necessary statement for junctional (saphenofemoral or saphenopopliteal as appropriate based on vein anatomy) incompetence. Rationale, Background and Reference sections updated.</td>
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<tr>
<td>Revised</td>
<td>08/08/2013</td>
<td>MPTAC review. Mechanochemical ablation of any vein added as an investigational and not medically necessary statement. Rationale, Coding, Reference and Index sections updated.</td>
</tr>
<tr>
<td>Revised</td>
<td>02/14/2013</td>
<td>MPTAC review. Position statement reformatted. Description, Rationale, Reference, and Index sections updated.</td>
</tr>
<tr>
<td>Revised</td>
<td>05/10/2012</td>
<td>MPTAC review. Medically Necessary criteria reorganized. Rationale and References updated.</td>
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<tr>
<td>Revised</td>
<td>05/19/2011</td>
<td>MPTAC review. Addition of reticular vein to position statement. Description, Rationale and References updated.</td>
</tr>
<tr>
<td>Revised</td>
<td>05/13/2010</td>
<td>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.</td>
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<tr>
<td>Revised</td>
<td>10/01/2009</td>
<td>Updated Coding section with 10/01/2009 ICD-9 changes; removed ICD-9 diagnosis code 453.8 (no longer applicable).</td>
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<td>Revised</td>
<td>05/21/2009</td>
<td>MPTAC review. Vein anatomy clarified in position statement. Background updated to address standard therapies. References updated.</td>
</tr>
<tr>
<td>Revised</td>
<td>11/20/2008</td>
<td>MPTAC review. Criteria updated to address saphenous vein tributaries and extensions. Rationale, Background, Coding and References updated.</td>
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<tr>
<td>Revised</td>
<td>11/29/2007</td>
<td>MPTAC review. Criteria for perforator ligation clarified. The phrase &quot;investigational/not medically necessary&quot; was clarified to read &quot;investigational and not medically necessary&quot; and the phrase &quot;cosmetic/not medically necessary&quot; was clarified to read &quot;cosmetic and not medically necessary&quot;.</td>
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</table>
References updated. MPTAC review. Minimal pressure criteria (30mmHg) for compression stockings deleted. Coding updated; removed HCPCS S2130, S2131 deleted 12/31/2004.

MPTAC review.

Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).

MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

### Pre-Merger Organizations

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