MEDICAL POLICY

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Medical Policy Title	Varicose Vein Treatments
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Endovenous laser ablation (EVLA), radiofrequency ablation (RFA), endovenous polidocanol 1% microfoam sclerotherapy (PEM; [i.e., Varithena]), and endovascular embolization with cyanoacrylate adhesive (i.e., VenaSeal Closure System) are considered **medically appropriate** treatments of symptomatic varicose veins (great, small, or accessory saphenous veins)/venous insufficiency when **ALL** of the following are met:

   A. Saphenous incompetence/reflux of at least 500 milliseconds (ms) is documented by duplex ultrasound;

   B. CEAP [clinical, etiology, anatomy, pathophysiology] class C2 or greater;

   C. Documentation of **one or more** of the following indications:

      1. Ulceration secondary to venous stasis;

      2. Recurrent superficial thrombophlebitis;

      3. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; **or**

      4. Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, **and both** of the following:

         a. Symptoms significantly interfere with activities of daily living (ADLs); **and**

         b. Conservative management with compression therapy (e.g., hosiery or stockings) and activity modification (e.g., elevating legs, exercise, weight loss) for at least 3-months, has not improved symptoms.

II. The following treatments are considered **medically appropriate** as a component of the treatment of symptomatic varicose tributaries when performed either concurrently or following prior treatment of the saphenous vein(s):

   A. Phlebectomy (also known as ambulatory phlebectomy, microphlebectomy, miniphlebectomy, hook phlebectomy, stab avulsion);

   B. Sclerotherapy;

   C. Transilluminated powered phlebectomy (TPP/TIPP, TriVex).

III. The following treatments are considered **not medically necessary**:

A. Sclerotherapy of small diameter veins (e.g., spider nevi, or telangiectasia [spider veins]);
B. Transcutaneous laser ablation of small diameter veins (e.g., spider nevi or telangiectasia [spider veins]);
C. Any treatment technique for asymptomatic varicose veins.

IV. The following treatments are considered **investigational**:
A. Balloon catheter-assisted vein sclerotherapy (e.g., KAVS catheter) (CPT 0542T);
B. Cryoablation (also referred to as, cryostripping, cryotherapy, cryosurgery) for any vein.
C. Coil embolization;
D. Mechanochemical (MOCA) or endomechanical ablation for any vein (e.g., ClariVein) (CPT 36473 or 36474);
E. Photothermal sclerosis (also known as intense pulsed light [IPL]) for the treatment of superficial veins;
F. Endovenous thermal ablation (radiofrequency or laser) of tributary veins;
G. Sclerotherapy of isolated tributary veins without concurrent or prior treatment/occlusion of saphenous veins;
H. Sclerotherapy of perforator veins;
I. Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins.

RELATED POLICIES

Corporate Medical Policy

4.01.10 Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome

7.01.11 Cosmetic and Reconstructive Procedures

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Sclerotherapy requires use of a sclerosant that is approved by the U.S. Food and Drug Administration for the intended use.

II. The CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system is an internationally accepted standard for describing patients with chronic venous disorders (Lurie, 2020). The clinical (C) classification descriptions include:

- C0: No visible or palpable signs of venous disease
- C1: Telangiectasias or reticular veins

- C2: Varicose veins
- C2r: Recurrent varicose veins
- C3: Edema
- C4: Changes in skin and subcutaneous tissue secondary to CVD
- C4a: Pigmentation or eczema
- C4b: Lipodermatosclerosis or atrophie blanche
- C4c: Corona phlebectatica
- C5: Healed
- C6: Active venous ulcer
- C6r: Recurrent active venous ulcer

DESCRIPTION

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory veins that travel in parallel with the great or small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. Tributaries are veins that empty into a larger vein. One-way valves are present within all veins to direct the return of blood up the lower limb. Because the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins.

Varicose veins are dilated, elongated, tortuous, subcutaneous veins three (3) millimeters or greater in diameter. They may involve the saphenous veins (great or small), saphenous tributaries, or nonsaphenous superficial leg veins. These visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, aching, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification of venous disease considers the clinical, etiologic, anatomic, and pathologic characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration). Most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions.

The term varicose vein does not apply to telangiectatic dermal veins, which may be described as spider veins or broken blood vessels. While abnormal in appearance, these veins typically are not associated with any symptoms (such as pain or heaviness), and their treatment is typically considered cosmetic in nature.

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgery, thermal ablation, sclerotherapy, cyanoacrylate adhesive (CAC), mechanochemical ablation (MOCA), and cryotherapy. The application of each modality is influenced by the severity of the symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent)

treatment. Treatment options typically focus, first, on identifying and correcting the site of reflux, and second, on redirecting venous flow through veins with intact valves.

Endovenous Radiofrequency Ablation (RFA)

A minimally invasive alternative to vein ligation and stripping. This thermal ablation technique relies on radiofrequency energy to damage the intimal wall of the vessel, resulting in fibrosis and, ultimately, obliteration of a long segment of the vein, thus eliminating reflux. The procedure is performed by means of a specifically designed catheter (VNUS ClosureFAST catheter, VNUS Technologies) inserted through a small incision in the distal medial thigh to within 1-2 cm of the sapheno-femoral junction. High frequency radiowaves (200-300 kHz) are delivered through the catheter electrode, causing direct heating of the adjacent tissues. The vein is heated to approximately 120º C for 20-second intervals, to sequentially heat and ablate the vein in 7 cm increments.

Endovenous Laser Ablation (EVLA) (also known as Endovenous Laser Treatment [EVLT])

A minimally invasive alternative to vein ligation and stripping, performed similarly to RFA, for symptomatic varicose veins. This thermal ablation procedure is performed by introducing a bare-tipped or ceramic-coated tip laser fiber through a small incision into the greater saphenous vein under ultrasound guidance. The laser is activated, and the resulting heat at the tip causes a reaction in the walls of the vein. Then, the tip fiber is slowly removed along the course of the saphenous vein. Damage to the intimal wall of the vessel results in fibrosis and, ultimately, obliteration of a long segment of the vein. The varicosities associated with this vein then disappear, and blood from the lower leg reroutes through deeper circulation.

In transcutaneous laser ablation treatment of small diameter veins, a small spot of laser travels through the skin and is absorbed by the blood within the vein. The resulting heat coagulates the blood and destroys the function of the vein. Over time the vein will be absorbed by the body and will disappear.

Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately occluding the vessel. Treatment success depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant.

Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations; however, technical improvements in sclerotherapy have included the routine use of ultrasound guided sclerotherapy injection (UGS) (also referred to as echosclerotherapy) to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant.

Foam sclerosants are produced by forcibly mixing a gas (e.g., air or carbon dioxide) and a liquid sclerosant (e.g., polidocanol [e.g., Asclera] or sodium tetradecyl sulfate). Physician-compounded foam is made by a healthcare provider at the time of treatment and can be inconsistent with varied bubble size and stability. A commercially available injectable microfoam sclerosant, polidocanol 1%

endovenous microfoam (PEM; Varithena), is proposed to provide a smaller and more consistent bubble size than what is produced with physician-compounded sclerosant foam.

Balloon catheter-assisted vein sclerotherapy (KAVS catheter) uses an intravascular double-lumen catheter with a balloon at the distal end to temporarily block blood flow to the segment of the vein being targeted for sclerotherapy. In theory, the procedure would improve sclerotherapy by avoiding drainage of the sclerosant foam and allowing for more control of the contract duration between the vessel wall and sclerosant foam (Brodersen 2007).

Cyanoacrylate Adhesive

Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (i.e., polymerizes into a solid material on contact with body fluids or tissue). Once the adhesive is injected, the area is manually compressed. and the adhesive changes into a solid. to seal the varicose vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and surgical incisions or other skin wounds.

Photothermal Sclerosis (Intense Pulsed Light)

The light source used for this procedure is not a laser and involves no needles or incisions. Treatment consists of small pulses of light energy traveling through the skin, which is absorbed by the blood, changed to heat, destroying the vein.

Mechanochemical Endovenous Ablation (MOCA)

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

Cryoablation (Cryostripping)

The principle of cryoablation (also known as cryostripping) consists of venous catheterization with a special probe that is cooled, causing it to adhere well to the vein, thus enabling its removal (Matei 2022). Cryostripping uses extreme cold to cause injury to the vessel and has been suggested as an alternative approach to traditional ligation and stripping.

Phlebectomy

Ambulatory phlebectomy (also known as microphlebectomy or microincisional phlebectomy) is the removal of varicose veins through a series of tiny incisions along the path of an enlarged vein. Prior to surgery, the degree of reflux in incompetent veins is evaluated, and the location of the veins is determined by Doppler ultrasound. The vessels are marked with a surgical marker. The surgical procedure is done under local tumescent anesthesia. Small pinhole incisions are made adjacent to the varicose veins. A small stripper head is inserted and used to turn the vein inside out and peel it away from the soft tissues of the leg through a minimal skin opening. Afterward, the leg is wrapped with a

compression bandage.

Stab phlebectomy (also known as “crochet hook” stab avulsion) is another type of ambulatory phlebectomy.

Transilluminated powered phlebectomy (TPP/TIPP), also known as the TriVex procedure, is a minimally invasive type of ambulatory phlebectomy offered as an alternative to standard surgery for symptomatic varicosities of the leg. It is a three-part procedure performed under general, regional, or local anesthesia. It begins with tumescent anesthesia, to enhance visualization surrounding the varicose veins and to reduce operative discomfort. Tumescence anesthesia involves infusion of large amounts of saline mixed with lidocaine, to reduce hemorrhage, and epinephrine, to delay absorption of lidocaine. Once adequate tumescent infiltration is achieved, the resector and illuminator are inserted and positioned underneath the skin through small (2-3 cm) incisions on either end of the varicosity. The tip of the resector follows the veins slowly, to chop the veins and aspirate fragments. Once removal of the affected vein(s) is complete, a second stage tumescent anesthesia is employed, to minimize blood loss, reduce bruising and hematoma formation, and decrease post-operative pain. The incisions are then closed using surgical tape or similar closures, and the leg is wrapped.

SUPPORTIVE LITERATURE

Endovenous Thermal Ablation (Radiofrequency and Laser) - Treatment of Saphenous Veins

Clinical evidence supports the safety and efficacy of endovenous ablation using laser energy or RFA (e.g., VNUS) of the greater saphenous vein, as an alternative to saphenous vein ligation and stripping, in patients with documented symptomatic saphenofemoral reflux. There are multiple large randomized controlled trials (RCTs) and systematic reviews of RCTs assessing endovenous ablation using radiofrequency or laser energy of the saphenous veins. Comparison with ligation and stripping at 2- to 5-year follow-up has indicated similar recurrence rates for the different treatments. Evidence has suggested that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization, resulting in similar outcomes for endovenous thermal ablation and surgery. Laser ablation and RFA have similar success rates.

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

Brittenden et al (2014) conducted a multicenter RCT in the United Kingdom. A total of 798 patients were randomized to compare foam sclerotherapy (n=292), EVLA (n=212), and surgical treatment (n=294). After adjustment for baseline scores and other covariates, the mean disease-specific quality of life was slightly worse after treatment with foam than after surgery (P=0.006) but was similar in the laser and surgery groups. There were no significant differences between the surgery group and the foam or the laser group in measures of generic quality of life. The frequency of procedural complications was similar in the foam group (6%) and the surgery group (7%) but was lower in the

laser group (1%) than in the surgery group (P<0.001). After noting study limitations, the authors concluded that the clinical effectiveness of EVLA, foam sclerotherapy, and surgery for the treatment of varicose veins showed no clinically substantial between-group differences in quality of life. Moderate differences in disease-specific quality of life favored surgery over treatment with foam, and moderate differences in generic quality of life favored laser treatment over foam. All treatments had similar clinical efficacy, but there were fewer complications after laser treatment, and ablation rates were lower after treatment with foam.

Brittenden et al (2019) reported the 5-year follow-up outcomes to their 2014 RCT. At 5-years, quality-of-life questionnaires were completed by 595 (75%) of the 798 trial participants, with significant differences between the treatments with respect to disease-specific quality of life. The Aberdeen Varicose Vein Questionnaire (AVVQ) scores were better among participants treated with laser ablation or surgery than among those treated with foam sclerotherapy, with effect sizes of 2.86 and 2.60, respectively. Quality of life was similar in the laser ablation and surgery groups. Study limitations include the lack of a sham procedure, patients and assessors were aware of the treatments, and there was a substantial amount of missing data at 5 years.

Wallace et al (2018) published the 5-year outcomes of an RCT that concluded EVLA was as effective as surgery for varicose veins but had a less negative impact on early postintervention Quality of Life (QoL). Of the initial 276 patients enrolled in the trial, 218 (79%) patients were available at the 5-year follow-up. Clinical recurrence was more frequent following surgery than EVLA at 5 years (34.3% versus 20.9%; P = 0.010). Both groups demonstrated sustained significant improvements at 5 years over baseline in Venous Clinical Severity Score (VCSS) and EuroQol Five Dimensions (EQ-5D). VCSS was better for EVLA than surgery at 5 years (P = 0.031). Technical success remained high at 5 years (85.4% for surgery and 93.2% for EVLA; P = 0.074). Study limitations include lack of blinding, single center design, and limited scope of recurrence rate since the study did not fully explore the functional implications of these recurrences or their impact on long-term symptoms. Overall, the study concluded that EVLA was more effective than surgery in preventing clinical recurrence 5 years after treatment of great saphenous varicose veins, and patient-reported outcome measures were similar.

A Cochrane review by Whing et al (2021) compared interventions for great saphenous vein incompetence. The review included 24 RCTs (N=5135) and the duration of follow-up ranged from 5 weeks to 8 years. When comparing EVLA to ligation and stripping, pooled data from 6 RCTs (n=1051) suggest that technical success may be better with EVLA up to 5 years, but not at 5 years and beyond based on data from 5 RCTs (n=874). The risk of recurrence is similar between treatments within 3 years and at 5 years based on data from seven RCTs each (n=1459 and n=1267, respectively). When comparing RFA to ligation and stripping, data from two RCTs (n=318) suggest that there is no significant difference in the rate of technical success up to 5 years; data from one RCT (n=289) with duration over 5 years also suggest no significant difference between treatments. Based on data from four RCTs (n=546), there is no significant difference in the risk of recurrence up to 3 years; but based on one trial (n=289), a possible long-term benefit for RFA is observed (low-certainty evidence). When comparing EVLA with RFA, technical success is comparable up to 5 years and over 5 years. Based on data from one study (n=291), there is no significant difference in the risk of recurrence between treatments at 3 years, but a benefit for RFA over EVLA may be seen at 5 years.

Farah et al (2022) conducted a systematic review and meta-analysis that informed the 2022 multiorganizational guideline on management of varicose veins. The review addressed three key questions related to treatment: whether there is a benefit of surgical stripping versus endovenous ablation, whether there is a benefit of thermal versus nonthermal ablation techniques, and whether ablation of incompetent perforator veins improves outcomes. Multiple outcomes of interest were assessed at various time points for each question. For the first key question, an analysis of 30 RCTs and 16 observational studies found few studies that reported the outcomes of interest at each time point (between 1 month and 5 years), but anatomic closure was better with surgical stripping compared to endovenous ablation techniques. Analysis for the second question included 16 RCTs and 11 observational studies, few of which included the outcomes of interest at the time points of interest. Overall, EVLA resulted in higher rates of anatomical closure at 1 year and 5 years versus nonthermal ablation techniques.

Sclerotherapy (Physician-Compounded) - Treatment of Saphenous Veins

Shadid et al (2012) conducted a noninferiority trial to compare foam sclerotherapy with ligation and stripping in 430 patients. Forty (17%) patients had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in both groups (11.3% sclerotherapy vs. 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs. 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. Two serious adverse events in the sclerotherapy group (deep venous thrombosis, pulmonary emboli) occurred within 1 week of treatment.

Long-term 8-year follow-up of the Shadid et al study was published by Lam and colleagues (2018). Of the initial 430 study patients, 53% were available for follow-up at 8 years. All measures of treatment success (e.g., symptomatic great saphenous vein reflux, saphenofemoral junction failure, and recurrent reflux in the great saphenous vein) were lower in the physician-compounded sclerotherapy group compared to the ligation and stripping group. The proportion of patients free from symptomatic great saphenous vein (GSV) reflux at 8 years was lower after ultrasound-guided foam sclerotherapy (UGFS) with high ligation and surgical stripping (HL/S) (55.1% versus 72.1%; P = 0.024). The rate of absence of GSV reflux, irrespective of venous symptoms, at 8 years was 33.1% and 49.7% respectively (P = 0·009). More saphenofemoral junction (SFJ) failure (P = 0.001) and recurrent reflux in the above-knee GSV (P = 0.001) was evident in the UGFS group. The VCSS was worse than preoperative scores in both groups after 8 years; CEAP classification and EQ-5D scores were similar in the two groups. The authors concluded that surgical stripping had a technically better outcome in terms of recurrence of GSV and SFJ reflux than UGFS in the long term. Long-term follow-up suggests significant clinical progression of venous disease measured by VCSS in both groups, but less after surgery.

In the 2013, Biemans and colleagues conducted the MAGNA trial. A total of 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or physician-compounded foam sclerotherapy (1 mL aethoxysclerol 3%: 3 cc air). At 1-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both EVLA (88.5%) and stripping (88.2%). Twenty-one patients in the sclerotherapy group had partial occlusion with reflux, though the clinical complaint was completely relieved. At 5-year follow-up (van der Velden 2015),

obliteration or absence of the great saphenous vein was observed in only 23% of patients treated with physician-compounded sclerotherapy compared with 85% of patients who underwent conventional surgery and 77% of patients who underwent EVLA. Thirty-two percent of legs treated initially with sclerotherapy required 1 or more reinterventions during follow-up compared with 10% in the conventional surgery and EVLA groups. However, clinically relevant grade II neovascularization was higher in the conventional surgery (17%) and EVLA (13%) groups than in the physician-compounded sclerotherapy group (4%). Quality of Life scores improved equally in all groups.

Venermo et al (2016) conducted a prospective randomized trial to compare the effect of surgery, EVLA (EVLA) (with phlebectomies), and ultrasound-guided foam sclerotherapy (UGFS) using polidocanol 1% (Aetoxysclerol) and sodium tetradecyl sulphate 1% and 3% on quality of life and the occlusion rate of the great saphenous vein (GSV) 12 months after surgery. The study included 214 patients (n=65 surgery, 73 EVLA, and 76 UGFS). At 1 year, the GSV was occluded or absent in 59/61 (97%) patients after surgery, 71/73 (97%) after EVLA, and 37/72 (51%) after UGFS ($P < 0.001$). The Aberdeen Varicose Vein Questionnaire (AVVQ) improved significantly in comparison with preoperative values in all groups, with no significant differences between them. Perioperative pain was significantly reduced and sick leave shorter after UGFS (mean 1 day) than after EVLA (8 days) and surgery (12 days).

Vahaaho et al (2018) published 5-year follow-up findings of patients with symptomatic great saphenous vein insufficiency who were randomized to undergo either open surgery, EVLA, or physician-compounded UGFS between 2007 and 2010. Of the 196 patients treated, 166 (94.7%) participated in the long-term follow-up. At 5-years, the great saphenous vein occlusion rate was 96% for open surgery, 89% for EVLA, and 51% for ultrasound-guided foam sclerotherapy ($p<.001$). For patients with no additional treatment during follow-up, occlusion rates for open surgery, EVLA, and ultrasound-guided foam sclerotherapy were 96%, 89%, and 41%, respectively. The study was limited by a lack of blinding and by non-standardized foam application.

Hamel-Desnos et al (2023) conducted a randomized trial of EVLA versus physician-compounded foam sclerotherapy (0.5 mL polidocanol at concentrations ranging from 1% to 3% depending on vessel diameter; 2 mL air) in 161 patients with isolated small saphenous vein incompetence. Tributary vein treatments were not allowed for the first 6 months after the procedure. After the first 6 months, 33% of patients who received physician-compounded foam sclerotherapy and 19% of patients who received EVLA received tributary treatment. The primary endpoint, absence of reflux in the treated segment at 3 years, was achieved in 86% of patients who received EVLA versus 56% of patients who received sclerotherapy. Rates of partial and total failure were higher in the sclerotherapy group than the EVLA group. Limitations include the pragmatic design that allowed clinicians to treat patients according to their normal practice except for the study intervention and a lack of blinding.

<u>Sclerotherapy (Microfoam) - Treatment of Saphenous Veins</u>

In 2013, polidocanol microfoam (Varithena) was approved by the U.S. Food and Drug Administration (FDA) under a new drug application for the treatment of varicose veins based on efficacy data from two randomized, blinded, multicenter studies. One compared polidocanol at 0.5%, 1.0%, and 2.0% with endovenous placebo or a subtherapeutic dose of polidocanol foam. The primary endpoint was an improvement in symptoms at week 8, as measured by the Varicose Vein Symptoms Questionnaire.

The improvement in symptoms was greater in the pooled polidocanol treatment group (p<.001) and in each of the individual dose-concentration groups compared with vehicle alone. Secondary and tertiary endpoints (appearance, duplex ultrasound response, quality of life) were also significantly better for the polidocanol groups compared with controls.

Todd et al (2014) published findings from the VANISH-2 randomized control trial to determine efficacy and safety of polidocanol endovenous microfoam (PEM), Varithena, in treatment of symptoms and appearance in patients with saphenofemoral junction incompetence due to reflux of the great saphenous vein or major accessory veins. Patients were randomized equally to receive PEM 0.5 %, PEM 1.0 % or placebo. In treated patients (n=232), PEM 0.5 % and PEM 1.0 % were superior to placebo, with a larger improvement in symptoms ($p < 0.0001$) and greater improvements in physician and patient assessments of appearance ($p < 0.0001$). There was no sign of an increase in neurologic adverse events, and there were no adverse cardiac or cardiopulmonary effects following treatment with polidocanol injectable foam. Rates of occlusion with Varithena are similar to those reported for EVLA or stripping. A randomized trial comparing EVLA and stripping with this new preparation of foam sclerotherapy is needed to evaluate its comparative effectiveness.

Vasquez et al (2017) reported on a double-blind RCT that evaluated the addition of polidocanol microfoam to endovenous thermal ablation. A total of 117 patients who were candidates for both endovenous thermal ablation and treatment of visible varicosities received endovenous thermal ablation plus placebo (n=38) or polidocanol 0.5% (n=39) or 1% (n=40). At 8-week follow-up, physician-blinded vein appearance was significantly better with the combined polidocanol groups (p=.001), but the improvement in patient ratings was not statistically significant. At 6-month follow-up, the percentages of patients who achieved a clinically meaningful change were significantly higher in both physician (70.9% vs. 42.1%; p=.001) and patient (67% vs. 50%; p=.034) ratings. The proportion of patients who received additional treatment for residual varicosities between week 8 and month 6 was modestly reduced (13.9% for the polidocanol vs. 23.7% for placebo; p=.037).

Deak (2018) conducted a retrospective review of 250 patients with C2-C6 symptomatic chronic venous insufficiency who were treated with polidocanol microfoam in a community practice and followed for 16 +/- 7 months. All patients completed the initial treatment, with 55 (22.0%) requiring planned secondary treatment during the follow-up period for residual venous reflux in the below-knee greater saphenous vein. Complete elimination of venous valvular reflux and symptom improvement was documented in 236 patients (94.4%). A small percentage of the patients (5.6%) were considered technical failures owing to the inability to cannulate the vein, or to completely abolish pathologic reflux in the symptomatic vein. Minor adverse events included asymptomatic deep vein thrombi (n= 2), common femoral vein thrombus extension (n= 1), and superficial venous thrombi (n = 4). Of the 16 patients with skin ulcers, 10 were C6 patients and 80% experienced wound closure within 4 weeks of treatment. The authors conclude that the overall data illustrated comparable safety and efficacy to other thermal and surgical-based intervention.

Kabnick and colleagues (2024) conducted a network systematic review and network meta-analysis to compare the effectiveness of non-compounded polidocanol 1% endovenous microfoam (PEM) (Varithena) ablation versus endovenous thermal ablation (ETA) in the primary treatment of adult patients with venous insufficiency caused by lower extremity truncal vein incompetence. A total of 13

studies met inclusion criteria (6 RCT and 7 comparative non-RCT) and included 233,801 patients. The authors reported that PEM was not significantly different statistically from ETA for vein closure (P = .16) but was significantly differentiated statistically from physician-compounded foam (PCF), with higher odds for vein closure (P < .01). A sensitivity analysis using the longest available time point for closure in each study, with a minimum of 12 months of follow-up (median, 48 months; range, 12-72 months), showed results similar to the main analysis for both ETA (p = .21) and PCF (P < .01). There was no evidence that PEM is associated with an increased risk of DVT compared with ETA, surgery, or PCF treatment.

Watanabe et al (2024) conducted a double-blinded trial RCT comparing transluminal injection of microfoam sclerosant plus EVLA to EVLA alone in 142 patients (160 legs) with small saphenous vein reflux. At one year, the transluminal injection of microfoam sclerosant plus EVLA reduced residual or recurrent reflux (4% vs. 16%; p=.027) and secondary interventions (4% vs. 16%; p=.027), without major complications. Improvements in venous clinical severity score were similar with both interventions.

<u>Cyanoacrylate Adhesive Embolization- Treatment of Saphenous Veins</u>

Morrison et al (2015) conducted the VenaSeal pivotal study (VeClose trial), a multi-center, non-inferiority trial with 222 patients, compared CAE (n = 108), the VenaSeal Sapheon Closure System with RFA (n = 114), and the ClosureFast system, for the treatment of symptomatic, incompetent great saphenous veins. After discharge, subjects returned to the clinic on day 3 and again at months 1 and 3. The study's primary endpoint was closure of the target vein at month 3, as assessed by Duplex ultrasound and adjudicated by an independent vascular ultrasound core laboratory. Statistical testing focused on showing non-inferiority with a 10% delta conditionally followed by superiority testing. No adjunctive procedures were allowed until after the month 3 visit, and missing month 3 data were imputed by various methods. Secondary end points included patient-reported pain during vein treatment and extent of ecchymosis at day 3. Additional assessments included general and disease-specific quality of life surveys and adverse event rates. The primary end point (the proportion of patients with complete closure of the target great saphenous vein at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. All primary end point analyses, which used various methods to account for the missing data rate (14%), showed evidence to support the study's non-inferiority hypothesis (all P < .01); some of the analyses supported a trend toward superiority (P = .07 in the predictive model). Pain experienced during the procedure was mild and similar between treatment groups (2.2 and 2.4 for CAE and RFA, respectively, on a 10-point scale; P = .11). The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs 2.4 for RFA, p=0.11). Scores on the Aberdeen Varicose Vein Questionnaire (AVVQ) and Venous Clinical Severity Score (VCSS) improved to a similar extent in the 2 groups. Other adverse events occurred at a similar rate between groups and were generally mild and well tolerated. The authors concluded that CAE was proven to be non-inferior to RFA for the treatment of incompetent great saphenous veins at month 3 after the procedure, that both treatment methods showed good safety profiles, and that CAE does not require tumescent anesthesia and is associated with less post-procedure ecchymosis. (Morrison 2015).

Morrison et al (2018) reported on the 36-month outcomes of the VeClose trial, which compared

treatment of incompetent great saphenous veins using cyanoacrylate closure (CAC) versus RFA. At 36 months, 146 patients completed the follow-up, 72 in the CAC group and 74 in the RFA group. The closure rates at months 3, 6, 12, and 24 were reported to be 99%, 99%, 96.8%, and 95.3%, respectively, for the CAC group. The closure rates at months 3, 6, 12, and 24 were reported to be 95.4%, 96.2%, 95.9%, and 94.0%, respectively, for the RFA group. The great saphenous vein closure rate at 36 months was 94.4% in the CAC group and 91.9% in the RFA group. The authors concluded that the trial reports similar great saphenous vein closure rates with both CAC and RFA at 36 months, further confirming the durability and non-inferiority of CAC compared to RFA.

Morrison et al (2020) published the 5-year VeClose extension study findings of 88 patients available from the initial trial (n=47 CAC group, n=33 RFA group, and 9 CAC roll-in patients). No new recanalization events have been observed in the groups between 36 and 60 months of follow-up. Estimates for freedom from recanalization in the randomized CAC and RFA groups were 91.4% and 85.2%, respectively, demonstrating noninferiority of CAC compared with RFA. CAC and RFA were effective in achieving complete target vein closure of the GSV at long-term follow-up, with CAC demonstrating continued noninferiority to RFA. CAC was also associated with sustained improvements in symptoms and quality of life, lower CEAP class, and high level of patient satisfaction without serious AEs between 36 and 60 months.

Ontario Health (2021) performed a health technology assessment systematic review and meta-analysis to evaluate the effectiveness, safety, and cost-effectiveness of nonthermal endovenous procedures (i.e., mechanochemical ablation [MOCA] and cyanoacrylate adhesive closure [CAC]) for people with symptomatic varicose veins. Reviewing a total of 19 studies, including a non-inferiority trial, the authors concluded that MOCA resulted in slightly poorer technical outcomes (vein closure and recanalization) than thermal endovenous ablation procedures (Grade: low to moderate). CCA resulted in little to no difference in technical outcomes, clinical outcomes, and quality of life improvement compared with RFA and EVLA (Grade: Moderate). CAC and MOCA produced similar patient-important outcomes, and slightly shorter recovery compared with thermal ablation. Major complication of any procedure was rare, with minor complication occurring as expected. Compared with surgical vein stripping, all endovenous treatments were more effective and less expensive.

Tang et al (2021 and 2024) reported the 3-month and 3-year follow-up findings of a real-world, prospective, single arm, multicentre, multi-investigator trial, A Singapore VenaSeal real world post-market evaluation Study (ASVS). ASVS evaluated the performance of cyanoacrylate closure (CAC) for ablating varicose veins in a multiracial Asian from Singapore. The 3-month findings reported on the initial 100 patients (151 legs and 156 truncal veins) who underwent CAC for treatment of unilateral and/or bilateral GSV and/or SSV incompetence. Early 3-month results were encouraging with significant continues quality of life improvement, and GSV and SSV occlusion rates of 99.3% and 100%, respectively. At the 3-year mark, 70 of the initial 100 patients were evaluated, and the findings demonstrated continued and sustained clinical efficacy with only three patients required reinterventions. There was a significant improvement of CEAP score at 3 years compared to baseline ($p<0.05$), and 51/70 (72.9%) experienced an improvement of at least 2 or more CEAP categories.

Alhewy et al (2024) conducted a prospective RCT at two centers in Egypt comparing VenaSeal CAC with RFA in 248 patients with venous reflux, with follow-up extending to 2 years postprocedure. The

primary outcome was complete closure of the target great saphenous vein at the 3-month visit, although results for this outcome were not reported by the authors. Authors reported that at the 1-month follow-up, all veins treated with CAC remained occluded, while 154 out of 158 (97%) veins treated with RFA remained occluded. At 24 months, 122 out of 128 (95%) veins treated with CAC and 146 out of 158 (93%) veins treated with RFA remained occluded. At month 24, there were 6 recanalizations in the CAC group and 12 in the RFA group, with recanalization-free survival in the CAC group found to be non-inferior to that of the RFA group (95.3% vs. 92.4%, respectively; p<.0001 for 10% noninferiority). The CAC group experienced fewer complications, with only 2 cases of paresthesia and 18 cases of bruises reported, whereas the RFA group encountered 18 cases of bruises, 2 cases of skin burns, and 2 cases of access site hematoma. Periprocedural outcomes showed a potentially shorter intervention time with CAC versus RFA. The authors suggest that Cyanoacrylate glue closure of the GSV and RFA are effective techniques for managing primary varicose veins. Cyanoacrylate glue closure of the GSV appears to have a lower rate of complications and higher satisfaction levels, rapid return to normal activities, and improved procedure time without the need for perivenous tumescent anesthesia and postprocedure compression stockings when compared to RFA.

Coil Embolization

Coil embolization, also known as coil occlusion, involves the use of a coil, either alone or combined with a sclerosant, to occlude the vein. Coil embolization is under investigation for treatment of lower extremity varicose veins. The technique may involve the use of more than one coil within the great saphenous vein. Evidence in the peer-reviewed, published literature evaluating this method of treatment for lower extremity varicosities is very limited (e.g., van Dijk 1999; Viani 2014; Kayssi 2017). Additional clinical trials are necessary, to develop strong conclusions regarding safety and efficacy.

Mechanochemical Endovenous Ablation (MOCA) - Treatment of Saphenous Veins

In 2017, Lane and colleagues reported on results from an RCT of 170 patients that compared ClariVein with RFA. Maximum visual analog scale (VAS) pain scores (out of 100) during the procedure were significantly lower in the MOCA group (median, 15 mm) than in the RFA group (median, 34 mm; p=0.003). Average VAS pain scores during the procedure were also significantly lower in the MOCA group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific quality of life, and generic quality of life scores were similar between the groups at one and six months. However, only 71% of patients were available for follow-up at six months, limiting the evaluation of closure rates at that time point.

Vahaaho et al (2019) published findings from a single-center RCT that compared MOCA with endovenous thermal ablation (EVLA or RFA). Patients with GSV reflux were randomized (2:1:1) to undergo MOCA, or thermal ablation with EVLA or RFA, respectively. The primary outcome measure was the occlusion rate of the GSV at 1 year. Of the 125 patients initially included in the RTC, 117 (93.6%) attended 1-year follow-up. At 1 year, the treated part of the GSV was fully occluded in all patients in the EVLA and RFA groups, and in 45 of 55 in the MOCA group (occlusion rates 100%, 100% and 82% respectively; P = 0.002). The preoperative GSV diameter was associated with the recanalization rate of the proximal GSV in the MOCA group. At 1 year after treatment, disease-

specific life quality was similar in the three groups.

Vahaao et al (2021) presented 3-year follow-up results of the single-center RCT that compared MOCA with endovenous thermal ablation (EVLA or RFA). At 3-years, 106 (84.8%) of the initial 117 trial patients underwent Doppler ultrasound imaging and completed the disease-specific quality of life assessment. The occlusion rate was significantly lower with MOCA than with either EVLA or RFA (82% vs 100%; P = .005). Quality of life was similar between the groups. In the MOCA group, GSVs that were larger than 7 millimeters (mm) in diameter preoperatively were more likely to recanalize during the follow-up period. The partial recanalizations of proximal GSV observed at 1 year progressed during the follow-up. This study is limited by a lack of blinding and strict inclusion criteria may not represent the real-life scope of patients requiring treatment for superficial venous insufficiency. The researchers concluded that the 3-year occlusion rates of MOCA are inferior compared with RFA or EVLA. Recanalization seems to be more common in veins with a preoperative diameter of more than 7 mm, and the researchers suggested that MOCA should be used with due consideration in large veins.

Mohamed et al (2020) reported on the ongoing LAMA randomized clinical trial comparing EVLA (EVLA) and mechanochemical ablation (MOCA; ClariVein) in the management of superficial venous insufficiency. Patients (n=150) were randomized to MOCA with 1.5% sodium tetradecyl sulfate or to EVLA. Anatomic success (occlusion) rates were lower in the MOCA group (77%) compared to the EVLA group (91%) with no significant difference between the two treatments in intraprocedural pain scores. In contrast to the difference in anatomical occlusion rates, clinical severity and quality of life scores were not significantly different between the groups at 1 year follow-up. Follow-up is continuing to evaluate the durability of the treatments.

In 2025, Lim and colleagues published five-year data from the LAMA trial described above. The LAMA randomized clinical trial compared EVLA with MOCA using the ClariVein device. At five years, 52 of 75 (69%) and 57 of 75 (76%) patients attended follow up in the EVLA and MOCA groups, respectively. Anatomical occlusion following EVLA was statistically significantly higher than after MOCA (91% vs. 47%; p < .001). The rate of re-intervention was also statistically significantly lower following EVLA (8% vs. 21%; p = .031). There was no statistically significant difference between groups in median quality of life scores. Five-year anatomical occlusion (AO) following MOCA remained significantly lower than EVLA, leading to a higher rate of re-intervention. Following these additional procedures, there was no statistically significant difference in QoL outcomes between groups. The authors note that MOCA has previously been shown to achieve no reduction in peri-procedural pain compared with EVLA. This extended follow up to five years confirmed that MOCA results in lower occlusion rates and higher re-intervention rates than endothermal ablation.

Oud et al (2025) reported the 8-year long-term outcomes of mechanochemical ablation (MOCA) using the ClariVein device for treating great saphenous vein (GSV) incompetence. Conducted as a single-center, prospective cohort follow-up of a multicenter randomized controlled trial, the study included 109 patients (115 limbs) with a mean follow-up of 8.4 years. The primary outcome was anatomical success, defined as complete vein occlusion or a recanalized segment under 10 cm, regardless of reflux. A secondary measure, reflux-free anatomical success (RF-AS), considered segments with no reflux over 10 cm. Findings showed that anatomical success was achieved in 60.5% of limbs and RF-

AS in 72.8%, indicating a decline in anatomical success over time. Despite this, clinical outcomes improved, with the VCSS decreasing from 5.3 to 4.1 and the AVVQ score improving from 13.5 to 10.5. These improvements were statistically significant only in patients who achieved AS. Although AS rates declined over time, the authors concluded that MOCA with ClariVein still led to meaningful clinical and disease-specific quality of life improvements. The study found no strong evidence that absence of reflux correlated better with clinical outcomes, suggesting that anatomical metrics alone may not fully predict patient benefit.

Cryoablation (Cryostripping)

Evidence is limited in quality and quantity, with mixed results. For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Klem et al (2009) reported on a randomized trial that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins.

Disselhoff et al (2011) reported on 5-year outcomes from a randomized trial that compared cryoablation with EVLA. Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP class C2) with saphenofemoral incompetence and great saphenous vein reflux. Neovascularization was more common after cryoablation, but incompetent tributaries were more common arteriovenous laser ablation. There were no significant differences between groups in the Venous Clinical Severity Score or AVVQ scores at either the 2 or 5-month follow-up for EVLA.

Matei et al (2022) conducted a retrospective analysis of 1,087 patients (1,182 operated limbs) with CVD who underwent cyrostripping between September 2013 to September 2021. The study group included 756 female and 331 male patients with an age range between 19 and 87 years old. The enrolled patients were in all stages of the disease in which venous reflux is encountered, as follows: 864 patients (79.48%) in C2 and C3 stages, 164 patients (15.08%) in C4 stage, 59 patients (5.42%) in C5 and C6 stages. Patient follow-up was performed at one week, one month, and six months postoperatively by clinical examination, Doppler ultrasonography, and questionnaires. Results: Generally, good functional and aesthetic outcomes defined by clinical symptom remission, absence of insufficient veins on Doppler ultrasonography, QoL and r-VCSS improvement ($p < 0.001$) were obtained. Complications included bruising less than 2 centimeters (32.38%), hematoma (8.92%), saphenous nerve injury (3.49%), and deep vein thrombosis (0.18%). Recurrence was noted in 2.94% cases. Compared to high ligation and conventional stripping, the postoperative complications were reduced. Based on retrospective analysis, the researchers concluded that cryostripping seems to combine the radicality and efficacy of the stripping technique with the cosmetic advantage of the endothermal procedures.

PROFESSIONAL GUIDELINE(S)

Professional Guidelines

The Society for Vascular Surgery, the American Venous Forum, and the American Vein and Lymphatic

Society published updated clinical practice guidelines in two parts.

- Part I (Gloviczki 2023) provides evidenced-based recommendations on the management of varicose veins of the lower extremities, including:
  - Guideline 1 recommends: duplex ultrasound scanning as the diagnostic test of choice to evaluate venous reflux; reflux is defined as a minimum value >500ms of reversed flow in the superficial truncal veins and in the tibial, deep femoral, and perforating veins; "pathological" perforating veins in patient with varicose veins (C2) includes those with outward flow duration of >500ms and a diameter of >3.5mm on duplex ultrasound; and recommends using the 2020 upgraded CEAP classification system for chronic venous disorders.
  - Guideline 2 states that for those who place a high priority on the long-term outcomes of treatment (quality of life and recurrence), ELA, RFA, and ligation are suggested over physician-compounded ultrasound-guided foam sclerotherapy for treatment of the great saphenous vein (weak recommendation, moderate quality evidence) and for treatment of the small and accessory saphenous vein (weak recommendation; low to very low quality evidence).
  - Guideline 4 recommends against treatment of incompetent perforating veins concomitant with initial ablation of the superficial truncal veins;
- Part II (Gloviczki 2024) offers evidence-based recommendations supporting the prevention and management of varicose vein patients with compression, on treatment with drugs and nutritional supplements. Additionally, part II addresses the evaluation and treatment of varicose tributaries, the management of superficial venous aneurysms and complications of varicose veins and their treatment.
  - Guideline 5.1.1 suggest against using truncal vein diameter to determine which symptomatic patients with C2 disease need venous ablation (weak recommendation, moderate evidence).
  - Guideline 7.2, for symptomatic varicose tributaries, recommends miniphlebectomy or ultrasound guided sclerotherapy using physician-compounded foam (PCF) or polidocanol endovenous microfoam (PEM) (strong recommendation, moderate evidence).

In 2011, the Society for Vascular Surgery and the American Venous Forum clinical practice guideline indicated that cryostripping is a technique that is new in the United States, and it has not been fully evaluated (Grade 1B) (Gloviczki 2011). This technique is not discussed as a management treatment option within updated guidelines.

American Vein & Lymphatic Society (AVLS) published several position statements regarding the coverage of vein procedures, including:

- Cyanoacrylate Endovenous Ablation (Cyanoacrylate Closure [CAC]): Vasquez et al (2024) published AVLS's position statement that, based on clinical evidence, cyanoacrylate endovenous ablation (cyanoacrylate closure [CAC]) has been proven to be an effective and safe treatment option for incompetent saphenous veins. The statement also discusses the off-label use of CAC

for the closure of pathologic perforator veins, noting its efficacy and safety profile; however, AVLS indicates that additional evidence is needed to support this approach.

- Mechanochemical Chemically Assisted Ablation (MOCA): Blebea et al (2025) published the following AVLS conclusion and recommendations: Mechanical occlusion chemically assisted venous ablation is effective in alleviating symptoms and a safe treatment option for venous insufficiency. It may be used in both the below knee distal GSV as well as the SSV with no risk of thermal injury to the adjacent nerves. However, it is associated with significantly lower rates of vessel closure and higher recanalization rates when followed for more than 1 year compared to both radiofrequency ablation and EVLA. It is an available option for those in whom thermal ablation is not suitable."
- Non-Compounded foam sclerotherapy - 1% polidocanol endovenous microfoam (PEM) (Varithena): Meissner et al (2025) published the AVLS position statement which supports, based on the published evidence, Varithena as a safe, effective, and clinically meaningful option for the treatment of superficial venous disease. Additionally, based upon clinical experience and the published data, the AVLS supports efforts to expand the approved indications for Varithena beyond the great saphenous, accessory saphenous, and associated tributary varicosities.

The American Vein & Lymphatic Society (AVLS) (2016), previously known as the American College of Phlebology, published revised practice guidelines for the treatment of superficial venous disease of the lower leg and include the following:

- 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. Grade 1A
- Recommend named veins must have a reflux time greater than 500 milliseconds (ms), regardless of the reported vein size. Grade 1A
- Recommend endovenous thermal ablation (laser and radiofrequency) as the preferred treatment for saphenous and accessory saphenous vein incompetence. Grade 1B
- Suggest mechanical/chemical ablation (Clarivein Device) may also be used to treat truncal venous reflux. GRADE 2B
- Recommend varicose (visible) symptomatic tributary veins can be treated by stab phlebectomy, liquid sclerotherapy or foam chemical ablation. Grade 1B
- Recommend (non-visible) symptomatic tributary veins be treated by ultrasound-guided liquid sclerotherapy or foam chemical ablation. Grade 1B
- Suggest treatment of incompetent perforating veins located beneath a healed or open venous ulcer. They should have outward flow of 500 ms, with a diameter of 3.5 mm. Grade 2B

The American College of Phlebology (ACP) published guideline for the treatment of refluxing accessory saphenous veins (Gibson 2017). The ACP Committee found that the large body of work that has already been published regarding GSV and SSV incompetence, and the benefit of treatment can be confidently extrapolated to the accessory saphenous veins.

- The ACP recommends that patients with symptomatic incompetence of the accessory GSVs (AAGSV and PAGSV) be treated with endovenous thermal ablation (laser or radiofrequency) or ultrasound-guided foam sclerotherapy to reduce/eliminate symptomatology. (Grade 1)

The National Institute for Health and Care Excellence (NICE) published several interventional procedure guidance (IPG) recommendations for treatment of varicose veins. NICE finds that the current evidence on the safety and efficacy appear adequate to support the use of ultrasound-guided foam sclerotherapy (2013), endovenous mechanochemical ablation (2016), and cyanoacrylate glue occlusion (2020).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates medical devices. All medical devices, including related components, require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sep 9]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2025 Sep 9]

Endovenous Thermal Ablation (Laser or Radiofrequency)

In 1999, the VNUS Closure System, a radiofrequency device, was cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." In 2005, the VNUS RFS and RFSFlex devices were cleared by the FDA for "use in vessel and tissue coagulation including treatment of incompetent (ie, refluxing) perforator and tributary veins." In 2008, the modified VNUS ClosureFast Intravascular Catheter was cleared by the FDA through the 510(k) process. FDA product code: GEI.

In 2002, the Diomed 810 nm surgical laser and EVLT (endovenous laser therapy) procedure kit were cleared by the FDA through the 510(k) process "...for use in the endovascular coagulation of the great saphenous vein of the thigh in patients with superficial vein reflux." FDA product code: GEX.

Mechanochemical Endovenous Ablation (MOCA)

The ClariVein infusion catheter (Vasular Insights), which is utilized to perform MOCA, received Section 510(k) approval from the FDA in February 2008. It is intended for the infusion of physician-specified agents into the peripheral vasculature.

Cryostripping (cryoablation)

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2025 Sep 10]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: https://www.fda.gov/drugs/drug-safety-and-availability [accessed 2025 Sep 10]

In 2005, a modified Erbe Erbokryo cryosurgical unit (Erbe USA) was approved by the FDA for marketing through the 510(k) process. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs

Sclerotherapy

The FDA has approved various sclerosant agents (e.g., sodium tetradecyl sulfate and sodium sulfate) have been approved by the FDA for the treatment of varicose veins of the lower extremity. Published clinical trials support the safety and efficacy of conventional sclerotherapy for lower extremity varicose veins.

In 2005, the FDA granted pre-market approval to the KAVS Catheter to temporarily inhibit blood flow in isolated section of peripheral veins to inject physician prescribed medications. Evidence evaluating the safety and efficacy of KAVS sclerotherapy is lacking published peer-reviewed scientific literature.

In March 2010, the FDA approved Asclera (polidocanol) as a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. It has not been studied in larger varicose veins > 3 mm in diameter.

In November 2013, the FDA approved Varithena (polidocanol injectable foam) a sclerosant foam that utilizes micro-bubbles (microfoam) to improve the symptoms of superficial venous incompetence. Varithena is dispensed from a canister with a controlled density and a more consistent bubble size. Varithena is used for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.

Cyanoacrylate Adhesive Embolization

On Feb 20, 2015, the FDA granted pre-market approval to the VenaSeal Closure System to treat superficial varicosities of the legs through endovascular embolization. It is intended for adults with clinically symptomatic venous reflux that has been diagnosed by Duplex ultrasound. The VenaSeal Closure System is a tumescentless technique that utilizes a cyanoacrylate-based adhesive, which is injected into a diseased vein via a catheter inserted through the skin, while being monitored by ultrasound.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0524T (E/I)	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
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein) (e.g., Varithena)
36466	multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg (reported once per extremity, regardless of the number of VEINS treated) (e.g., Varithena)
36468 (NMN)	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk (e.g., Asclera)
36470	Injection of sclerosing solution; single incompetent vein (other than telangiectasia)
36471	multiple incompetent veins (other than telangiectasia), same leg (reported once per extremity, regardless of the number of veins treated)
36473 (E/I)	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated (MOCA) (e.g., ClariVein)
36474 (E/I)	subsequent vein(s) treated in a single extremity, each through separate access sites (list separately, in addition to code, for primary procedure) (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated (e.g., Venefit)
36476	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate - CAE) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein

Code	Description
	treated (e.g., VenaSeal)
36483	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure and may only be reported once per extremity, regardless of the number of additional vein(s) treated) (e.g., VenaSeal)
37241 (*E/I)	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 (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) (e.g., coil embolization) *E/I for the ICD-10-CM diagnosis codes listed below
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
37766	; more than 20 incisions
37799*	Unlisted procedure, vascular surgery *Note: Code may be used for stab phlebectomy of varicose veins; less than 10 incisions

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HCPCS Codes

Code	Description
S2202	Echosclerotherapy

ICD10 Codes

Code	Description
I83.001-I83.229	Varicose veins of lower extremities with ulcer and/or inflammation (code range)
I83.811-I83.899	Varicose veins of lower extremities with other complications (code range)
I87.2	Venous insufficiency (chronic) (peripheral)
I87.9	Disorder of vein, unspecified

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Varicose Veins of The Lower Extremity, Treatment of (LCD L33575) [accessed 2025 Sep 9]

Billing and Coding: Treatment of Varicose Veins of the Lower Extremity (A52870) [accessed 2025 Sep 9]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
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- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
04/19/01, 04/17/02, 12/19/02, 07/17/03, 03/18/04, 05/19/04, 04/21/05, 04/20/06, 04/19/07, 03/20/08, 09/17/09, 10/28/10, 05/19/11, 05/24/12, 06/20/13, 05/22/14, 06/18/15, 05/25/16, 05/18/17, 03/15/18, 03/21/19, 08/15/19, 08/20/20, 08/19/21, 08/18/22, 10/19/23, 10/17/24, 10/16/25	
Date	**Summary of Changes**
10/16/25	• Annual review, clarifying edits, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
04/19/01	• Original effective date