

MEDICAL POLICY



SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION	EFFECTIVE DATE: 04/19/01 REVISED DATE: 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
POLICY NUMBER: 7.01.47 CATEGORY: Technology Assessment	PAGE: 1 OF: 12
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

***Note: This policy does not address vein stripping and ligation. Please refer to the nationally recognized InterQual standards regarding vein stripping and ligation. ***

POLICY STATEMENT:

- I. Based on our criteria and review of peer-reviewed literature, treatment of documented symptomatic* varicose veins with reflux is considered **medically appropriate** when treated with the following techniques and when the patient has failed a course of conservative therapy:
- A. Ambulatory phlebectomy, transilluminated powered phlebectomy (TPP/TIPP, TriVex) and stab phlebectomy;
 - B. Endoluminal radiofrequency ablation (RFA) (e.g., VNUS® ClosureFAST™, ClosurePlus™, Venefit™);
 - C. Laser ablation of the saphenous vein, including endovenous laser ablation (EVLA) of the saphenous vein (ELAS) or endovenous laser treatment (EVLT); or
 - D. Compressive sclerotherapy (liquid or foam, including microfoam [e.g. Varithena™]) as an adjunct to prior or concomitant surgical treatment of venous reflux disease.
- *A patient is considered to have symptomatic varicose veins if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record:
- A. stasis ulcer of the lower leg, or
 - B. significant symptoms (e.g., pain, heaviness) that are refractory to a 12 week course of conservative therapy (e.g., utilization of compressive hose, systematic anti-inflammatories/analgesics, or activity modification), or
 - C. bleeding associated with the diseased vessels of the lower extremities, or
 - D. recurrent episodes of superficial phlebitis, or
 - E. stasis dermatitis, or
 - F. refractory dependent edema
- II. Based upon our criteria and review of peer-reviewed literature, the following are considered **not medically necessary**:
- A. Compressive sclerotherapy when performed for dermal or subdermal cosmetic lesions, for star and/or flare lesions, spider nevi, and/or telangiectasia;
 - B. Microsclerosis (injection of telangiectasia or spider veins);
 - C. Non-compressive sclerotherapy; or
 - D. Transcutaneous laser ablation of telangiectasia.
- III. Based upon our criteria and review of the peer-reviewed literature, the following are considered **investigational** as the treatments have not been medically proven to be effective:
- A. Endovascular embolization with a *cyanoacrylate adhesive* (CAE) (e.g., VenaSeal™ Closure System);
 - B. Intense pulsed light source (photothermal sclerosis) in the treatment of superficial veins;
 - C. *Mechanochemical endovenous ablation* (MOCA) (e.g., ClariVein®) (36473, 36474);
 - D. Sclerotherapy as the sole treatment of varicose tributaries with documented reflux of the saphenofemoral junction or reflux isolated to the perforator veins of the upper thigh;

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- E. Sclerotherapy of the great saphenous vein with or without associated ligation of the saphenofemoral junction;
- F. Transcutaneous laser ablation of small diameter veins.

POLICY GUIDELINES:

- I. Treatment of some varicose veins may be considered cosmetic in nature. Treatment of varicose veins for cosmetic purposes is **not medically necessary**.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

The venous system of the lower extremities consists of the *superficial* system (great and small saphenous veins) and the *deep* system (popliteal and femoral veins). These two parallel systems are interconnected via *perforator* veins. One-way valves are present at the junctions between the bifurcation point of the deep and superficial system (e.g., saphenofemoral and the saphenopopliteal junction).

Varicose veins of the superficial system are typically secondary to valve reflux (incompetence). While most are secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, a minority may be secondary to incompetence of valves within the perforator veins. Varicose veins may be asymptomatic or symptomatic. Although many varicose veins are asymptomatic, when they are present symptoms include itching, heaviness, aching legs, tension, and pain. In addition, varicose veins may be complicated by peripheral edema due to venous insufficiency, hemorrhage, thrombophlebitis, venous ulceration, and chronic skin changes. Larger varicose veins may be tortuous protruding above the surface of the skin.

Treatment options typically focus first on identifying and correcting the site of reflux, and second to redirecting venous flow through veins with intact valves. Thus surgical treatment of varicosities associated with valve incompetence is based on the following three principles:

- I. Control of the most proximal point of reflux, typically at the saphenofemoral junction, as identified by preoperative Doppler ultrasonography. Surgical ligation is the most common form of treatment of the site of reflux.
- II. Isolation of the refluxing greater saphenous from the circulation. The most typical strategy for isolation is vein stripping, which is always preceded by ligation.
- III. Removal of the varicose tributaries. Strategies for this removal may include procedures such as stab avulsion or injection sclerotherapy, either at the time of the initial treatment, or subsequently.

Over the years various different minimally invasive alternatives to ligation and stripping have been investigated. For example, sclerotherapy of the saphenous vein (as opposed to sclerotherapy of the varicose tributaries) is designed to promote fibrosis of the saphenous vein and thus remove it from the circulation.

The term “varicose veins” 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.

Ambulatory 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, turns the vein inside out and peels it away from the soft tissues of the leg through a minimal skin opening. Afterward the leg is wrapped with a compression bandage.

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Stab phlebectomy is a type of ambulatory phlebectomy also known as the “crochet hook” method of stab avulsion.

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 3-part procedure performed under general, regional, or local anesthesia, beginning with tumescent anesthesia to enhance visualization surrounding the varicose veins and to reduce operative discomfort. Tumescent 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, to reduce bruising and hematoma formation, and to decrease post-operative pain. The incisions are then closed using surgical tape or similar closures, and the leg is wrapped.

Endoluminal Radiofrequency Ablation of Varicose Veins (VNUS®)

Endoluminal radiofrequency ablation (RFA) is a minimally invasive alternative to vein ligation and stripping. The 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 and cause direct heating of the adjacent tissues. The vein is heated to approximately 120° C for 20-second intervals to sequentially heat and ablate the vein in seven cm increments.

Intense Pulsed Light Source

Intense pulsed light source or photothermal sclerosis (such as PhotoDerm® Vasculite™). The light source 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, and the vein is destroyed. It is used for smaller surface veins.

LASER (Light Amplification by the Stimulated Emission of Radiation) Ablation

Laser ablation of symptomatic varicose veins, such as but not limited to endovenous laser ablation (EVLA) of the saphenous vein (ELAS) or endovenous laser treatment (EVLT), consists of a bare-tipped or ceramic coated tip laser fiber being introduced through a small incision into the greater saphenous vein under ultrasound guidance. The laser is activated, with the resulting heat at the tip causing a reaction in the walls of the vein, and then being 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.

Transcutaneous laser ablation 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 from sight.

Laser Ablation of Telangiectasia (spider veins). Telangiectasis is a vascular lesion formed by dilation of a group of small blood vessels. Telangiectasia may appear as birthmarks or become apparent in young children. Acquired telangiectasia may also be caused by long-term sun exposure. Although the lesions may occur anywhere on the skin, they are seen most frequently on the face and thighs. Hereditary hemorrhagic telangiectasia is a disease transmitted by autosomal dominant inheritance marked by thinness of the walls of the blood vessels of the nose, skin, and digestive tract as well as a tendency to hemorrhage. Rendu-Osler Weber syndrome is a form of hereditary hemorrhagic telangiectasia.

Mechanochemical endovenous ablation (MOCA)

Mechanochemical endovenous 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

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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 radiofrequency ablation or endovenous laser ablation. The ClariVein® Infusion Catheter is utilized to perform MOCA and received 510(k) approval by the U.S. Food and Drug Administration (FDA) in February 2008. The system includes an infusion catheter, motor drive, stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature.

Sclerotherapy (Sclerosing Injection/Compression Therapy)

Sclerotherapy is a method of eliminating cutaneous varicose veins in which a sclerosing agent is injected into the veins. The principle of sclerotherapy is to cause irreversible endothelial injury in the desired location, while avoiding any damage to normal vessels that may be interconnected with the abnormal vessel being treated. Sclerotherapy usually requires no anesthesia and is performed in the outpatient setting or in the practitioner’s office setting. It is sometimes performed in situations that might otherwise require surgery. Since the saphenous vein is not visible with the naked eye, injection may be guided by ultrasonography, and the combined procedure may be referred to as *echosclerotherapy*.

Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). In November 2013, the FDA approved Varithena™, a foam sclerosant that utilizes micro bubbles (microfoam) and is composed of polidocanol. 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.

Compressive sclerotherapy involves injection of the sclerosant into an “empty” vein (elevated limb) followed by application of compressive dressings. This is the most commonly performed sclerotherapy procedure for varicose veins of the lower extremities.

Non-compressive sclerotherapy implies injection of the sclerosant into veins when the patient is upright and the veins are “full”. Technically this is thrombotic therapy, not sclerotherapy.

Other treatments

On Feb 20, 2015, the FDA granted pre-market approval of the VenaSeal Closure System to treat superficial varicosities of the legs through *endovascular embolization* and is intended for adults with clinically symptomatic venous reflux diagnosed by duplex ultrasound. The VenaSeal system is a tumescentless technique that utilizes a cyanoacrylate- based adhesive that is injected into a diseased vein via a catheter inserted through the skin, while being monitored by ultrasound. Once the adhesive is injected the area is manually compressed and the adhesive changes into a solid to seal the varicose vein.

Other proposed methods of treating varicose veins include steam injection (Steam Vein Sclerosis System [SVST™, VenoSteam™], CermaVEIN, France) and endovenous microwave ablation (Microwave Intracavitary Coagulation System, Shanghai Medical Electronics, China). Results of a small, preliminary study performed outside of the U.S., for each system, have been reported. Neither of these procedures have been approved or cleared for marketing by U.S. Food and Drug Administration (FDA). A search of the FDA website did not identify any information regarding either system.

RATIONALE:

Ambulatory phlebectomy, including but not limited to transilluminated powered phlebectomy (TPP/TIPP, TriVex) and stab phlebectomy, are variations of currently accepted surgical techniques for the treatment of varicose veins. In October 2003, the Trivex system, a device for transilluminated powered phlebectomy, was approved by the FDA. A variety of case series describe initial experience with transilluminated powered phlebectomy. In general, these studies demonstrate its technical feasibility and report that the technique is associated with decreased surgical time and decreased number of

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incisions compared to historical controls. A randomized study of 141 patients (188 limbs) compares removal of superficial varicosities with either stab avulsions or the TriVex system. Authors concluded that the TriVex system was a safe and effective method of excision of varicosities that compared well to standard stab avulsion.

Endoluminal Radiofrequency Ablation. In 1999, the VNUS® Closure™ System was approved by the FDA for endovascular coagulation of blood vessels in patients with superficial vein reflux. Clinical evidence supports the safety and efficacy of endoluminal radiofrequency ablation (such as VNUS®) of the greater saphenous vein as an alternative to saphenous vein ligation and stripping in patients with documented symptomatic saphenofemoral reflux. Although the studies have a short follow-up period, in one study of 301 limbs 89% of procedures were successful after five months with no evidence of recannulation. In a randomized controlled clinical trial of 28 patients, all cases were considered successful after a 50-day follow-up based on the absence of Duplex detected flow in the treated segments of the greater saphenous veins. In a clinical trial of 26 limbs in 26 patients the long saphenous vein was successfully occluded in 88% of patients. These studies suggest that endoluminal radiofrequency ablation of the greater saphenous vein is effective as a treatment option for symptomatic varicose veins and is associated with a faster postoperative recovery and less pain.

Cyanoacrylate Adhesive: In 2015, the VenaSeal® Closure System (Sapheon, part of Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA P140018) process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation. The VenaSeal® Closure System seals the vein using a cyanoacrylate adhesive agent. FDA product code: PJQ. Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material on contact with body fluids or tissue). The adhesive is gradually injected along the length of the vein in conjunction with ultrasound and manual compression. The acute coaptation halts blood flow through the vein until the implanted adhesive becomes fibrotically encapsulated and establishes chronic occlusion of the treated vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and surgical incisions or other skin wounds.

The VenaSeal pivotal study (VeClose), a multicenter noninferiority trial with 222 patients, compared VenaSeal with RFA for the treatment of venous reflux.^{24,25} The primary end point (the proportion of patients with complete closure of the target great saphenous vein at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs 2.4 for RFA, p=0.11). Ecchymosis at day 3 was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA (p<0.01). Scores on the AVVQ and VCSS improved to a similar extent in the 2 groups. Twenty-four-month follow-up was reported for 24 of 38 patients enrolled in a study by Almeida et al (2015).²⁶ Thirty-three-month follow-up (2015) was reported for 467 (58.7%) of 795 veins treated at 1 institution in Germany.²⁷ An inflammatory reddening of the skin was observed at 1 week posttreatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins reexamined, the sealing rate was 97.7%. This series had a high loss to follow-up. Section Summary: Cyanoacrylate Adhesive Evidence on cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with 3 months of follow-up and case series with longer follow-up. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at 3 months. Longer follow-up in trials with a larger number of patients is needed to determine durability of this treatment.

Endovascular embolization (VenaSeal™ Closure System). In April 2015, the results of a multicenter, prospective, randomized study – the VeClose study - comparing *cyanoacrylate embolization (CAE)* with radiofrequency ablation (RFA) for the treatment of symptomatic, incompetent, great saphenous veins (GSV), was published. 222 subjects with symptomatic GSV incompetence were randomly assigned to receive either CAE (n = 108) with the VenaSeal™ Sapheon Closure System or RFA (n = 114) with the ClosureFast system. 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

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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. By use of the predictive method for imputing missing data, 3-month closure rates were 99% for CAE and 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; $P = .11$). At day 3, less ecchymosis in the treated region was present after CAE compared with RFA ($P < .01$). Other adverse events occurred at a similar rate between groups and were generally mild and well tolerated. The authors concluded CAE was proven to be non-inferior to RFA for the treatment of incompetent GSVs at month 3 after the procedure; both treatment methods showed good safety profiles; CAE does not require tumescent anesthesia; and is associated with less post-procedure ecchymosis. Study follow-up will continue for 3 years to obtain long term success rates, likelihood of recanalization, and chronic venous disorder (CVD) progression. (Morrison, et al, 2015).

Endovenous Laser Ablation. In 2002, the Diomed 810 nm surgical laser and EVLT (endovenous laser therapy) procedure kit received FDA clearance for use in the endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux. There is little clinical evidence in the form of randomized prospective clinical trials to support endovenous laser ablation of the greater saphenous vein (ELAS, EVLT) or transcatheter laser ablation of small diameter veins. Available studies are small with short-term follow-up. However, available studies support the safety and efficacy of ELAS and EVLT in patients with documented symptomatic saphenofemoral reflux.

Mechanochemical Endovenous Ablation (MOCA): The evidence on mechanochemical ablation includes an RCT with short-term results and case series. Mechanochemical ablation is a combination of liquid sclerotherapy plus mechanical abrasion. One RCT with short-term follow-up has been published. These short-term results suggest that intraprocedural pain is slightly lower with mechanochemical ablation than with RFA. However, mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up is needed to evaluate the efficacy and durability of this procedure compared to established procedures. Very few peer-reviewed studies of have been published that address MOCA. Studies that have been published address the safety and efficacy of the ClariVein® system. One study (Elias and Raines, 2012), reported an industry-sponsored safety and efficacy study of the ClariVein® system. Thirty greater saphenous veins in 29 patients were treated with the device. Greater saphenous veins with diameters greater than 12 mm were excluded. 77% of veins were CEAP class 2 with 7% in class 3 (varicose veins and edema) and 16% in class 4a (varicose veins with skin changes). At 6-month follow-up 1 vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events were reported. There is insufficient evidence to permit conclusions regarding the efficacy and safety of mechanochemical endovenous ablation and further controlled studies with longer follow-up are needed.

The available data on MOCA treatment for varicose veins from studies has significant limitations that could introduce bias and imprecision. Further controlled studies with long-term effectiveness data are needed. Although they state long-term follow-up data are needed, the authors of the NICE (2016) study do recommend the use of MOCA for treatment of varicose veins. However, this recommendation is based primarily on using data from the single poor-quality, industry sponsored RCT by Lane et al. (2015), which has significant methodological limitations. These are not addressed nor included into the language of the NICE (2016) recommendation statement.

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Currently there are two active trials registered with clinicaltrials.gov. Early results of an RCT and several prospective cohort studies have been reported. In 2017, Lane et al reported on results from an RCT of 170 patients that compared ClariVein with RFA.20 Maximum visual analog scale (VAS) pain scores (out of 100) during the procedure were significantly lower in the mechanochemical ablation group (median, 15 mm) than in the RFA group (median, 34 mm; p=0.003). Average VAS pain scores during the procedure were also significantly lower in the mechanochemical ablation group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific QOL, and generic QOL scores were similar between the groups at 1 and 6 months. However, only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point.

The National Institute for Health and Clinical Evidence (United Kingdom) issued guidance on endovenous mechanochemical ablation in 2013, concluding that current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins is inadequate in quantity and quality and the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Sclerotherapy. Two sclerosants (sodium tetradecyl sulfate and sodium sulfate) have been approved by the U.S. Food and Drug Administration (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.

Compressive sclerotherapy has been found to be as effective as surgery in relieving the symptoms associated with varicose veins with few complications. Studies consider sclerotherapy successful based on the absence of Duplex detected flow in the treated segments of the greater saphenous veins, and is associated with a faster postoperative recovery.

Clinical evidence indicates that *sclerotherapy of varicose tributaries alone* is less effective than treatment that includes control of the underlying refluxing veins. However, since recurrence typically arises after 2 to 4 years, isolated sclerotherapy may be medically appropriate for patients in whom long-term control of venous reflux is not a treatment goal. Such patients may include older patients who experience recurrent bleeding from varicose blebs or older patients with recurrent thrombophlebitis in varicose tributaries.

Sclerotherapy of the greater saphenous vein raises issues regarding appropriate volume and concentration of the sclerosant and the ability to provide adequate post-procedure compression, since the greater saphenous vein is larger and deeper than telangiectatic dermal veins. Also the use of sclerotherapy, as opposed to the physical removal of the vein with stripping, raises the issue of recurrence due to recanalization.

Non-compressive sclerotherapy has not been shown to be effective in producing long-term obliteration of the incompetent veins.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)

<u>CPT:</u>	36465	Injection of non-compounded <i>foam sclerosant</i> with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein) (<i>effective 1/1/2018</i>) (e.g. Varithena™)
	36466	Injection of non-compounded <i>foam sclerosant</i> with ultrasound compression maneuvers

<p>SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION</p> <p>POLICY NUMBER: 7.01.47</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 04/19/01</p> <p>REVISED DATE: 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</p> <p>PAGE: 8 OF: 12</p>
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- to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg (reported once per extremity, regardless of the number of VEINS treated) (*effective 1/1/2018*) (e.g. Varithena™)
- 36468 (NMN) Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
- 36470 Injection of sclerosing solution; single vein
- 36471 multiple veins, 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) Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, *mechanochemical*; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (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. Covidien, 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 (E/I) Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, *cyanoacrylate* - CAE) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated (*effective 1/1/2018*)(e.g. *VenaSeal™*)
- 36483 (E/I) Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, *cyanoacrylate* - CAE) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure and may only be reported once per extremity, regardless of the number of additional vein(s) treated) (*effective 1/1/2018*) (e.g. *VenaSeal™*)
- 37241 (E/I) Vascular embolization or occlusion, inclusive of all radiological supervision and

<p>SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION</p> <p>POLICY NUMBER: 7.01.47</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 04/19/01</p> <p>REVISED DATE: 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</p> <p>PAGE: 9 OF: 12</p>
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interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) (e.g. coil embolization)

37765 Stab phlebectomy of varicose veins, one extremity; 10-20* stab incisions

37766 more than 20 incisions

37799 Unlisted procedure, vascular surgery

***Note: Used for stab phlebectomy of varicose veins; less than 10 incisions**

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HCPCS: S2202 Echosclerotherapy

ICD10: 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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<p>SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION</p> <p>POLICY NUMBER: 7.01.47</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 04/19/01</p> <p>REVISED DATE: 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</p> <p>PAGE: 10 OF: 12</p>
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<p>SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION</p> <p>POLICY NUMBER: 7.01.47</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 04/19/01</p> <p>REVISED DATE: 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</p> <p>PAGE: 11 OF: 12</p>
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KEY WORDS:

Ambulatory phlebectomy, ClariVein®, Endoluminal radiofrequency ablation, Endovascular embolization, Endovenous laser ablation, Endovenous microwave ablation, Mechanochemical endovenous ablation (MOCA), Microfoam

<p>SUBJECT: VARICOSITIES, TREATMENT ALTERNATIVES TO VEIN STRIPPING AND LIGATION</p> <p>POLICY NUMBER: 7.01.47</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 04/19/01</p> <p>REVISED DATE: 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</p> <p>PAGE: 12 OF: 12</p>
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sclerotherapy, Pulse light source, Sclerotherapy, Stab phlebectomy, Steam Vein Sclerosis System, SVS™, Varithena™, VenaSeal™, VenoSteam™, Transilluminated powered phlebectomy, VNUS.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) and a supplemental article addressing Treatment of Varicose Veins of the Lower Extremity. Please refer to the following LCD websites for Medicare Members:

LCD:

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33575&ver=33&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=varicose+veins&KeyWordLookUp=Title&KeyWordSearchType=And&FriendlyError=NoLCDIDVersion&bc=gAAAABABAAAA&>

Article:

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52870&ver=24&LCDId=33575&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=varicose+veins&KeyWordLookUp=Title&KeyWordSearchType=And&FriendlyError=NoLCDIDVersion&bc=gAAAABAAgAAA&>