MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Varicosities, Treatment Alternatives to Vein Stripping and Ligation**
Policy Number	**7.01.47**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval 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, 03/21/19, 08/15/19, 08/20/20, 08/19/21, 08/18/22**
Current Effective Date	**02/18/21, 08/19/21, 08/18/22**
Deleted Date	**N/A**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

******Note: This policy addresses treatment of the veins of the lower extremity (e.g., great and small saphenous veins, tributary veins, and lower extremity perforator veins). This policy does not address vein stripping and ligation. Please refer to the nationally recognized InterQual standards regarding vein stripping and ligation. Embolization, ablation, and sclerotherapy of the ovarian, internal iliac, or gonadal veins for treatment of pelvic congestion syndrome or varicoceles are not addressed in this policy.******

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, the following techniques for treatment of documented, symptomatic* varicose veins with reflux have been medically proven to be effective and, therefore, are considered **medically appropriate** when the patient has failed a course of conservative therapy (including utilization of compressive hose, systematic anti-inflammatories/analgesics, and activity modification):
   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);
   D. Compressive sclerotherapy (liquid or foam, including microfoam (e.g., Varithena)) as an adjunct to prior or concomitant surgical treatment of venous reflux disease; and
   E. Endovascular embolization with a cyanoacrylate adhesive (CAE) (e.g., VenaSeal Closure System).

* 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:
- stasis ulcer of the lower leg;
- significant symptoms (e.g., pain, heaviness) that are refractory to a 12-week course of conservative therapy (including utilization of compressive hose, systematic anti-inflammatories/analgesics, and activity modification);

- bleeding associated with the diseased vessels of the lower extremities;
- recurrent episodes of superficial phlebitis;
- stasis dermatitis; or
- refractory dependent edema.

II. Based upon our criteria and assessment of the peer-reviewed literature, the following treatments do not improve patient outcomes and, therefore, are considered **not medically necessary**:
   A. Compressive sclerotherapy, when performed for dermal or subdermal cosmetic lesions, star and/or flare lesions, spider nevi, and/or telangiectasia;
   B. Microsclerosis (injection of telangiectasia or spider veins);
   C. Non-compressive sclerotherapy; and
   D. Transcutaneous laser ablation of telangiectasia.

III. Based upon our criteria and assessment of the peer-reviewed literature, the following treatments have not been medically proven to be effective and, therefore, are considered **investigational**:
   A. Intense pulsed light source (photothermal sclerosis) for the treatment of superficial veins;
   B. Mechanochemical endovenous ablation (MOCA) (e.g., ClariVein) (CPT codes: 36473, 36474);
   C. 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;
   D. Sclerotherapy of the great saphenous vein, with or without associated ligation of the saphenofemoral junction;
   E. Transcutaneous laser ablation of small diameter veins; and
   F. Coil embolization.

Refer to Corporate Medical Policy #7.01.11 Cosmetic and Reconstructive Procedures, for treatment of facial telangiectasia.

POLICY GUIDELINE

I. Treatment of asymptomatic varicose veins may be considered cosmetic in nature. Treatment of varicose veins for cosmetic purposes is considered **not medically necessary**.

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 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, on 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 pre-operative 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 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 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.

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, causing direct heating of the adjacent tissues. The vein is heated to approximately 120^{o} C for 20-second intervals, to sequentially heat and ablate the vein in 7 cm increments.

Intense Pulsed Light Source
Intense pulsed light source or photothermal sclerosis (such as PhotoDerm Vasculite). 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. 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 endovenous laser ablation (EVLA) of the saphenous vein (ELAS) or endovenous laser treatment (EVLT), 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 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.

Another laser procedure is used for 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. It is 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)
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. The ClariVein Infusion Catheter, which is utilized to perform MOCA, received Section 510(k) approval from the FDA in February 2008. The system includes an infusion catheter, motor drive, stopcock, and syringe. It is intended for the infusion of physician-specified agents into 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. As the saphenous vein is not visible with the naked eye, injection may be guided by ultrasonography; the combined procedure is sometimes 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 involves the injection of sclerosant into veins while the patient is upright and the veins are "full." Technically, this is thrombotic therapy, not sclerotherapy.

Cyanoacrylate Adhesive
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. 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.

Other treatments

Other proposed methods of treating varicose veins include steam injection (Steam Vein Sclerosis System [SVS, 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., have been reported for each system. Neither of these procedures has been approved or cleared for marketing by the FDA. A search of the FDA website did not identify any information regarding either system.

RATIONALE

Ambulatory phlebectomy

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. Various 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 incisions, compared to historical controls. A randomized study of 141 patients (188 limbs) compared 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 RFA (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 RFA of the greater saphenous vein is effective as a treatment option for symptomatic varicose veins and is associated with faster post-operative recovery and less pain.

Cyanoacrylate Adhesive

The VenaSeal pivotal study (VeClose), 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, $p=0.11$). 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 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 et al, 2015).

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

Endovenous Laser Ablation

In 2002, the Diomed 810 nm surgical laser and EVLT 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 ablationof the greater saphenous vein (ELAS, EVLT) or transcutaneous 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.

The American College of Phlebology (ACP) published revised practice guidelines for the treatment of superficial venous disease of the lower leg (ACP, 2014, rev 02/03/16). ACP recommended endovenous thermal ablation (laser and radiofrequency) as the preferred treatment for saphenopus and accessory saphenous vein incompetence (Grade 1B: strong recommendation, moderate quality of evidence).

Mechanochemical Endovenous Ablation (MOCA)

The evidence on MOCA includes one randomized, controlled trial (RCT) with short-term results and case series. MOCA is a combination of liquid sclerotherapy plus mechanical abrasion. Published reports of these short-term results suggest that intraprocedural pain is slightly lower with mechanochemical ablation than with RFA. However, MOCA 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. Of the veins analyzed, 77% were CEAP class 2, with 7% in class 3 (varicose veins and edema) and 16% in class 4a (varicose veins with skin changes). At six-month follow-up, one vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events was reported. There is insufficient evidence to permit conclusions regarding the efficacy and safety of MOCA, and further controlled studies with longer follow-up are needed.

The available data from studies on MOCA treatment for varicose veins have significant limitations that could introduce bias and imprecision. Further controlled studies with long-term effectivenss data are needed. Although the authors of the NICE (2016) study state that long-term follow-up data are needed, they 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 had significant methodological limitations. These are not addressed or included in the language of the NICE (2016) recommendation statement.

In 2017, Lane et al. 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.

Sclerotherapy
Various sclerosants (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.
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 sclerotherapy is associated with a faster post-operative recovery.

Clinical evidence indicates that sclerotherapy of varicose tributaries alone is less effective than treatment that includes control of the underlying refluxing veins. However, as recurrence typically arises after two to four years, isolated sclerotherapy may be medically appropriate for patients in whom long-term control of venous reflux is not a treatment goal (for example, older patients who experience recurrent bleeding from varicose blebs or who have 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, as 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.

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 et al. 1999; Viani et al. 2014; and Kayssi et al. 2017). Additional clinical trials are necessary, to develop strong conclusions regarding safety and efficacy.

CODES

- *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).*

CPT Codes

Code	Description
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
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)

Code	Description
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) (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	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., *cyanoacrylat*e - CAE) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein 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	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
37799	Unlisted procedure, vascular surgery **Note: Used for stab phlebectomy of varicose veins; less than 10 incisions**

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)

Code	Description
I87.9	Disorder of vein, unspecified

REFERENCES

*American College of Phlebology. Treatment of superficial venous disease of the lower leg. Practice guidelines. 2016 Feb 03. [https://www.myavls.org/assets/pdf/SuperficialVenousDiseaseGuidelinesPMS313-02.03.16.pdf].accessed 07/7/22.

Brittenden J, et al. Five-year outcomes of a randomized trial of treatments for varicose veins. N Engl J Med 2019 Sep 5;381(10):912-922.

*Carroll C, et al. Systematic review, network meta-analysis and exploratory cost-effectiveness model of randomized trials of minimally invasive techniques versus surgery for varicose veins. Br J Surg 2014 Aug;101(9):1040-52.

Chan YC, et al. Predictors of Recanalization for Incompetent Great Saphenous Veins Treated with Cyanoacrylate Glue. J Vasc Interv Radiol 2017 May;28(5):665-671.

*Elias S and Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. Phlebology 2012;27(2):67-72.

Epstein D, et al. Cost-effectiveness of current and emerging treatments of varicose veins. Value Health 2018 Aug;21(8):911-920.

Gibson K, et al. Twenty-four month results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord 2018 Sep;6(5):606-613.

*Gloviczki P, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2011 May;53(5 Suppl):2S-48S.

Gohel MS. The ongoing search for clarity regarding the role of cyanoacrylate closure for superficial venous reflux. J Vasc Surg Venous Lymphat Disord 2020 Nov;8(6):990.

Hamann SAS, et al. Randomized clinical trial of endovenous laser ablation versus direct and indirect radiofrequency ablation for the treatment of great saphenous varicose veins. Br J Surg 2019 Jul;106(8):998-1004.

Hassanin A, et al. A systematic review and meta-analysis of comparative studies comparing nonthermal versus thermal endovenous ablation in superficial venous incompetence. J Vasc Surg Venous Lymphat Disord 2019 Nov;7(6):902-913.e3.

Holewijn S, et al. Two-year results of a multicenter randomized controlled trial comparing mechanochemical endovenous ablation to radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA Trial). J Vasc Surg Venous Lymphat Disord 2019 May;7(3):364-374.

Kawai Y, et al. Endovenous laser ablation with and without concomitant phlebectomy for the treatment of varicose veins: a retrospective analysis of 954 limbs. Ann Vasc Surg 2020 Jul;66:344-350.

*Kayssi A, et al. Combined coil embolization and foam sclerotherapy for the management of varicose veins. Ann Vasc Surg 2017 Jan;38:293-297.

Kim SY, et al. Mechanochemical ablation as an alternative to venous ulcer healing compared with thermal ablation. J Vasc Surg Venous Lymphat Disord 2019 Sep;7(5):699-705.

Kolluri R, et al. Network meta-analysis to compare VenaSeal with other superficial venous therapies for chronic venous insufficiency. J Vasc Surg Venous Lymphat Disord 2020 May;8(3):472-481.e3.

Kolvenbach RR, et al. The V-block occlusion stent and sclerotherapy device for varicose vein treatment: a retrospective analysis. Ann Vasc Surg 2019 Aug;59:231-236.

Lam LY et al. A multicenter, randomized, dose-finding study of mechanochemical ablation using ClariVein and liquid polidocanol for great saphenous vein incompetence. Vasc Surg Venous Lymphat Disord 2022 Jul;10(4):856-64.

*Lane T, et al. A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins - Final results of the Venefit versus Clarivein for varicose veins trial. Phlebology Mar 2017;32(2):89-98

*Lane TRA, et al. Retrograde inversion stripping as a complication of the ClariVein® mechanochemical venous ablation procedure. Annals of the Royal College of Surgeons 97: e18–20 (2015)

Liu X, et al. A retrospective cohort study comparing two treatments for active venous leg ulcers. Medicine (Baltimore) 2020 Feb;99(8):e19317.

Masuda E, et al. The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology. J Vasc Surg Venous Lymphat Disord 2020 Jul;8(4):505-525.e4.

Mohamed AH, et al. A randomized controlled trial of endovenous laser ablation versus mechanochemical ablation with ClariVein in the management of superficial venous incompetence (LAMA Trial). Ann Surg 2020 Jan 21 [Online ahead of print].

Mohamed AH, et al. A randomized controlled trial of endovenous laser ablation versus mechanochemical ablation with clarivein in the management of superficial venous incompetence (LAMA trial). Annals of Surgery 2021 Jun;273(6):e188-95.

Morrison N, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg 2015 Apr;61(4):985-94.

Morrison N, et al. Comparison of cyanoacrylate embolization and radiofrequency ablation for the treatment of incompetent great saphenous veins: 36-month outcomes of VeClose randomized controlled trial. Phlebology 2018 Nov 7; 0(0)1-11.

Morrison N, et al. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venbous Lymphat Disord 2020 Mar 20;S2213-333X(20)30105-0 [Online ahead of print].

NICE Guidelines Endovenous mechanochemical ablation for varicose veins. Interventional procedures guidance [IPG557]. 2016 May 25 [https://www.nice.org.uk/guidance/ipg557] accessed 07/7/22.

*Sarvananthan T, et al. Neurological complications of sclerotherapy for varicose veins. J Vasc Surg 2012 Jan;55(1):243-51.

Tang TY, et al. ClariVein® - Early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins. Phlebology 2017 Feb;32(1):6-12. doi: 10.1177/0268355516630154

Tang TY, et al. Early results (3 months) of an Asian prospective multi-centre VenaSeal™ real world post-market evaluation to investigate the efficacy and safety of cyanoacrylate endovenous ablation for varicose veins (ASVS Study). J Vasc Surg Venous Lymphat Disord 2020 May 6;S2213-333X(20)30238-9 [Online ahead of print].

Tawfik AM, et al. Laser ablation versus mechanochemical ablation in the treatment of primary varicose veins: a randomized clinical trial. J Vasc Surg Venous Lymphat Disord 2020 Mar;8(2):211-215.

Thierens N, et al. Five-year outcomes of mechano-chemical ablation of primary great saphenous vein incompetence. Phlebology 2020 May;35(4):255-261.

*Tisi PV, et al. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev 2006(4):CD001732.

U.S. Food and Drug Administration. Drug approval package. Varithena, (polidocanol) injectable foam. 2014 Jul 23 [https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/205098orig1s018ltr.pdf] accessed 07/7/22.

Vähäaho S, et al. Randomized clinical trial of mechanochemical and endovenous thermal ablation of great saphenous varicose veins. Br J Surg 2019 Apr;106(5):548-554.

Vähäaho S, et al. Three-year results of a randomized controlled trial comparing mechanochemical and thermal ablation in the treatment of insufficient great saphenous veins. J Vasc Surg Venous Lymphat Disord 2021 May;9(3):652-659.

*van Dijk LC, et al. Ultrasound-guided percutaneous coil embolization of incompetent perforating veins: not effective for treatment of venous ulcers and recurrent varicosities. J Vasc Interv Radiol 1999 Oct;10(9):1271-4.

*van Eekeren RR, et al. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. J Vasc Surg 2013 Feb;57(2):445-50.

*van Eekeren RR, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011 Jun;18(3):328-34.

*Viani MP, et al. One-shot scleroembolization: a new technique for the treatment of varicose veins disease of lower extremities. Preliminary results. Phebology 2014 Dec;29(10):694-7.

Whiteley MS, et al. Mechanochemical ablation causes endothelial and medial damage to the vein wall resulting in deeper penetration of sclerosant compared with sclerotherapy alone in extrafascial great saphenous vein using an ex vivo model. J Vasc Surg Venous Lymphat Disord 2017 May;5(3):370-377

Woo HY, et al. Outcome of ClosureFAST radiofrequency ablation for large-diameter incompetent great saphenous vein. Ann Surg Treat Res 2019 Jun;96(6):313-318.

*Key Article

KEY WORDS

Ambulatory phlebectomy, ClariVein, Endoluminal radiofrequency ablation, Endovascular embolization, Endovenous laser ablation, Endovenous microwave ablation, Mechanochemical endovenous ablation (MOCA), Microfoam 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/view/lcd.aspx?lcdid=33575&ver=43&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=varicose+veins&KeyWordLookUp=Title&KeyWordSearchType=And&FriendlyError=NoLCDIDVersion&bc=gAAAABAAgAAA&=

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&