Miscellaneous Treatment for Varicose Veins/Venous Insufficiency

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DESCRIPTION

The venous system of the lower extremities is separated into two main systems: the deep venous and the superficial venous system. The two systems are connected by perforator veins. The deep venous system comprises the popliteal and femoral veins; the superficial venous system comprises the great saphenous (GSV) and small saphenous (SSV) veins (formerly called the short or lesser saphenous vein). The GSV generally measures 3–4 mm in diameter in the upper thigh; the GSV meets the femoral vein at the saphenofemoral junction (SFJ). The SSV is not usually larger than 3 mm in diameter and connects with the deep veins at the saphenopopliteal junction (SPJ) in the knee area. The accessory saphenous vein (ASV) arises from the GSV and is considered a GSV tributary. Anatomically the ASV originates at the distal thigh, courses upwards outside the saphenous compartment parallel to the GSV, and drains into the femoral vein, GSV or tributary above or below the SFJ. Perforator veins are veins of the lower extremity that drain from the superficial veins to the deep veins. Varicose tributaries are veins that empty into a larger vein.

GSV reflux is the most common source of chronic venous insufficiency in up to 70% of individuals, followed by the SSV in 18- 20% and AASV lest commonly in 10%. Incompetence of the superficial venous system typically results from failure of valves at the SFJ and the SPJ with resulting pressure that is worse at the more distal area of the vein. Incompetence of the perforating veins also leads to increased pressure in the superficial venous system due to the pump mechanism of the calf.

Varicose veins vary in size from 3–10 mm, on average. Symptoms that have been associated with varicose veins of the lower extremities result from inadequate emptying of the vein (i.e., venous insufficiency) and include pain, cramping, aching, burning, throbbing, swelling and the feeling of heaviness or fatigue in the leg. Typically, symptoms are exacerbated by standing and warm weather. Saphenous varicose veins can ultimately result in intractable ulcerations and recurrent bleeding. Patients with larger varicosities (e.g., varicose veins greater than 3 mm in diameter) are more prone to thrombophlebitis and other complications than those with smaller varicosities. Chronic cellulitis may also be associated with varicosities.

Varicose veins of the upper extremity are rare and there are few reports in the published, peer-reviewed medical literature dealing with the management of upper extremity varicosities. Varicose veins may develop during pregnancy. Treatment is not medically necessary as most varicosities will spontaneously resolve within 4–6 months after delivery.

Telangiectasis are permanently dilated blood vessels, also called spider veins that create fine red or blue lines on the skin. They are similar to varicose veins but are limited to the dermis and are not usually more than 3 mm in diameter, they are not typically associated with symptoms, and treatment is generally considered cosmetic in nature (*See medical policy 10.01.02 Cosmetic and Reconstructive Services*).

The diagnosis of chronic venous disease is suggested by the presence of typical symptoms (leg pain, fatigue, heaviness) and physical examination findings. Venous duplex ultrasound examination confirms the diagnosis demonstrating the presence of venous reflux (>500 milliseconds for superficial or perforator veins; >1000 milliseconds for deep veins). The majority of symptomatic patients should undergo venous duplex ultrasonography to evaluate the nature and extent of venous reflux, which impacts the choice of treatment. Any combination of superficial, perforator or deep venous reflux, or deep venous obstruction can be present.

The CEAP classification is a method commonly used to document the severity of chronic venous disease and is based on clinical presentation (C), etiology (E), anatomy (A), and pathophysiology (P). Each classification can be further defined as follows:

Class	Definition
C - Clinical Classification	**C0:** No visible or palpable signs of venous disease

	C1: Telangiectases or reticular veins **C2**: Varicose veins **C3**: Edema **C4a:** Pigmentation and/or eczema **C4b:** Lipodermatosclerosis and/or atrophie blanche **C5**: Healed venous ulcer **C6**: Active venous ulcer **CS**: Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction **CA:** Asymptomatic
E - Etiology	**Ec:** Congenital **Ep:** Primary **Es:** Secondary (post-thrombotic) **En:** No venous etiology identified
A - Anatomy	**As:** Superficial veins **Ap:** Perforator veins **Ad:** Deep veins **An:** No venous location identified
P - Pathophysiology	**Pr:** Reflux **Po:** Obstruction **Pr.o:** Reflux and obstruction **Pn:** No venous pathophysiology identifiable

Classification of disease starts with an initial assessment and is often not entirely completed until after surgery and histopathologic assessment. As a result, it is recommended that CEAP classification value be followed by the date of examination. Venous disease can be reclassified at any given time.

Conservative medical practices that may be used in the management of varicose veins include leg elevation, analgesia for symptom relief and avoidance of prolonged periods of standing. Compression therapy, the use of custom-fit compression stockings with pressure gradients, a mainstay of initial/conservative management, is routinely attempted prior to stripping, ligation, sclerotherapy, or other, more invasive procedures. The amount of compression required for treatment of stasis dermatitis or ulceration is between 35- and 40-mm Hg, for varicose veins, for mild edema and leg fatigue the recommended

pressure is 20 to 30 mm Hg. When conservative measures fail, treatment options rely on identifying and correcting the site of reflux and on redirecting the flow of blood through veins with properly functioning valves. No single method of treatment is universally employed in the literature; the intervention selected is generally dependent upon the competency of deep and perforating veins, and the site and degree of reflux. Surgery is commonly used to treat mainstem varicose veins.

Initial treatment may be referred to as primary treatment and secondary treatment may be referred to as retreatment. Many patients require a combination of techniques to correct symptoms associated with venous insufficiency, most of which can be performed in a single treatment session.

Clinical Context and Therapy Purpose
Treatment of venous reflux/venous insufficiency seeks to reduce abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of elevation of the extremities, graded compression, and wound care when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or the deep venous system. The competence of any single valve is not static and may be pressure dependent. For example, accessory saphenous veins may have independent saphenofemoral or saphenopopliteal junctions that become incompetent when the great or small saphenous veins are eliminated, and blood flow is diverted through the accessory veins.

This document will address the following miscellaneous treatments/therapies that may be utilized in the treatment of varicose veins/venous insufficiency:

- Coil embolization
- CryoStripping (cryoablation, cryofreezing, transilluminated cryosurgery)
- Cyanoacrylate adhesive (VenaSeal Closure System)
- Endomechanical ablative approaches using rotating catheter (e.g., ClariVein Catheter) (e.g., mechanical occlusion chemically assisted ablation [MOCA], mechanic-chemical endovenous ablation [MCEA], mechanically enhanced endovenous chemical ablation [MEECA)
- Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure)
- Transilluminated powered phlebectomy (TIPP, TriVex)

Population
The relevant populations of interest are those who have symptomatic varicose veins/venous insufficiency.

Interventions
The treatment/therapies being considered are the following miscellaneous treatments

that may be utilized in the treatment of varicose veins/venous insufficiency:

- Coil embolization
- CryoStripping (cryoablation, cryofreezing, transilluminated cryosurgery)
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- Transilluminated powered phlebectomy (TIPP, TriVex)

Comparators

Established treatments for varicose veins/venous insufficiency are conservative medical treatment/therapies consisting of the following: elevation of the extremities, graded compression, and wound care when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or the deep venous system. The competence of any single valve is not static and may be pressure dependent.

Outcomes

Outcomes of interest for venous interventions include healing and recurrence, recanalization of the vein, and neovascularization. Recanalization is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques. Neovascularization is the proliferation of new blood vessels in tissue and occurs more frequently following vein stripping. Direct comparisons of the durability of endovenous and surgical procedures are complicated by these mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

Specific measures may include the visual analog score (VAS) for pain, the Venous Clinical Severity Score (VCSS), and the Aberdeen Varicose Veins Questionnaire (AVVQ). AVVQ scores range from 0 to 100 (worst possible quality of life). Follow-up at 1 and 2 years from randomized controlled trials (RCTs) is of interest to monitor treatment success (vein occlusion and recanalization), with follow-up to 5 years to assess durability of the treatment.

Coil Embolization

Coil embolization, also known as coil occlusion, involves the use of a coil combined with a sclerosant to occlude the vein and is under investigation for treatment of lower extremity varicose veins. It is a technique generally reserved for larger diameter veins

such as perforating veins; the coil is curled up into the vein and may involve the use of more than one coil. Evidence in the peer-reviewed published literature evaluating this method of treatment for lower extremity varicosities is very limited, additional randomized clinical trials (RCTs) are necessary to develop strong conclusions regarding safety and efficacy. The evidence is insufficient in determining this technology improves net health outcome

CryoStripping (Cryoablation, Cryofreezing, Transilluminated Cryosurgery)
Cryoablation uses extreme cold to cause injury to the vessel. Cryostripping of the GSV has been suggested as an alternative approach to traditional ligation and stripping. During this procedure, a cryoprobe is passed through the GSV, the probe freeze attaches to the GSV, and stripping is performed by pulling back the probe. Theoretically cryosurgery requires less time, has fewer complications and results in less hospital day. Results of cryotherapy procedures for treatment of varicose veins in the published scientific literature are mixed and do not lend strong support to improved clinical outcomes when compared to more conventional methods of varicose vein treatment. Further randomized clinical trials (RCTs) are needed to demonstrate safety, efficacy, and the clinical utility of cryostripping including cryoablation, cryofreezing, transilluminated cryosurgery. The evidence is insufficient in determining this technology improves net health outcomes.

Cyanoacrylate Adhesive
Cyanoacrylate adhesive (VenaSeal Closure System) 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). 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 radiofrequency ablation (RFA) for the treatment of venous reflux. The pivotal registration study for the VeClose study and follow-up through 36 months have been published. These reports are summarized in the below tables. The primary endpoint (the proportion of patients with complete closure of the target great saphenous vein (GSV) at 3 months measured by ultrasound) was noninferior to radiofrequency ablation (RFA), with a 99% closure rate for VenaSeal compared with 96% for RFA. The secondary endpoint (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal versus 2.4 for RFA, p=.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 ($p<.01$). Scores on the AVVQ and Venous Clinical Severity Score improved to a similar extent in both groups. The mean time to return to work in a prospective cohort of 50 patients reported by Gibson et. al. (2017) was 0.2 days

For the cyanoacrylate (CAC) and radiofrequency ablation (RFA) groups, the complete occlusion rates were 97.2% and 97.0%. Freedom from recanalization was also similar between the 2 groups (p=.08). Twenty-four-month results were reported by Gibson et. al. (2018), which included 171 patients (87 from CAC and 84 from RFA). Thirty-six-month results were reported by Morrison et. al. (2019), with follow-up on 146 (66%) patients (72 from CAC and 74 from RFA). Loss to follow-up was similar in the two groups. The complete closure rates for CAC and RFA were 94.4% and 91.9% (p=.005 for non-inferiority), respectively. Recanalization-free survival through 36 months was not statistically different for the 2 groups. No significant device- or procedure-related adverse events were reported for either group.

VariClose cyanoacrylate (CAC) was compared with radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) by Eroglu et. al. (2018) in a randomized controlled trial (RCT) with 525 patients (below tables). Periprocedural outcomes showed a shorter intervention time, less pain, and shorter return to work with CAC compared to endovenous thermal ablation (EVLA) (see below tables). There was no significant difference in occlusion rates between the three treatments at 6-, 12-, and 24-month follow-up.

Summary of Key RTC Characteristics

Study Trial	**Countries**	**Sites**	**Dates**	**Particpants**	**Interventions[2]**
FDA SSED (2015); Morrison et al (2015, 2017, 2019); Gibson et al (2018); [VeClose trial]	US	10	2013-2014	Age ≥21 and ≤ 70 years with symptomatic[1] GSV reflux and CEAP C2-C4b GSV diameter while standing of 3-12 mm	Active 108 VenaSeal CAC Comparator 114 RFA

CAC: cyanoacrylate ; CEAP: Clinical Etiology Anatomy Pathophysiology; EVLA: endovenous laser ablation; FDA: Food and Drug Administration; GSV: great saphenous vein; NR: not reported; RCT: randomized controlled trial; RFA: radiofrequency ablation; SSV: small saphenous vein; SSED; Summary of Safety and Effectiveness Data;
[1] One or more of the following symptoms related to the target vein: aching, throbbing, heaviness, fatigue, pruritus, night cramps, restlessness, generalized pain or discomfort, swelling.
[2] Protocol mandated use of compression stockings for 7 days post-procedure

Periprocedural Outcomes

Study Trial: Eroglu and Yasim (2018)	Duration of Procedure min (SD)	Average Periprocedure Pain[1]	2 or More Analgesics Used Daily n (%)	1 Day to Return to Work n (%)	2 Days to Return to Work n (%)	3 or More Days to Return to Work n (%)
N	503	503	456	456	456	456
VariClose	15.3 (2.6)	1 (mild)	105 (62.5)	161 (95.8)	7 (4.2)	0 (0)
RFA	27.3 (7.7)	2 (moderate)	98 (65.8)	75 (50.3)	53 (35.6)	21 (14.1)
EVLA	35.0 (5.2)	2 (moderate)	105 (75.5)	105 (75.5)	24 (17.3)	10 (7.2)
p-Value[2]	<.001		.1472	<.0012		

[1]Scale of 1 to 4; [2]overall p-Value
EVLA: endovenous laser ablation; RFA: radiofrequency ablation.

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

Summary of Evidence
Evidence assessing cyanoacrylate adhesive (CAC) for the treatment of varicose veins/venous insufficiency includes a multicenter noninferiority trial with follow-up through 36 months, a randomized controlled trial (RCT) with follow-up through 24 months, and a prospective cohort with 30-month follow-up. The short-term efficacy of VenaSeal CAC has been shown to be noninferior to radiofrequency ablation (RFA) at up to 36-month follow-up. At 24 and 36 months the study had greater than 20% loss to follow-up, but loss to follow-up was similar in the 2 groups at the long-term follow-up and is not expected to influence the comparative results. A second RCT (n=525) with the same active CAC ingredient (N-butyl cyanoacrylate) that is currently available outside of the U.S. found no significant differences in vein closure between CAC and thermal ablation controls at 24-month follow-up. The CAC procedure and return to work were

shorter and pain scores were lower compared to thermal ablation; the subjective pain scores may have been influenced by differing expectations in this study. A prospective cohort reported high closure rates at 30 months. A five-year extension study of VeClose trial showed at 36 and 60 months of follow-up, no new recanalization events occurred in either group. At study-end, freedom from recanalization in the randomized VenaSeal and RFA groups were 91.4% and 85.2%, respectively and both groups demonstrated sustained improvements in quality-of-life scores. Furthermore, 41.1% of the VenaSeal group and 39.4% of the RFA group were at least two CEAP clinical classes lower than at baseline. Overall, results indicate that outcomes from CAC are at least as good as thermal ablation techniques, the current standard of care. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Endomechanical Ablative Approaches using Rotating Catheter
Minimally invasive methods for treatment of varicose veins continue to evolve. One method under current investigation is the endomechanical ablative approach to varicose vein treatment utilizing a percutaneous infusion catheter. The procedure is also referred to as mechanical occlusion chemically assisted ablation (MOCA), mechanic-chemical endovenous ablation (MCEA), and mechanically enhanced endovenous chemical ablation (MEECA).The approach involves the use of a special catheter (ClariVein) which combines two modalities of treatment for varicose veins: endovenous mechanical vein destruction with a rotating wire and the simultaneous infusion of an FDA approved liquid sclerosant, sodium tetradecyl sulfate to enhance venous occlusion. This mechanical-chemical ablative modality (endomechanical ablative approach) is described as minimally invasive and purported to accomplish great saphenous vein occlusion without the use of tumescent anesthesia.

Evidence in the published peer-reviewed medical literature evaluating endomechanical ablative approaches using rotating catheter is in the form few randomized controlled trials. Evidence in the peer-reviewed published scientific literature supporting long-term safety and efficacy of endomechanical ablative approaches to treatment of varicose veins is currently lacking. Randomized controlled trials comparing MOCA anatomical success to endothermal ablation are few. Evidence lends support to improved quality of life scores and clinical success in the short to mid-term, however anatomic success (occlusion rate) has been shown to deteriorate at one- to- three-year follow-up; additional well-designed randomized clinical trials (RCTs) are needed to support the long- term efficacy of this approach. The evidence is insufficient in determining this technology improves net health outcomes.

Endovenous Catheter Directed Chemical Ablation with Balloon Isolation
The KAVS procedure [catheter-assisted vein sclerotherapy] procedure involves an intravascular catheter with a balloon at the distal end to temporarily block the blood flow to that segment of the vein being targeted for sclerotherapy; this may also be referred to as endovenous catheter directed chemical ablation with balloon isolation. Evidence evaluating the safety and efficacy of endovenous catheter-directed chemical ablation in conjunction with balloon isolation as a treatment of varicose veins has not been published

in the peer-reviewed literature. The evidence is insufficient in determining this technology improves net health outcomes.

Endovascular embolization with cyanoacrylate adhesive (VenoSeal Closure System)
VenoSeal Closure System uses cyanoacrylate embolization (CAE) and does not require tumescent anesthesia; a cyanoacrylate adhesive is injected into the vein via a catheter inserted through the skin under ultrasound, the vein is compressed, and the adhesive material changes into a solid to seal the varicose vein.

In 2020, Morrison et. al. published 60 - month results for 89 subjects: 47 from the cyanoacrylate embolization (CAE) group, 33 from the radiofrequency ablation (RFA) group, in addition to 9 roll-in CAE subjects. At 60 months CAE continued to demonstrate noninferiority to RFA, both CAE and RFA were effective in achieving complete target vein closure with no serious long-term device or procedure related adverse events. The primary author noted that all of his subjects had cyanoacrylate still visible at 60 months, suggesting it was a permanent implant. This study is limited by the lack of blinding as noted by the authors and the small number of subjects available at the final five- year outcome.

Summary of Evidence
Evidence in the published peer-reviewed medical literature evaluating cyanoacrylate adhesive embolization (VenaSeal) includes randomized controlled trials (RCTs) and systematic reviews. Although there is a growing body of evidence evaluating cyanoacrylate adhesive embolization (VenaSeal) in the peer-reviewed literature at present there is insufficient evidence in the literature to firmly establish long-term safety and efficacy of cyanoacrylate adhesive (VenaSeal) for treatment of varicose veins. Outcomes extending beyond 36 months are limited and although the adhesive in theory breaks down over time, in at least one clinical trial it remained present at five years post procedure. Uncertainty remains regarding the comparative effectiveness of the VenaSeal System with other endovenous techniques due to the lack of well-designed comparative trials. Additional well-designed RCTs consisting of large sample populations, with long term outcomes that consistently demonstrate anatomic and clinical success are needed to firmly establish safety and efficacy. The evidence is insufficient in determining this technology improves net health outcomes.

Transilluminated Powered Phlebectomy (TIPP)
Transilluminated Powered Phlebectomy (TIPP), which is similar to ambulatory phlebectomy, is another minimally invasive alternative to standard surgery for the treatment of symptomatic varicosities. Also known as the TriVex procedure, TIPP involves endoscopic resection and ablation of the superficial varicosity.

Subcutaneous transillumination and tumescent anesthesia help visualize and locate the varicosity, while subcutaneous vein ablation is performed using a powered resector to obliterate the vein. Tumescent anesthesia involves the infusion of large amounts of saline and lidocaine to reduce hemorrhage and of epinephrine to delay absorption of the

lidocaine. During this procedure, the veins are marked with a marker, and a bright light is introduced into the leg through a small incision (2–3 cm) to enhance visualization of the veins. The power vein resector is then inserted to cut and remove the vein through suction.

Proponents of this method assert the illuminating light allows quicker and more accurate removal of the vein, leading to a more effective yet less traumatic procedure. TIPP is intended for patients who are suitable candidates for conventional ambulatory phlebectomy and may also be used as an adjunctive method to other varicose vein treatments (e.g., ligation and stripping). A reported advantage of TIPP is the need for fewer incisions and that cosmetic outcomes do not appear to be superior to conventional ligation/excision techniques.

Summary of Evidence
Evidence evaluating Transilluminated Powered Phlebectomy (TIPP) for the treatment of varicose veins is primarily in the form of published reviews, few comparative trials (few involving randomized groups) and both retrospective and prospective case series involving small populations and evaluating short-term outcomes. Overall evidence in the published, peer-reviewed, scientific literature does not lead to strong conclusions that TIPP results in clinical outcomes (e.g., improved pain, less varicose vein recurrence) that are as good as treatment with standard conventional methods (i.e., hook phlebectomy). Furthermore, long-term safety and efficacy of the procedure has not been adequately demonstrated. The evidence is insufficient in determining this technology improves net health outcomes.

Practice Guideline and Position Statements

American Venous Forum, Society for Vascular Surgery, American Vein and Lymphatic Society, and the Society of Interventional Radiology
In 2020, in response to published reports of potentially inappropriate application of venous procedures, the American Venous Forum, Society for Vascular Surgery, American Vein and Lymphatic Society, and the Society of Interventional Radiology published appropriate use criteria for the treatment of chronic lower extremity venous disease. Appropriate use criteria were developed using the RAND/UCLA method incorporating best available evidence and expert opinion.

Appropriate use criteria were determined for various scenarios (e.g., symptomatic, asymptomatic, CEAP [Clinical, Etiology, Anatomy and Pathophysiology] class, axial reflux, saphenofemoral junction reflux) for the following:

- Saphenous vein ablation
    - Great saphenous vein
    - Small saphenous vein
- Accessory great saphenous vein
- Nontruncal varicose veins
- Diseased tributaries associated with saphenous ablation

- Perforator Veins
- Iliac Vein or inferior vena cava stenting as a first line treatment
- Duplex ultrasound
- Timing and Reimbursement.

Treatment of saphenous veins for asymptomatic CEAP class 1 and 2, or symptomatic class 1, was considered to be rarely appropriate or never appropriate, and treatment of symptomatic CEAP class 2, 3, and 4-6 without reflux was rated as never appropriate. Based on the 2011 Guidelines from the Society for Vascular Surgery and American Venous Forum (see below), treatment of perforator veins for asymptomatic or symptomatic CEAP class 1 and 2 was considered to be rarely appropriate or never appropriate. Perforator vein treatment was rated as appropriate for CEAP classes 4-6 and may be appropriate for CEAP class 3. Except for a recommendation to use endovenous procedures for perforator vein ablation, techniques used to treat veins in these scenarios were not evaluated.

American Vein and Lymphatic Society
In 2017, the American Vein and Lymphatic Society (AVL) published guidelines on the treatment of refluxing accessory saphenous veins. The College gave a Grade 1 recommendation based on level C evidence that patients with symptomatic incompetence of the accessory saphenous veins be treated with endovenous thermal ablation or sclerotherapy to reduce symptomatology. The guidelines noted that although accessory saphenous veins may drain into the great saphenous vein before it drains into the common femoral vein, they can also empty directly into the common femoral vein.

In 2015, the American Vein and Lymphatic Society (AVL, previously named the American College of Phlebology) published guidelines on the treatment of superficial vein disease.

AVL gave a Grade 1 recommendation based on high quality evidence that compression is an effective method for the management of symptoms, but when patients have a correctable source of reflux definitive treatment should be offered unless contraindicated. AVL recommends against a requirement for compression therapy when a definitive treatment is available. AVL gave a strong recommendation based on moderate quality evidence that endovenous thermal ablation is the preferred treatment for saphenous and accessory saphenous vein incompetence, and gave a weak recommendation based on moderate quality evidence that mechanochemical ablation may also be used to treat venous reflux.

Society for Vascular Surgery and American Venous Forum
The Society for Vascular Surgery and the American Venous Forum (2011) published a joint clinical practice guideline which includes the below recommendations:

Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases

Recommendation	Grade[a]	SOR	QOE
Compression therapy for venous ulcerations and varicose veins			
Compression therapy is recommended as the primary treatment to aid healing of venous ulceration	1B	Strong	Moderate
To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended	1A	Strong	High
Use of compression therapy for patients with symptomatic varicose veins is recommended	2C	Weak	Low
Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended	1B	Strong	Moderate
Treatment of the incompetent great saphenous vein			
Endovenous thermal ablation (radiofrequency or laser) is recommended over chemical ablation with foam or high ligation and stripping due to reduced convalescence and less pain and morbidity. Cryostripping is a technique that is new in the United States, and it has not been fully evaluated.	1B	Strong	Moderate
Varicose tributaries			
Phlebectomy or sclerotherapy are recommended to treat varicose tributaries	1B	Strong	Moderate
Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy	2C	Weak	Low
Perforating vein incompetence			
Selective treatment of perforating vein incompetence in patients with	1B	Strong	Moderate

simple varicose veins is not recommended			
Treatment of pathologic perforating veins (outward flow of ≥500 ms duration, with a diameter of ≥3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6) is recommended	2B	Weak	Moderate

QOE: quality of evidence; SOR: strength of recommendation.
[a] Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.

Regulatory Status
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 (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.

In 2008, the ClariVein Infusion Catheter (Vascular Insights) was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process for mechanochemical ablation.

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

In 2005, the KAVS catheter was approved by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The KAVS Catheter is intended to temporarily inhibit blood flow in isolated sections of peripheral veins in order to inject physician prescribed medications.

In 2003, the Trivex system (InaVein), a device for transilluminated powered phlebectomy, was cleared by the FDA through the 510(k) process for ambulatory phlebectomy procedures for the resection and ablation of varicose veins.

PRIOR APPROVAL

Not applicable

Note: *See Wellmark Authorization Table for the codes requiring prior approval for the treatment of varicose veins/venous insufficiency.*

POLICY

See related medical policy

- 10.01.02 Cosmetic and Reconstructive Services

Medically Necessary

Cyanoacrylate Adhesive (VenaSeal Closure System) (36482, 36483)

Great Saphenous Vein (GSV) and/or Small Saphenous Vein (SSV)
Cyanoacrylate adhesive (VenaSeal Closure System) for closure of the great saphenous vein (GSV) and/or small saphenous vein (SSV) may be considered **medically necessary** as a treatment for symptomatic varicose veins/venous insufficiency when **ALL** the following criteria are met:

- Duplex ultrasound demonstrates the diameter of the target vessel is greater than 3 mm to no more than 12 mm; **and**
- Duplex ultrasound is performed while the patient is standing documents reflux of 0.5 seconds or greater; **and**
- There is documentation of one or more of the following indications:
    - Ulceration secondary to venous stasis; **or**
    - Recurrent superficial thrombophlebitis; **or**
    - Hemorrhage or recurrent bleeding episodes from a ruptured or superficial varicosity; **or**
    - Symptoms characterized by persistent pain, swelling, itching, burning or other symptoms associated with saphenous reflux, **AND** the symptoms significantly interfere with activities of daily living (ADLs) (e.g., impaired mobility), **AND** conservative management including compression therapy for at least 3 months has not improved the symptoms.

Treatment of the great saphenous vein (GSV) and/or small saphenous vein (SSV) by cyanoacrylate adhesive (VenaSeal Closure System) (36482, 36483) not meeting the above criteria is considered **not medically necessary.**

Accessory Saphenous Veins
Cyanoacrylate adhesive (VenaSeal Closure System) (36482, 36483) closure of accessory saphenous veins may be considered **medically necessary** as a treatment of symptomatic varicose veins/venous insufficiency when **ALL** the following criteria are met:

- Duplex ultrasound of the deep and superficial venous system demonstrates that the incompetence of the accessory saphenous vein is isolated, or the great or small saphenous veins have been previously eliminated; and
- There is documentation of one or more of the following indications:
    - Ulceration secondary to venous stasis; **or**
    - Recurrent superficial thrombophlebitis; **or**

- Hemorrhage or recurrent bleeding episodes from a ruptured or superficial varicosity; **or**
- Symptoms characterized by persistent pain, swelling, itching, burning or other symptoms associated with saphenous reflux, **AND** the symptoms significantly interfere with activities of daily living (ADLs) (e.g., impaired mobility), **AND** conservative management including compression therapy for at least 3 months has not improved the symptoms.

Treatment of accessory saphenous veins by cyanoacrylate adhesive (VenaSeal Closure System) (36482, 36483) not meeting the above criteria is considered **not medically necessary.**

Ultrasound Guidance Related to Sclerotherapy in the Treatment of Symptomatic Varicose Veins/Venous Insufficiency
Since ultrasound-monitored techniques for sclerotherapy have not been shown to definitively increase the effectiveness or safety of this procedure, these tests are only considered medically necessary when initially performed to determine the extent and configuration of varicose veins.

Ultrasound monitoring techniques are of no proven value when performed solely to guide the needle or introduce the sclerosant into the varicose veins and is considered not medically necessary.

Investigational
The following treatments for symptomatic varicose veins/venous insufficiency are considered investigational, because the evidence is insufficient to determine this technology improves net health outcomes (this list may not be all-inclusive):

- Coil embolization
- Cryostripping (including cryoablation, cryofreezing, transilluminated cryosurgery)
- Endomechanical ablative approaches using rotating catheter (e.g., ClariVein Catheter) (e.g., mechanical occlusion chemically assisted ablation [MOCA], mechanic-chemical endovenous ablation [MCEA], mechanically enhanced endovenous chemical ablation [MEECA) (36473, 36474)
- Endovenous catheter directed chemical ablation with balloon isolation (e.g., KAVS procedure) (0542T)
- Transilluminated powered phlebectomy (TIPP, TriVex)

Policy Guidelines

Documentation Requirements
Medical records document the following, when applicable:

- Diagnosis
- History of the medical condition(s) requiring treatment or surgical intervention
- Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left or both)

- Relevant medical history include:
    - DVT (deep vein thrombosis)
    - Aneurysm
    - Tortuosity
- Physical exam, including:
    - Which extremity (right, left or both)
    - Vein(s) that will be treated (e.g., great saphenous vein (GVS), small saphenous vein (SSV), etc.)
    - Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thing, proximal calf, etc.)
    - Duration of reflux including the position of the member at the time of the measurement and the anatomic location where the measurement was taken (e.g., standing, saphenofemoral junction [SFJ])
- Functional disability(ies) as documented on a validated function disability scale, interfering with the ability to stand or sit for long periods of time (preparing meals, performing work functions, driving, walking, etc.)
- Diagnostic study/imaging reports
- Pulses
- Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation
- Proposed treatment plan with procedure code, including the specific vein(s) that will be treated (e.g., great saphenous vein (GVS), small saphenous vein (SSV), etc.), which extremity (left, right, or both).

CEAP classification

The CEAP classification is a method commonly used to document the severity of chronic venous disease and is based on clinical presentation (C), etiology (E), anatomy (A), and pathophysiology (P). Each classification can be further defined as follows:

Class	Definition
C - Clinical Classification	**C0:** No visible or palpable signs of venous disease **C1**: Telangiectases or reticular veins **C2**: Varicose veins **C3**: Edema **C4a:** Pigmentation and/or eczema **C4b:** Lipodermatosclerosis and/or atrophie blanche **C5**: Healed venous ulcer **C6**: Active venous ulcer

	CS: Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction **CA:** Asymptomatic
E - Etiology	**Ec:** Congenital **Ep:** Primary **Es:** Secondary (post-thrombotic) **En:** No venous etiology identified
A - Anatomy	**As:** Superficial veins **Ap:** Perforator veins **Ad:** Deep veins **An:** No venous location identified
P - Pathophysiology	**Pr:** Reflux **Po:** Obstruction **Pr.o:** Reflux and obstruction **Pn:** No venous pathophysiology identifiable

Definitions:

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

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

Echosclerotherapy; Also known as ultrasound-guided sclerotherapy or ultrasound guided foam sclerotherapy [UGFS] [for example, Varithena], or microfoam sclerotherapy)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 37799 Unlisted procedure, vascular surgery (may be utilized for Trannsilluminated Powered Phlebectomy ([TIPP, TriVex]; or cryostripping [cryoablation, cryofreezing and transilluminated cryosurgery])
- 37241 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) (may be utilized for coil embolization)
- 36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring percutaneous, mechanochemical; first vein treated (Mechanochemical Ablation [MCA; MOCA] (ClariVein System)
- 36474 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (Mechanochemical Ablation [MCA; MOCA] (ClariVein System)
- 36482 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive, (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated (VenaSeal Closure System)
- 36483 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive, (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (VenaSeal Closure System)
- 0524T Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring (KAVS Procedure)

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POLICY HISTORY

Date	Reason	Action
May 2022	Annual Review	Policy Revised
May 2021	Annual Review	Policy Revised
May 2020	Annual Review	Policy Revised
May 2019	Annual Review	Policy Revised
May 2018	Annual Review	Policy Revised
February 2018	Interim Review	Policy Revised
May 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
September 2014	Interim Review	Policy Revised
August 2014	New Policy	New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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