

Protocol

Treatment of Varicose Veins/Venous Insufficiency

(701124)

Medical Benefit		Effective Date: 07/01/18	Next Review Date: 05/19
Preauthorization	No	Review Dates: 11/07, 11/08, 09/09, 09/10, 07/11, 07/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With varicose veins/ venous insufficiency and saphenous vein reflux	Interventions of interest are: • Thermal endovenous ablation (radiofrequency or laser)	Comparators of interest are: • Conservative therapy • Ligation and stripping	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/ venous insufficiency and saphenous vein reflux	Interventions of interest are: • Microfoam sclerotherapy	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radio- frequency or laser ablation	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/ venous insufficiency and saphenous vein reflux	Interventions of interest are: • Mechanochemical ablation	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radio- frequency or laser ablation • Microfoam sclerothe- rapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/ venous insufficiency and saphenous vein reflux	Interventions of interest are: • Cyanoacrylate adhesive	Comparators of interest are: • Conservative therapy • Ligation and stripping • Endovenous radio- frequency or laser ablation	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With varicose veins/ venous insufficiency and saphenous vein reflux	Interventions of interest are: • Cryoablation	Comparators of interest are: • Conservative therapy • Ligation and stripping	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events

Populations	Interventions	Comparators	Outcomes
		<ul style="list-style-type: none"> Endovenous radio-frequency or laser ablation 	<ul style="list-style-type: none"> Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With varicose tributary veins 	Interventions of interest are: <ul style="list-style-type: none"> Ablation of tributary veins (stab avulsion, sclerotherapy, or phlebectomy) 	Comparators of interest are: <ul style="list-style-type: none"> Conservative therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Morbid events Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With perforator vein reflux 	Interventions of interest are: <ul style="list-style-type: none"> Ablation of perforator veins (e.g., subfascial endoscopic perforator surgery) 	Comparators of interest are: <ul style="list-style-type: none"> Conservative therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Morbid events Quality of life Treatment-related morbidity

DESCRIPTION

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

SUMMARY OF EVIDENCE

SAPHENOUS VEINS

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive thermal endovenous ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at two- to five-year follow-up has supported use of both radiofrequency ablation (RFA) and endovenous laser ablation. Evidence has suggested that ligation and stripping leads to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For physician-compounded sclerotherapy, there is high variability in success rates of this procedure and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration (FDA) are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that, once occluded, recurrence rates at two years are similar to those of ligation and stripping. Together, this evidence indicates that the more consistent occlusion with the microfoam sclerotherapy preparation will lead to recurrence rates similar to ligation and stripping in the longer term. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation, the evidence includes two RCTs and case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that mechanochemical ablation does not require multiple needle sticks with tumescent anesthesia and may result in a faster recovery. One RCT with high loss to follow-up has been published and a larger RCT comparing mechanochemical ablation with RFA has reported early results. These short-term results have suggested that intraprocedural pain is 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 its efficacy and durability compared to established procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes an RCT and case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RFA at three months in a multicenter noninferiority trial. Longer follow-up in a larger number of patients is needed to determine the durability of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs and multicenter series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

VARICOSE TRIBUTARY VEINS

For individuals who have varicose tributary veins who receive ablation of tributary veins (stab avulsion sclerotherapy or phlebectomy), the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

PERFORATOR VEINS

For individuals who have perforator vein reflux who receive ablation of perforator veins (e.g., subfascial endoscopic perforator surgery), the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (i.e., ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (e.g., deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating or ablating incompetent perforator veins. Subfascial endoscopic perforator surgery has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only one case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared

with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY

SAPHENOUS VEINS

Great or Small Saphenous Veins

Treatment of the great or small saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, or microfoam sclerotherapy may be considered **medically necessary** for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 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 superficial varicosity; OR
 - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least three months has not improved the symptoms.

Treatment of great or small saphenous veins by surgery or endovenous radiofrequency or laser ablation, or microfoam sclerotherapy that do not meet the criteria described above is considered **not medically necessary**.

ACCESSORY SAPHENOUS VEINS

Treatment of accessory saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, or microfoam sclerotherapy may be considered **medically necessary** for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

- Incompetence of the accessory saphenous vein is isolated, OR the great or small saphenous veins had been previously eliminated (at least three months); AND
- there is demonstrated accessory saphenous reflux; 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 superficial varicosity; OR
 - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least three months has not improved the symptoms.

Treatment of accessory saphenous veins by surgery or endovenous radiofrequency or laser ablation, or microfoam sclerotherapy, that do not meet the criteria described above is considered **not medically necessary**.

SYMPTOMATIC VARICOSE TRIBUTARIES

The following treatments are considered **medically necessary** as a component of the treatment of symptomatic *varicose tributaries* when performed either at the same time or following prior treatment (surgical, radiofrequency or laser) of the saphenous veins (none of these techniques has been shown to be superior to another):

- Stab avulsion
- Hook phlebectomy
- Sclerotherapy
- Transilluminated powered phlebectomy.

Treatment of symptomatic *varicose tributaries* when performed either at the same time or following prior treatment of saphenous veins using any other techniques than noted above is considered **investigational**.

PERFORATOR VEINS

Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered **medically necessary** as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met:

- There is demonstrated perforator reflux; AND
- The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; AND
- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least three months; AND
- The venous insufficiency is not secondary to deep venous thromboembolism.

Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is **not medically necessary**.

TELANGIECTASIA

Treatment of telangiectasia such as spider veins, angiomas, and hemangiomas is considered **not medically necessary**.

OTHER VEINS

Techniques for conditions not specifically listed above are **investigational**, including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins
- Sclerotherapy of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins
- Endovenous radiofrequency or laser ablation of tributary veins
- Endovenous cryoablation of any vein
- Mechanochemical ablation of any vein
- Cyanoacrylate adhesive of any vein.

POLICY GUIDELINES

The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. The following is the Clinical portion of the CEAP.

Class	Definition
C0	No visible or palpable signs of venous disease
C1	Telangiectasies or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation and eczema
C4b	Lipodermatosclerosis and atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer
S	Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
A	Asymptomatic

Adapted from <https://www.veinforum.org/wp-content/uploads/2018/03/Revised-CEAP-Classification-May-2004.pdf>

It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. When ultrasound guidance is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

MEDICARE ADVANTAGE

For Medicare Advantage **medically necessary** treatments for eliminating saphenous (great saphenous vein (GSV), anterior accessory GSV (AAGSV), small saphenous vein (SSV)) reflux (saphenofemoral or saphenopopliteal) are listed below. Only devices with FDA approval or clearance consistent with saphenous ablation and used according to its approved instructions for use (IFU) are **medically necessary**. The treatments to eliminate the saphenous vein reflux will be considered **medically necessary** if the patient remains symptomatic after a six-week trial of conservative therapy and has reflux in a saphenous vein. (see Medicare Advantage Policy Guidelines)

- radiofrequency ablation (RFA),
- laser ablation (EVLA),
- polidocanol microfoam (PEM),
- cyanoacrylate embolization (CAE) ablation, and
- mechanochemical ablation (MOCA).

The treatments for symptomatic varicose tributaries are either compressive sclerotherapy or microphlebectomy. The treatments of the tributary veins will be considered **medically necessary** if saphenous reflux is not present or already successfully eliminated, the veins are > than four mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy (see Medicare Advantage Policy Guidelines).

Endovenous ablation therapy is considered **medically necessary** for members with:

- a maximum vein diameter of 12 mm for CAE, PEM and MOCA; and,
- absence of thrombosis or vein tortuosity, which would impair catheter advancement (except for PEM).

The following interventional treatments are considered to be cosmetic:

- Interventional treatment of asymptomatic varicosities,
- Treatment of telangiectases,
- Sclerotherapy for cosmetic purposes.

The following interventional treatments are considered **not medically necessary**:

- Surgery, endovenous ablation, or sclerotherapy are typically not performed for varicose veins that develop or worsen during pregnancy because most will spontaneously resolve or improve after delivery.
- Reinjection following recanalization or failure of vein closure without recurrent signs or symptoms.
- Sclerotherapy of the saphenous vein at its junction with the deep system.
- Noncompressive sclerotherapy.
- Compressive sclerotherapy for large, extensive or truncal varicosities.
- Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy are generally not covered for patients with severe distal arterial occlusive disease; obliteration of deep venous system; an allergy to the sclerosant; or a hypercoagulable state.
- Any interventional treatment that uses equipment or sclerosants not approved for such purposes by the FDA.

MEDICARE ADVANTAGE POLICY GUIDELINES

While saphenous vein ligation and stripping remains an important option in selected cases, it has been largely supplanted by endovenous ablation therapy as primary treatment of saphenous (axial/truncal) vein incompetence.

The components of the conservative therapy include, but are not limited to:

- weight reduction,
- a daily exercise plan,
- periodic leg elevation, and
- the use of graduated compression stockings.

The member is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented:

- stasis ulcer of the lower leg,
- significant pain and significant edema that interferes with activities of daily living,
- bleeding associated with the diseased vessels of the lower extremities,
- recurrent episodes of superficial phlebitis,
- stasis dermatitis, or
- refractory dependent edema.

Refer also to the Cosmetic vs. Reconstructive Services Protocol.

BACKGROUND**VENOUS REFLUX/VENOUS INSUFFICIENCY**

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory, or duplicate, veins that travel in parallel with the great and small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins with visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification considers the clinical, etiologic, anatomic, and pathologic (CEAP) characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment

Treatment of venous reflux/venous insufficiency is aimed at reducing 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 in 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.

Saphenous Veins and Tributaries

Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux typically includes the following:

1. Identification by preoperative Doppler ultrasonography of the valvular incompetence
2. Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
3. Removal of the superficial vein from circulation, e.g., by stripping of the great and/or small saphenous veins
4. Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. They include sclerotherapy, transilluminated powered phlebectomy (TIPP), and thermal ablation using cryotherapy, high-frequency radio waves (200-300 kHz), or laser energy.

Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately resulting in the occlusion of the vessel. The success of the treatment depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations. 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 commonly produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation uses 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 at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without need for the tumescent anesthesia used with thermal endovenous ablation techniques (radiofrequency ablation [RFA], endovenous laser ablation).

Thermal Ablation

RFA is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within one to two cm of the saphenofemoral junction. The catheter is slowly withdrawn, closing the vein. Laser ablation is performed similarly; a laser fiber is introduced into the great saphenous vein under ultrasound guidance; the laser is activated and slowly removed along the course of the saphenous vein. Cryoablation uses extreme cold to cause injury to the vessel. The objective of endovenous techniques is to injure the vessel, causing retraction and subsequent fibrotic occlusion of the vein. Technical developments since thermal ablation procedures were initially introduced include the use of perivenous tumescent anesthesia, which allows successful treatment of veins larger than 12 mm in diameter and helps to protect adjacent tissue from thermal damage during treatment of the small saphenous vein.

Cyanoacrylate Adhesive

Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (i.e., polymerizes into a solid material on contact with body fluids or tissue). 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.

Transilluminated Powered Phlebectomy

TIPP is an alternative to stab avulsion and hook phlebectomy. This procedure uses two instruments: an illuminator, which also provides irrigation, and a resector, which has an oscillating tip and suction pump. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of the varicosity. The resector is then inserted under the skin from the opposite direction, and the oscillating tip is placed directly beneath the illuminated veins to fragment and loosen the veins from the supporting tissue. Irrigation from the illuminator is used to clear the vein fragments and blood through aspiration and additional drainage holes. The illuminator and resector tips may then be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or hook phlebectomy. It has been proposed that TIPP might decrease surgical time, decrease complications such as bruising, and lead to faster recovery than established procedures.

TREATMENT OF PERFORATOR VEINS

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally treated with an open surgical procedure, called the Linton procedure, which

involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may occasionally be used to close incompetent perforator veins that cannot be reached by less invasive procedures.

Subfascial endoscopic perforator surgery is a less invasive surgical procedure for treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin, and the perforating veins are clipped or divided by endoscopic scissors. The surgery can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and RFA has also been reported.

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 (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.

In 2013, Varithena™ (formerly known as Varisolve®; BTG, London), a sclerosant microfoam made with a proprietary gas mix, was approved by FDA under a new drug application (NDA 205-098) 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.

The following devices were cleared for marketing by FDA through the 501(k) process for endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ System, a radiofrequency device, was cleared by FDA through the 510(k) process for “endovascular coagulation of blood vessels in patients with superficial vein reflux.” In 2005, the VNUS RFS™ and RFSFlex™ devices were cleared by FDA for “use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins.” In 2008, the modified VNUS® ClosureFast™ Intravascular Catheter was cleared by FDA through the 510(k) process. FDA product code: GEI.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit was cleared by FDA through the 510(k) process “...for use in the endovascular coagulation of the great saphenous vein of the thigh in patients with superficial vein reflux.” FDA product code: GEX.
- In 2005, a modified Erbe Erbokryo® cryosurgical unit (Erbe USA) was approved by FDA for marketing. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.
- In 2003, the Trivex® system (InaVein), a device for transilluminated powered phlebectomy, was cleared by FDA through the 510(k) process for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.” FDA product code: DNQ.
- In 2008, the ClariVein® Infusion Catheter (Vascular Insights) was cleared by FDA through the 510(k) process (K071468) for mechanochemical ablation. FDA determined that this device was substantially equivalent to the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). 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. FDA product code: KRA.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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