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

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** 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.*

Description

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

Background

The venous system of the lower extremities consists of the superficial veins (this includes the greater and lesser saphenous and accessory, or duplicate, veins that travel in parallel with the greater and lesser 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. Since 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 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 greater or lesser saphenous veins are eliminated and blood flow is diverted through the accessory veins.

Saphenous Veins and Tributaries

Saphenous veins include the greater and lesser saphenous and accessory saphenous veins that travel in parallel with the greater or lesser 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, for example by stripping of the greater and/or lesser 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. These include sclerotherapy, transilluminated powered phlebectomy (TIPP), and thermal ablation using cryotherapy, high-frequency radiowaves (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 to be 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 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 and is considered an off-label use. A proprietary microfoam sclerosant (Varisolve, BTG PLC, London) with a controlled density and more consistent bubble size is being developed in Europe.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and 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] and endovenous laser treatment [EVLT]).

Thermal Ablation

Radiofrequency ablation is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within 1 to 2 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 greater 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 cause injury to 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 lesser saphenous vein.

Transilluminated Powered Phlebectomy

TIPP is an alternative to stab avulsion or hook phlebectomy. This procedure uses two instruments: an illuminator, which also provides irrigation, and a resector, which has an oscillating tip and can perform suction.

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 result in decreased operative time, decreased complications such as bruising, and faster recovery compared to the 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 addressed 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 be occasionally utilized for the closure of 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 operation can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and RFA has also been reported.

Other

Deep vein valve replacement is being investigated.

Outcomes of interest for venous interventions include healing and recurrence, recannulation of the vein, and neovascularization. Recannulation (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 durability for endovenous and surgical procedures are complicated by these different mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

Regulatory Status

The following devices have received specific U.S. Food and Drug Administration (FDA) marketing clearance for the endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ system (a radiofrequency device) received FDA clearance through the 510(k) process for “endovascular coagulation of blood vessels in patients with superficial vein reflux.” The VNUS RFS™ and RFSFlex™ devices received FDA clearance in 2005 for “use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins.” The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit received FDA clearance through the 510(k) process, “... for use in the endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.”
- A modified Erbe Erbokryo® cryosurgical unit (Erbe USA) received FDA clearance for marketing in 2005. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.

- The Trivex® system (InaVein, LLC) is a device for transilluminated powered phlebectomy that received FDA clearance through the 510(k) process in October 2003. According to the label, the intended use is for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.”
- Varisolve® (BTG PLC, London) is a sclerosant microfoam made with a proprietary gas mix. A Phase II safety study for FDA has been completed. In late October 2009, the sponsor submitted a request to the FDA for a protocol assessment to agree on the design, end points, and statistical analyses for the Phase III trial.
- The ClariVein® Infusion Catheter received marketing clearance through the 510(k) process in 2008 (K071468). It is used for mechanochemical ablation. Predicate devices were listed as 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.

Policy (Formerly Corporate Medical Guideline)

Greater or Lesser Saphenous Veins

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

There is demonstrated saphenous reflux; AND

There is documentation of one or more of the following indications:

- Ulceration secondary to venous stasis that fails to respond to compressive therapy; OR
- Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; 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 greater or lesser saphenous veins by surgery or endovenous radiofrequency or laser ablation 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) or endovenous radiofrequency or laser ablation 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 greater or lesser 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 that fails to respond to compressive therapy; OR
- Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; 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 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 (greater, lesser, 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 cosmetic and **not medically necessary**.

Other

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

- Sclerotherapy of perforator, greater or lesser saphenous, or accessory saphenous veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, greater or lesser saphenous, or accessory saphenous veins
- Endovenous radiofrequency or laser ablation of tributary veins
- Endovenous cryoablation of any vein
- Mechanochemical ablation of any vein.

Benefit Application

Based on currently available evidence, health outcomes for stab avulsion, hook phlebectomy, or

transilluminated powered phlebectomy appear to be comparable. For general business, if more costly than stab avulsion or hook phlebectomy, transilluminated powered phlebectomy would be considered **not medically necessary**.

Medicare Advantage

Medicare Advantage will consider interventional treatment of varicose veins (sclerotherapy, ligation with or without stripping, and endovenous radiofrequency or laser ablation) **medically necessary** if the member remains symptomatic after a documented six-week trial of conservative therapy. 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, as above,
- 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.

In addition to the requirement for failure of a six-week trial of conservative treatment and the symptoms described above, endovenous ablation therapy is considered **medically necessary** for members with:

- a maximum vein diameter of 20 mm for laser ablation,
- absence of thrombosis or vein tortuosity, which would impair catheter advancement, and
- absence of significant peripheral artery disease.

Radiofrequency/laser ablation is **medically necessary** only for treatment of the lesser or greater saphenous veins to improve symptoms attributable to saphenofemoral or saphenopopliteal reflux, and only for FDA devices specifically approved for these procedures.

Non-cosmetic sclerotherapy will also be considered **medically necessary** if performed in conjunction with surgical ligation or stripping procedures in appropriately selected patients and to medium sized vessels (less than 4 mm in diameter).

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**:

- Interventional treatment of symptomatic varicosities without documentation of a failed six week trial of conservative therapy,
- Sclerotherapy for vessels larger than 4 mm in diameter,

- 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,
- Any interventional treatment that uses equipment or sclerosants not approved for such purposes by the FDA,
- Laser ablation of veins with a diameter greater than 20 mm,
- Endovenous ablation therapy in the presence of thrombosis or venous tortuosity which would impair catheter advancement.

Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy are **not appropriate** for pregnant women, patients on anti-coagulant therapy, or patients with the inability to tolerate compressive bandages or stockings; severe distal arterial occlusive disease; obliteration of deep venous system; an allergy to the sclerosant; or a hypercoagulable state.

Foam sclerotherapy of the saphenous vein at its junction with the deep venous system as an alternative to ligation or saphenectomy is **investigational**.

Refer also to Protocol Cosmetic vs. Reconstructive Services.

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.**

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

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