Medical Coverage Policy | Varicose Vein Treatment

EFFECTIVE DATE:11|01|2016
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OVERVIEW

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. This policy addresses the criteria for treatment and method.

PRIOR AUTHORIZATION

Prior authorization is recommended and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Blue CHiP for Medicare and Commercial Products

Treatment of symptomatic varicose veins is considered medically necessary when the medical criteria is met for both treatment and the method.

Mechanochemical ablation of any vein is considered not medically necessary as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

BlueCHiP for Medicare

Sclerotherapy when used in the treatment of telangiectasias (spider veins) is considered a cosmetic procedure and is not performed to correct a functional impairment. Medicare does not cover cosmetic procedures.

Non-compressive sclerotherapy is not covered by Medicare because it is not effective in producing long-term obliteration of incompetent veins.

Commercial Products:

Sclerotherapy when used in the treatment of telangiectasias is contract exclusion as it is always considered to be a cosmetic procedure.

Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial

Medical treatment of varicose veins of the lower extremities is considered medically necessary when the medical criteria below are met:

The patient must have had a duplex ultrasound and meet one of the listed criteria below:

- Varicosities causing pain or functional impairment, such as complications of venous stasis as in dermatitis or superficial ulceration not satisfactorily relieved by a trial of conservative medical management (e.g., rest with elevation, analgesics, compression hose) of one month duration, and

there is reflux incompetency of greater saphenous vein and/or lesser saphenous and/or accessory saphenous vein (with the exception of all forms of sclerotherapy which requires a competent greater saphenous and/or lesser saphenous and/or accessory saphenous vein)
- Superficial thrombophlebitis of greater saphenous vein and/or lesser saphenous and/or accessory saphenous vein
- Hemorrhaging from a ruptured varix

In addition to meeting the above treatment criteria, the patient must meet the following medical criteria for the methods of treatment specified below:

Ligation and Stripping by either Radiofrequency/Thermal ablation(RFA/EVLA) or endovenous laser therapy (EVLT®)

- The greater saphenous and/or lesser saphenous and/or accessory saphenous vein is incompetent

Sclerotherapy

- The veins must be >2 mm and <6 mm; and
- The greater saphenous and/or lesser saphenous and/or accessory saphenous vein is competent; removed, ablated, or EVLT/RFA/EVLA is planned.

Note: Requests for greater than 3 sclerotherapy sessions in a 12 month period will be reviewed to determine the need for additional treatment

Echosclerotherapy (Using duplex Ultrasound)

- The perforator veins greater than 3.5 mm in size; and
- The greater saphenous and/or lesser saphenous and/or accessory saphenous vein is competent; or removed or ablated.

Note: Requests for greater than 3 sclerotherapy sessions in a 12 month period will be reviewed to determine the need for additional treatment

Transilluminated powered phlebectomy and ambulatory phlebectomy

- The greater saphenous and/or lesser saphenous and/or accessory saphenous vein is competent; or has been removed or ablated.

Surgical ligation of incompetent subfascial perforator veins by subfascial endoscopic perforator surgery (SEPS), endovenous radiofrequency, laser ablation or Linton Procedure when all of the criteria are met

- There is demonstrated perforator reflux
- chronic venous insufficiency (greater, lesser, or accessory saphenous and symptomatic varicose tributaries) has been eliminated
- Leg ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months
- The venous insufficiency is not secondary to deep venous thromboembolism.

BACKGROUND

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 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, for example 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.

Types of Treatment

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 commonly produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment. Varithena™ (previously known as Varisolve; BTG Plc, London) is a proprietary microfoam sclerosant that is dispersed from a canister with a controlled density and more consistent bubble size.

Thermal Ablation

RFA/ELVA/EVLT 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 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 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 small saphenous vein.

Cyanoacrylate Adhesive

Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material on contact with body fluids or tissue). The adhesive is gradually injected along the length of the vein in conjunction with ultrasound and manual compression.
The acute coaptation halts blood flow through the vein until the implanted adhesive becomes fibrotically encapsulated and establishes chronic occlusion of the treated vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and to seal surgical incisions or other skin wounds.

Transilluminated Powered Phlebectomy

TIPP is an alternative to stab avulsion or hook phlebectomy. This procedure uses 2 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 with 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 occasionally be used 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.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation (MOCA™) 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] and endovenous laser treatment [EVLT]).

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.

The evidence on mechanochemical ablation, cyanoacrylate adhesive, and cryoablation in patients with varicose veins/venous insufficiency includes randomized controlled trials (RCTs) and multicenter series. Relevant outcomes are symptoms, morbid events, functional outcomes, and change in disease status. Several series have been reported on mechanochemical ablation (MCA), and a large RCT comparing MCA with radiofrequency (RF) ablation is ongoing. Efficacy of cyanoacrylate adhesion at 3 months has been shown to be noninferior to RF in a multicenter RCT. Longer term follow-up is needed to determine durability of this treatment. Results from a recent RCT of cryoablation indicate that this therapy is inferior to conventional stripping. The evidence is insufficient to determine the effects of the technology on health outcomes.

In 2015, the VenaSeal® Closure System (Sapheon, a part of Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval 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 Plc, London), a sclerosant microfoam made with a proprietary gas mix, was approved by FDA under a new drug application 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 the endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ System (a radiofrequency device) received FDA clearancethrough the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." The VNUS RFS™ and RFS*Flex*™ devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (ie, refluxing) perforator and tributary veins." The modified VNUS® ClosureFast™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008. FDA product code: GEI.
- 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 great saphenous vein of the thigh in patients with superficial vein reflux." FDA product code: GEX.
- 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. FDA product code: GEH.
- 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." FDA product code: DNQ.
- The ClariVein® Infusion Catheter (Vascular Insights) 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. FDA product code: KRA.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable surgery services benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial

The following CPT Codes are medically necessary when medical criteria are met:

36470	Injection of sclerosing solution; single vein
36471	Injection of sclerosing solution; multiple veins, same leg
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476*	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479*	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excisions of deep fascia
37760	Ligation of perforator veins, subfascial, radical (Linton type), with or without skin graft, open
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab
37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
37780	Ligation and division of short saphenous vein at saphenopopliteal junction
37785	Ligation, division, and/or excision of varicose vein cluster(s), one leg
S2202	Echosclerotherapy

*only the primary procedure needs preauthorization

Note: The use of ultrasound guidance performed in conjunction with the injection of sclerosing solution into the varicose tributaries, would be considered incidental to the primary injection procedure and is not separately reimbursed.

The following CPT code is non-covered for all product lines:

36468 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia)

The following CPT codes are not medically necessary. (New Codes Effective)

36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated

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 the primary procedure)

Note for claims filed prior to 1/1/2017, providers should file with the unlisted code below:

37501 Unlisted vascular endoscopic procedure

RELATED POLICIES
Preauthorization via Web-Based Tool for Procedures

PUBLISHED
Provider Update, November/December 2016
Provider Update, June 2013
Provider Update, March 2013
Provider Update, March 2012
Provider Update, November 2010
Provider Update, August 2009
Provider Update, November 2007
Provider Update, September 2006
Policy Update, September 2001

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