

Corporate Medical Policy

Ablative and Surgical Treatment for Venous Insufficiency

Description of Procedure

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, the type of vein, the source of venous reflux, and the use of other (prior or concurrent) treatments.

Background

Varicose veins are a common condition. In adult populations visible varicose veins are present in 20 to 25% of women and 10 to 15% of men. The venous system of the lower extremities consists of the superficial veins, including the greater (GSV) and lesser/small (LSV) saphenous, and accessory veins (ASV), 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 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.

Most varicose veins do not require medical treatment. In some cases, however, the circulation may be hindered enough to cause swelling of the foot and ankle, discomfort, a tingling sensation, or a feeling of heaviness. For most people with varicose veins, wearing specially fitted elastic stockings is all that is needed. 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, exercise, avoidance of prolonged immobility, weight loss and graded compression stockings. 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.

When conservative measures are insufficient to manage the symptoms of venous reflux, treatment typically consists of the following:

1. Identification of valvular incompetence via diagnostic Doppler ultrasound assessment;
2. Control of the most proximal point of reflux, via surgical intervention: ligation at the incompetent saphenofemoral or saphenopopliteal junction as the classic standard;
3. Removal of the incompetent superficial vein from circulation, such as via stripping of a saphenous vessel;
4. Removal of varicose tributaries by phlebectomy or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping include: sclerotherapy, transilluminated powered phlebotomy and thermal ablation using cryotherapy, high frequency radiowaves or laser energy.

Endovenous Catheter Ablation (EVCA)

This is a non-specific term that refers to catheter based minimally invasive alternatives to surgical stripping such as radiofrequency endovenous occlusion (i.e. VNUS procedure) and endovenous laser ablation of the saphenous vein (EVLA). These procedures are generally considered equally effective in the treatment of venous insufficiency of the GSV. Both modalities use thermal energy to seal off the diseased vein via an intraluminal catheter system.

Microfoam Chemical Ablation- (polidocanol injectable foam)

Varithena (polidocanol injectable foam) is a sclerosing agent indicated 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. Varithena is used to address the symptoms of superficial venous incompetence and the appearance of visible varicosities. Varithena is contraindicated in patients with a known allergy to polidocanol and acute thromboembolic disease.

Surgical Ligation and Stripping

This has been the standard of surgical care for refractory venous insufficiency prior to the introduction of alternative procedures. Two incisions are made. One at the top of the leg just below the groin and one behind the knee joint or ankle. The vein is then tied or clamped off at the top incision using a technique called vein ligation. A long wire is sent through the lower incision up through the vein, and at the lower end a button-like cap is attached to the wire. This allows the entire vein to be pulled out through the incision near the groin. An updated Cochrane review from 2014 compared EVLA and RFA and foam sclerotherapy versus ligation/stripping for saphenous vein varices. For EVLA versus surgery, there were no significant differences between the treatment groups for clinician noted or symptomatic recurrence, or for recanalization. This was confirmed by Britten et al.

Ambulatory Phlebectomy (including Transilluminated Powered Phlebectomy (TIPP) or (TriVex))

Ambulatory phlebectomy, also called stab avulsion, is one accepted surgical method for removal of varicose tributaries. TIPP is similar to ambulatory phlebectomy but slightly more invasive. It is performed on an outpatient basis in an operating room under light anesthesia. After making two small incisions near the varicose vein, the surgeon inserts a tumescent cannula illuminator (TCI) that contains a fiber optic light that makes the veins easily visible. Fluid containing a local anesthetic is infused under the skin, loosening the vein from the surrounding tissue. A vein remover instrument is guided to the vein, which is suctioned into the instrument where it is cut into small pieces and removed. Due to the large amount of local anesthetic used, patients usually awake without any pain and are able to return home in about an hour. While TIPP had the advantage of fewer surgical incisions, it was associated with a more prolonged recovery due to more extensive bruising, prolonged pain, and reduced early postoperative quality of life. The current literature does not show an advantage of TIPP over conventional treatment referred to within this policy.

Subfascial Endoscopic Perforator Surgery (SEPS)/Linton Procedure

Historically, incompetent perforating veins were 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. SEPS represents a minimally invasive alternative to the Linton procedure, and has been investigated since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin unaffected by the changes of severe chronic venous insufficiency. Using endoscopic techniques, the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure.

Sclerotherapy and Ultrasound Guided Foam Sclerotherapy

Sclerotherapy effectively treats varicose and spider veins. It's often considered the treatment of choice for small varicose veins. Sclerotherapy involves injecting a solution directly into the vein. The sclerotherapy solution causes the vein to scar, forcing blood to reroute through healthier veins. The collapsed vein is reabsorbed into local tissue and eventually fades. The 2013 MAGNA trial, studied 223 consecutive patients (240 legs) with greater saphenous vein reflux who were randomized to EVLA, ligation and stripping, or physician compounded foam sclerotherapy (1 cc aethoxysclerol 3%). At 1-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both EVLA and stripping. However, it has been shown to be effective for adjunctive treatment of symptomatic saphenous veins, varicose tributaries,

accessory, and perforator veins 2.5 mm or greater in diameter for persons who have undergone EVLA or similar procedures for incompetence at the saphenofemoral junction or saphenopopliteal junction.

Endomechanical or Mechanicochemical Ablation (MOCA)

This technique is also referred to as Endomechanical ablation, mechanico-chemical endovenous ablation (MCEA) and mechanically enhanced endovenous chemical ablation (MEECA) (including but not limited to ClariVein, VenaSeal, etc). Mechanochemical endovenous 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. A wire rotates within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in radiofrequency ablation or endovenous laser ablation. Initial studies appear to indicate that this procedure results in less post-operative pain with comparable outcomes, further long term studies remain to be completedⁱⁱ before considering this procedure to be non-investigational.

Photothermal Sclerosis

Also referred to as an intense pulsed light source, e.g., the PhotoDerm VascuLight, VeinLase. This procedure is used to treat small veins such as small varicose veins and spider veins. Photothermal Sclerosis is considered cosmetic because such small veins do not cause pain, bleeding, ulceration, or other medical problems.

Endovenous Cryoablation

Cryoablation uses extreme cold to cause injury to the vessel. Kelm et al concluded that cryo-stripping accounts for numerous procedural failures and hence residual GSV in patients. The Aberdeen Varicose Vein Questionnaire (AVVQ) showed small but significantly better results for patients after a conventional stripping. Thus, cryo-stripping has no benefits over conventional stripping. Disselhoff et al reported long lasting and more effective outcomes with EVLA as opposed to cryoablation.

Asclera polidocanol injection

GEHA considers Asclera polidocanol injection as cosmetic; although Asclera has been approved by the Food and Drug Administration (FDA) for the treatment of telangiectasias and reticular veins less than 3 mm in diameter, treatment of these small veins is considered cosmetic.

Regulatory Status

Ablative and surgical treatment for venous insufficiency is a procedure and, as such, is not subject to regulation by the FDA.

However, the FDA does regulate manufacturing practices and use of devices and drugs for such procedures. These include but are not limited to the ClariVein infusion catheter, VenaSeal Closure System, and Varithena.

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the member's benefit booklet for availability of benefits.

Policy Statement

Ablative and surgical treatment for venous insufficiency is covered when it is determined to be medically necessary when the medical criteria and guidelines hereafter mentioned have been demonstrated and documented.

When treatment is covered:

A. Surgical and/or ablative interventions (ligation/stripping, ablation, microfoam sclerotherapy) to treat incompetence of the greater saphenous vein (GSV) and small saphenous vein (LSV) may be considered if the following are met per lower extremity:

- i. Ultrasound documented saphenous reflux with duration of 500 milliseconds or greater in the vein to be treated; and vein size is 4.5 mm or greater in diameter measured by ultrasound immediately below the saphenofemoral or saphenopopliteal junction (not the valve diameter at the junction), AND
- ii. Ulceration secondary to venous stasis; OR
- iii. Recurrent superficial thrombophlebitis; OR
- iv. Recurrent bleeding from a ruptured superficial varicosity; OR
- v. Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux AND
 - a. The symptoms significantly interfere with activities of daily living, AND
 - b. Conservative management including compression therapy for at least 3 months has not improved the symptoms.

B. Surgical and/or ablative interventions for accessory saphenous veins of the same leg may be considered medically necessary when performed either at the same time or following prior treatment (surgical or ablation) to the proximal saphenous veins and with documentation of one or more of the following indications:

- i. Ultrasound documented saphenous reflux with duration of 500 milliseconds or greater in the vein to be treated; AND
- ii. Ulceration secondary to venous stasis; OR
- ii. Recurrent superficial thrombophlebitis; OR

- iii. Recurrent bleeding from a ruptured superficial varicosity; OR
- iv. Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux AND
 - a. The symptoms significantly interfere with activities of daily living, AND
 - b. Conservative management including compression therapy for at least 3 months has not improved the symptoms.

C. 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:

- i. There is demonstrated perforator reflux; AND
- ii. The vein diameter is 3.5 mm or greater;
- iii. The superficial saphenous veins (great, small, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; AND
- iv. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; AND
- v. The venous insufficiency is not secondary to deep venous thromboembolism.

Perforator veins, even with reflux demonstrated, do not require surgery or ablation unless persistent venous ulcers are present or a history of ulcers. Frequently the incompetence in the perforator will improve with treatment of the saphenous vein¹.

D. Phlebectomy procedures are considered medically necessary for the treatment of the residual tributary veins in the saphenous distribution if the following criteria are met:

- i. Procedure must be performed along with an ablation, ligation/stripping, or an approved microfoam sclerotherapy to a primary vessel of the same leg; OR
- ii. These procedures of the same leg have been done within 6 months and the above criteria are met.
- iii. Phlebectomy is limited to one session per extremity in conjunction with an approved treatment plan.

E. Sclerotherapy is considered medically necessary for the treatment of residual tributary veins when a diameter of greater than 2.5 mm is still present after the successful treatment of the GSV, LSV and/or ASV.

- i. Veins less than 2.5 mm are considered cosmetic;

jj. Sclerotherapy as the sole treatment of varicose veins without associated treatment of the primary veins is not considered standard of care and is thus not covered as medically necessary;

iii. A maximum of 3 sclerotherapy sessions per leg will be allowed within 6 months of primary treatment only when the above criteria are met and the plan of care is associated with covered treatments of one or more primary veins in the target extremity.

When treatment is not covered:

GEHA considers the following vein therapy procedures as experimental and investigational and are therefore not covered. This includes, but is not limited to, the following:

1. Procedures for which the above criteria is not met; and/or
2. Endomechanical or Mechanicochemical Ablation (MOCA)
3. Photothermal Sclerosis
4. Endovenous Cryoablation

GEHA considers the following vein therapy procedures as cosmetic and are therefore not covered. This includes, but is not limited to, the following:

1. Procedures for when the above criteria are not met; and/or
2. Asclera polidocanol injection.

Policy Guidelines

GEHA considers the following as absolute contraindications to venous surgery and/or ablation:

- A. Acute deep vein thrombosis (DVT)
- B. Acute superficial phlebitis
- C. Acute infections at puncture sites
- D. Deep venous obstruction if the vein to be treated is a functional collateral
- E. Pregnancy or nursing
- F. Extreme arterial insufficiency

Physician Documentation

- Completed GEHA Vein Surgery Authorization form (this can be found at geha.com)
- Current history and physical
- All supporting medical records documenting clinical findings, including:

- Signs and symptoms, including member’s complaint and duration of severity of the condition;
- Documentation of symptoms that are causing functional impairment, if present;
- Physical findings;
- Radiology and imaging study reports.
- Doppler and duplex scanning report with clear results completed pre-treatment showing valve incompetence with reflux and diameter of veins
- Clinical records documenting the following:
 - Activities the member must modify or cannot perform due to varicose vein conditions;
 - Documentation of conservative and adjunctive measures, including duration and outcome. This would include elevation of the extremities, exercise, avoidance of prolonged immobility, weight loss and graded compression stockings ;
 - Plan of care for treatment of the varicose vein(s).

Applicable codes include but are not limited to:

36470 sclerotherapy for one vein

36471 sclerotherapy for multiple veins

36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated

36476 second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

36479 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 vein

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 excision of deep fascia

37760 Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg

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 incisions [ambulatory]

37766 more than 20 incisions [ambulatory]

37780 Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)

37785 Ligation, division, and/or excision of varicose vein cluster(s), one leg

37799 unlisted procedure; used for stab phlebectomy <10 stabs

37799 unlisted procedure and J3490 unclassified drug; used for foam sclerotherapy

CPT or HCPCS CODE(S) NOT COVERED FOR INDICATIONS LISTED WITHIN THIS COVERAGE POLICY:

S2202 Echosclerotherapy

10140 Incision and drainage of hematoma, seroma or fluid collection

10160 Incision and drainage of abscess (e.g., carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single

36011 Selective catheter placement, venous system; first order branch (e.g., renal vein, jugular vein)

36465 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)

36466 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg

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

36469 Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face

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 primary procedure)

36482 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated

36483 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, 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)

37204 Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck

37241 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, 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)

37244 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation

75894 Trans catheter therapy, embolization, any method, radiological supervision and interpretation

76942 Ultrasonic guidance for needle placement (e.g. biopsy, aspiration, injection and localization device), imaging supervision and interpretation [not covered when performed solely to guide the needle or introduce sclerosant into the varicose veins

76998 Ultrasonic guidance, intraoperative [not covered when solely performed to guide the needle or introduce sclerosant into the varicose veins]

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Policy implementation and updates:
