Effective February 26, 2018
Policy Replaced by LCD L33454

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Management of Varicose Veins

Policy #: 045
Category: Surgery

Latest Review Date: May 2017
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

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. A careful physical exam should be done to determine the nature, extent and location of varicose veins. An intact venous system is documented with venous ultrasound duplex imaging. The duplex ultrasound is considered the gold standard for evaluation of varicose veins.

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. 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 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 greater or lesser 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 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 phlebotomy, 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 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 sclerosant 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. Varithena™ (previously known as Varisolve, BTG PLC, London) is different in that it is a proprietary microfoam sclerosant that is dispersed from a canister with a controlled density and more consistent bubble size.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation (MCOA) 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 3,500 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 1–2 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 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 to seal surgical incisions or other skin wounds.

Transilluminated Powered Phlebectomy
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.

<u>Treatment of Perforator Veins</u>
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 (SEPS) 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 radiofrequency has also been reported.

Policy:

Effective for dates of service on or after February 26, 2018 refer to LCD L33454

Effective for dates of service on or after August 26, 2016 and prior to February 26, 2018: Greater or Lesser Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented saphenous reflux and CEAP* (Clinical-Etiology-Anatomy-Pathophysiology) class C2 – C6** as a **covered benefit** when **all** of the following conditions/criteria are met for procedure codes: 36475, 36476, 36478, 36479, 37700, 37718, 37722, 37735, 37780, 37785:

- Persistent pain, itching or burning, associated with one or more of the following:
    - Bleeding
    - Bulging, ropy varicose veins
    - Clotting in vessels
    - Edema
    - Stasis dermatitis
    - Ulceration

  AND

- the symptoms significantly interfere with activities of daily living, **AND**
- conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 3 months has not improved the symptoms, **AND**
- there is duplex ultrasound documentation of a patent deep venous system

Contraindications for stripping and ligation:

- Within 6 months of pregnancy
- Presence of lymphedema
- Arterial insufficiency
- Deep Vein Thrombosis or a non-patent vein system

Blue Advantage will treat **treatment of the great or small saphenous veins** by surgery, endovenous radiofrequency, laser ablation, or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic** and as a **non-covered benefit**.

*The standard classification of venous disease is the CEAP classification system. The following is the Clinical portion of the CEAP.

Clinical Classification	
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

Accessory Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented accessory saphenous reflux** as a **covered benefit** when **all** of the following conditions/criteria are met:

1. Incompetence of the accessory saphenous vein is isolated; **AND**
   - Persistent pain, itching or burning, associated with one or more of the following:
     - Bleeding
     - Bulging, ropy varicose veins
     - Clotting in vessels
     - Edema
     - Stasis dermatitis
     - Ulceration

   AND
   - the symptoms significantly interfere with activities of daily living, **AND**
   - conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 3 months has not improved the symptoms, **AND**
   - there is duplex ultrasound documentation of a patent deep venous system

OR

2. The great or small saphenous veins have been previously eliminated (at least 3 months); **AND**
   - Persistent pain, itching or burning, associated with one or more of the following:
     - Bleeding
     - Bulging, ropy varicose veins
     - Clotting in vessels
     - Edema
     - Stasis dermatitis
     - Ulceration

   AND
   - the symptoms significantly interfere with activities of daily living, **AND**
   - there is duplex ultrasound documentation of a patent deep venous system

Blue Advantage will treat **treatment of accessory saphenous veins** by surgery, endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic and non-covered**.

Symptomatic Varicose Tributaries

Blue Advantage will treat **Hook Phlebectomy, Sclerotherapy, Stab avulsion, or Transilluminated powered phlebectomy** as a **covered benefit for the treatment of symptomatic varicose tributaries that are greater than 3.0mm in diameter with demonstrated reflux** when the following criteria are met:

- Performed at the same time as surgical (stripping and ligation), endovenous radiofrequency, laser ablation, or microfoam sclerotherapy (Varithena) which meets the criteria for the Great or Small Saphenous Vein,

  OR
- Performed for the treatment of residual or recurrent symptoms which meet the following criteria:
    - Surgical ligation and stripping, endovenous radiofrequency, laser ablation, or microfoam sclerotherapy (Varithena™) of the great or small saphenous veins was previously performed; **AND**
    - Persistent pain, itching or burning, associated with one or more of the following:
        - Bleeding
        - Bulging, ropy varicose veins
        - Clotting in vessels
        - Edema
        - Stasis dermatitis
        - Ulceration

  AND
    - the symptoms significantly interfere with activities of daily living, **AND**
    - conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 6 weeks has not improved the symptoms.

Blue Advantage will treat **treatment of symptomatic varicose tributaries** when performed either at the same time or following prior treatment of saphenous veins using any other techniques other than noted above as a **non-covered benefit** and as **investigational**.

Perforators

Blue Advantage will treat **ligation of perforators, subfascial, radical** (**Linton type**) (CPT **37760)**, with or without skin graft as a **covered benefit** when the presence of diseased skin is documented and requires extensive subcutaneous dissection.

Blue Advantage will treat **subfascial endoscopic perforator surgery (SEPS)** (CPT **37500**) as a **covered benefit** as a treatment for leg ulcers associated with chronic venous insufficiency when the following conditions have been met:

- There is demonstrated perforator reflux; **AND**
- The superficial saphenous veins have been previously eliminated; **AND**
- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; **AND**

- The venous insufficiency is not secondary to deep venous thromboembolism

Blue Advantage will treat **ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery** as a **non-covered benefit**.

Blue Advantage will treat **endovenous radiofrequency or laser ablation of incompetent perforator veins** as a **non-covered benefit** and as **investigational**.

Telangiectasias
Blue Advantage will treat **treatment of telangiectasia such as spider veins, angiomata, and hemangiomata by any technique** as a **non-covered benefit** and as **cosmetic**.

Echosclerotherapy
Blue Advantage will treat **the use of ultrasound guidance/duplex ultrasound** (CPT 76942, 93970 or 93971) during sclerotherapy, (echosclerotherapy), for the treatment of varicose veins or their tributaries as a **non-covered benefit** and as **investigational**.

Other
Blue Advantage will treat techniques for conditions not specifically listed above as a **non-covered benefit** and as **investigational**, including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) as the sole treatment of great or small saphenous, accessory saphenous.
- Sclerotherapy as the sole treatment of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) of the greater or lesser saphenous vein with or without associated ligation of the saphenofemoral junction
- Sclerotherapy as the sole treatment of varicose tributaries with documented reflux of the saphenofemoral junction or reflux isolated to the perforator veins of the upper thigh
- Stab avulsion, hook phlebectomy, or TIPP of great or small saphenous, accessory saphenous or perforator veins
- COMPASS technique (i.e. echosclerotherapy) for management of greater saphenous varicosities with saphenofemoral incompetence
- Endoluminal radiofrequency or laser ablation of tributary veins
- Endoluminal cryoablation of any vein
- Endomechanical or mechanochemical ablative approach of any vein(e.g., ClariVein™ Catheter)
- Cyanoacrylate adhesive of any vein

Effective for dates of service on or after February 26, 2016 through August 25, 2016:

Greater or Lesser Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented saphenous reflux and CEAP* (Clinical-Etiology-Anatomy-Pathophysiology) class C2 – C6** as a **covered benefit** when **all** of the following conditions/criteria are met for procedure codes: 36475, 36476, 36478, 36479, 37700, 37718, 37722, 37735, 37780, 37785:

- Persistent pain, itching or burning, associated with one or more of the following:
    - Bleeding
    - Bulging, ropy varicose veins
    - Clotting in vessels
    - Edema
    - Stasis dermatitis
    - Ulceration

  AND

- the symptoms significantly interfere with activities of daily living, **AND**
- conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 3 months has not improved the symptoms, **AND**
- there is duplex ultrasound documentation of a patent deep venous system

Contraindications for stripping and ligation:

- Within 6 months of pregnancy
- Presence of lymphedema
- Arterial insufficiency
- Deep Vein Thrombosis or a non-patent vein system

Blue Advantage will treat **treatment of the greater or lesser saphenous veins** by surgery, endovenous radiofrequency, laser ablation, or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic** and as a **non-covered benefit**.

*The standard classification of venous disease is the CEAP classification system. The following is the Clinical portion of the CEAP.

Clinical Classification	
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

Accessory Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented accessory saphenous reflux** as a **covered benefit** when **all** of the following conditions/criteria are met:

1. Incompetence of the accessory saphenous vein is isolated; **AND**
   - Persistent pain, itching or burning, associated with one or more of the following:
     - Bleeding
     - Bulging, ropy varicose veins
     - Clotting in vessels
     - Edema
     - Stasis dermatitis
     - Ulceration

   AND
   - the symptoms significantly interfere with activities of daily living, **AND**
   - conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 3 months has not improved the symptoms, **AND**
   - there is duplex ultrasound documentation of a patent deep venous system

OR

2. The great or small saphenous veins have been previously eliminated (at least 3 months); **AND**
   - Persistent pain, itching or burning, associated with one or more of the following:
     - Bleeding
     - Bulging, ropy varicose veins
     - Clotting in vessels
     - Edema
     - Stasis dermatitis
     - Ulceration

   AND
   - the symptoms significantly interfere with activities of daily living, **AND**
   - there is duplex ultrasound documentation of a patent deep venous system

Blue Advantage will treat **treatment of accessory saphenous veins** by surgery, endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic and as a non-covered benefit**.

Symptomatic Varicose Tributaries

Blue Advantage will treat **the following treatments** as a **covered benefit as a component of the treatment of symptomatic varicose tributaries when performed either at the same time**

or for a period of up to 12 months following prior treatment (surgical, radiofrequency or laser) of the saphenous veins:

- Hook phlebectomy, **or**
- Sclerotherapy, **or**
- Stab avulsion, **or**
- Transilluminated powered phlebectomy

Blue Advantage will treat **treatment of symptomatic varicose tributaries** when performed either at the same time or following prior treatment of saphenous veins using any other techniques other than noted above as a **non-covered benefit** and as **investigational**.

Perforators

Blue Advantage will treat **ligation of perforators, subfascial, radical** (**Linton type**) (CPT **37760)**, with or without skin graft as a **covered benefit** when the presence of diseased skin is documented and requires extensive subcutaneous dissection.

Blue Advantage will treat **subfascial endoscopic perforator surgery (SEPS)** (CPT **37500**) as a **covered benefit** as a treatment for leg ulcers associated with chronic venous insufficiency when the following conditions have been met:

- There is demonstrated perforator reflux; **AND**
- The superficial saphenous veins have been previously eliminated; **AND**
- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; **AND**
- The venous insufficiency is not secondary to deep venous thromboembolism

Blue Advantage will treat **ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery** as a **non-covered benefit**.

Blue Advantage will treat **endovenous radiofrequency or laser ablation of incompetent perforator veins** as a **non-covered benefit** and as **investigational**.

Telangiectasias

Blue Advantage will treat **treatment of telangiectasia such as spider veins, angiomata, and hemangiomata by any technique** as a **non-covered benefit** and as **cosmetic**.

Echosclerotherapy

Blue Advantage will treat **the use of ultrasound guidance/duplex ultrasound** (CPT 76942, 93970 or 93971) during sclerotherapy, (echosclerotherapy), for the treatment of varicose veins or their tributaries as a **non-covered benefit** and as **investigational**.

Other

Blue Advantage will treat techniques for conditions not specifically listed above as a **non-covered benefit** and as **investigational**, including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) as the sole treatment of greater or lesser saphenous, accessory saphenous.

- Sclerotherapy as the sole treatment of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) of the greater or lesser saphenous vein with or without associated ligation of the saphenofemoral junction
- Sclerotherapy as the sole treatment of varicose tributaries with documented reflux of the saphenofemoral junction or reflux isolated to the perforator veins of the upper thigh
- Stab avulsion, hook phlebectomy, or TIPP of greater or lesser saphenous, accessory saphenous or perforator veins
- COMPASS technique for management of greater saphenous varicosities with saphenofemoral incompetence
- Endoluminal radiofrequency or laser ablation of tributary veins
- Endoluminal cryoablation of any vein
- Endomechanical ablative approach (e.g., ClariVein™ Catheter)
- Cyanoacrylate adhesive of an vein

Effective for dates of service on or after November 1, 2014 and prior to February 26, 2016:
Greater or Lesser Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented saphenous reflux** as a **covered benefit** when **all** of the following conditions/criteria are met for procedure codes: 36475, 36476, 36478, 36479, 37700, 37718, 37722, 37735, 37780, 37785:

- Persistent pain, itching or burning, associated with one or more of the following:
    - Bleeding
    - Bulging, ropy varicose veins
    - Clotting in vessels
    - Edema
    - Stasis dermatitis
    - Ulceration

  AND

- the symptoms significantly interfere with activities of daily living, **AND**
- conservative management (elevation of lower extremity above heart level 2-3 times per day, compression therapy or exercise) for at least 3 months has not improved the symptoms, **AND**
- there is duplex ultrasound documentation of a patent deep venous system

Contraindications for stripping and ligation:

- Within 6 months of pregnancy

- Presence of lymphedema
- Arterial insufficiency
- Deep Vein Thrombosis or a non-patent vein system

Blue Advantage will treat **treatment of the greater or lesser saphenous veins** by surgery, endovenous radiofrequency, laser ablation, or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic** and as a **non-covered benefit**.

Accessory Saphenous Veins

Blue Advantage will treat **surgery (stripping and ligation), endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) of symptomatic varicose veins/venous insufficiency with ultrasound documented accessory reflux** as a **covered benefit** when **all** of the following conditions/criteria are met:

1. Incompetence of the accessory saphenous vein is isolated, **OR** the greater or lesser saphenous veins have been previously eliminated (at least 3 months); **AND**

- Persistent pain, itching or burning, associated with one or more of the following:
    - Bleeding
    - Bulging, ropy varicose veins
    - Clotting in vessels
    - Edema
    - Stasis dermatitis
    - Ulceration

AND

- the symptoms significantly interfere with activities of daily living, **AND**
- there is duplex ultrasound documentation of a patent deep venous system

Blue Advantage will treat **treatment of accessory saphenous veins** by surgery, endovenous radiofrequency, laser ablation or microfoam sclerotherapy (Varithena™) **that do not meet the criteria** described above as **cosmetic and** as a **non-covered benefit**.

Symptomatic Varicose Tributaries

Blue Advantage will treat **the following treatments** as a **covered benefit as a component of the treatment of symptomatic varicose tributaries when performed either at the same time or for a period of up to 12 months following prior treatment (surgical, radiofrequency or laser) of the saphenous veins:**

- Hook phlebectomy, **or**
- Sclerotherapy, **or**
- Stab avulsion, **or**
- Transilluminated powered phlebectomy

Blue Advantage will treat **treatment of symptomatic varicose tributaries** when performed either at the same time or following prior treatment of saphenous veins using any other techniques other than noted above as a **non-covered benefit** and as **investigational**.

Perforators

Blue Advantage will treat **ligation of perforators, subfascial, radical** (**Linton type**) (CPT **37760)**, with or without skin graft as a **covered benefit** when the presence of diseased skin is documented and requires extensive subcutaneous dissection.

Blue Advantage will treat **subfascial endoscopic perforator surgery (SEPS)** (CPT **37500**) as a **covered benefit** as a treatment for leg ulcers associated with chronic venous insufficiency when the following conditions have been met:

- There is demonstrated perforator reflux; **AND**
- The superficial saphenous veins have been previously eliminated; **AND**
- Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months; **AND**
- The venous insufficiency is not secondary to deep venous thromboembolism

Blue Advantage will treat **ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery** as a **non-covered benefit**.

Blue Advantage will treat **endovenous radiofrequency or laser ablation of incompetent perforator veins** as a **non-covered benefit** and as **investigational**.

Telangiectasias

Blue Advantage will treat **treatment of telangiectasia such as spider veins, angiomata, and hemangiomata by any technique** as a **non-covered benefit** and as **cosmetic**.

Echosclerotherapy

Blue Advantage will treat **the use of ultrasound guidance/duplex ultrasound** (CPT 76942, 93970 or 93971) during sclerotherapy, (echosclerotherapy), for the treatment of varicose veins or their tributaries as a **non-covered benefit** and as **investigational**.

Techniques that are considered investigational:

Blue Advantage will treat techniques for conditions not specifically listed above as a **non-covered benefit** and as **investigational**, including, but not limited to:

- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) as the sole treatment of greater or lesser saphenous, accessory saphenous.
- Sclerotherapy as the sole treatment of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Sclerotherapy techniques, other than microfoam sclerotherapy (Varithena™) of the greater or lesser saphenous vein with or without associated ligation of the saphenofemoral junction

- Sclerotherapy as the sole treatment of varicose tributaries with documented reflux of the saphenofemoral junction or reflux isolated to the perforator veins of the upper thigh
- Stab avulsion, hook phlebectomy, or TIPP of greater or lesser saphenous, accessory saphenous or perforator veins
- COMPASS technique for management of greater saphenous varicosities with saphenofemoral incompetence
- Endoluminal radiofrequency or laser ablation of tributary veins
- Endoluminal cryoablation of any vein
- Endomechanical ablative approach (e.g., ClariVein™ Catheter)

Mechanochemical ablation should be reported with the unlisted vascular surgery procedure code 37799.

There is no specific CPT code for transilluminated powered phlebectomy. Providers might elect to use CPT codes describing stab phlebectomy (37765 or 37766) or unlisted vascular surgery procedure (37799).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was performed through March 23, 2017.

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 following section addresses the efficacy of the conventional treatments, specifically on the appropriate length of a trial of compression therapy and evaluation of recurrence rates for surgical treatment (i.e., ligation and stripping) compared to compression therapy.

Conventional Treatment of Saphenous Reflux

Compression Therapy

A 2009 Cochrane review on compression for venous leg ulcers included a total of 39 randomized, controlled trials (RCTs), with 47 different comparisons. The review was updated in 2012, and included 48 RCTs with 59 different comparisons. Most of the RCTs were small. Objective measures of healing were the time to complete healing, the proportion of ulcers healed within the trial period (typically 12 weeks), the change in ulcer size, and the rate of change in ulcer size. Evidence from eight trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multi-component systems (bandages or stockings) were more effective than single-component compression. In addition, multi-component systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses did not include time to healing, studies included in the review reported that the mean time to ulcer healing was approximately two months, while the median time to healing in other reports was three to five months.

A Cochrane review on compression stockings for the initial treatment of varicose veins in patients without venous ulceration was published in 2011. Included in the review were seven studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] classification C2 to C4). Six of the studies compared different types or pressures of stockings. Subjectively, participants' symptoms improved, but results were not compared with a control arm. Due primarily to inadequate reporting, the methodologic quality of the included trials was unclear. Meta-analyses were not performed due to inadequate reporting and suspected heterogeneity. The authors concluded that there is insufficient high-quality evidence to determine whether or not compression stockings are effective as the sole and initial treatment of varicose veins in patients without venous ulceration, or whether any type of stocking is superior to any other type.

COMPASS Technique

McDonagh and Huntley et al reported on the COMPASS technique for managing saphenofemoral incompetence with greater saphenous varicosities. This technique includes: comprehensive objective mapping, precise image-guided injection, anti-reflux positioning and sequential sclerotherapy. The reported success rate for the saphenofemoral junction and GSV was almost 100% and 98%, respectively. According to the authors, the results do not conclusively demonstrate the utility in avoidance of compression in sclerotherapy but opens avenues for future randomized controlled trials and long-term follow-up studies.

Ligation and Stripping

Systematic literature reviews published in 2008 indicate a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery. In general, recurrence rates after ligation and stripping are estimated at around 20% in short term follow up. Jones and colleagues (1996) reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping. At one year, reflux was detected in 9% of patients, rising to 26% at two years. Rutgers and Kitslaar (1994) reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with

sclerotherapy. At two years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at three years.

Endovenous Thermal Ablation (Laser or Radiofrequency)

Systematic Reviews

An updated Cochrane review from 2014 compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus ligation/stripping for saphenous vein varices. Included in the review were 13 randomized studies with a combined total of 3081 patients. The overall quality of the evidence was moderate. There was no significant difference between sclerotherapy and surgery in the rate of recurrence as rated by clinicians (odds ratio (OR) =1.74, p=0.06) or for symptomatic recurrence (OR=1.28). For endovenous laser ablation (EVLA) versus surgery, there were no significant differences between the treatment groups for clinician noted or symptomatic recurrence, or for recanalization. Neovascularization and technical failure were reduced in the laser group (OR 0.05, p <0.0001 and OR 0.29, p=0.0009, respectively). For endovenous radiofrequency ablation (RFA) versus surgery, there were no significant differences between the groups in clinician noted recurrence, recanalization, neovascularization, or technical failure. The authors concluded that sclerotherapy, EVLA, and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins.

A 2016 Cochrane review compared endovenous laser ablation or RFA to surgical repair for short saphenous veins with reflux at the saphenopopliteal junction. Three RCTs identified compared endovenous laser ablation with surgery. There was moderate-quality evidence that recanalization or persistence of reflux at 6 weeks occurred less frequently after endovenous laser ablation than after surgery (OR=0.07; 95% confidence interval [CI], 0.02 to 0.22), and low-quality evidence that recurrence of reflux was lower after endovenous laser ablation at 1 year (OR=0.24; 95% CI, 0.07 to 0.77).

Randomized Controlled Trials

The largest randomized controlled trial (RCT) is a 2014 trial by Brittenden et al that compared foam sclerotherapy, endovenous laser ablation, and surgical treatment in 798 patients. The study was funded by U.K.'s Health Technology Assessment Programme of the National Institute for Health Research. Veins greater than 15 mm were excluded from the study. At the six-week follow-up visit, patients who were assigned to treatment with foam or laser had the option of treatment with foam for any residual varicosities; this was performed in 38% of patients in the foam group and 31% of patients in the EVLA group. Disease-specific quality of life was similar for the laser and surgery groups. The frequency of procedural complications was similar for the foam sclerotherapy (6%) and surgery (7%) groups, but was lower in the laser group (1%).

Endovenous RFA

In 2008, Luebke and colleagues reported a meta-analysis of eight studies that included a total of 224 patients who underwent RFA and 204 patients who underwent stripping. There was no significant difference between RFA and surgery in immediate or complete greater saphenous vein occlusion, incomplete greater saphenous vein closure, freedom from reflux, recurrent varicose veins, recanalization, or neovascularization between the two treatments. There were significant reductions in tenderness and ecchymosis at one week and fewer hematomas at 72

hours, one week, and three weeks with RFA. Quality-of-life results, including return to normal activity and return to work, favored RF over surgery. The authors noted that rates of recanalization, retreatment, occlusion, and reflux may alter with longer follow-up and that further RCTs with longer follow-up are needed.

Long-term outcomes of endovenous RFA were reported from the Closure Study Group clinical registry in 2005. Thirty-four centers (1,006 patients, 1,222 limbs) participated in the registry, with 12 centers contributing five-year data (406 limbs). The registry included data on the treatment of 52 small saphenous veins and 16 accessory saphenous veins. Follow-up at one week showed a 97% anatomical success rate and a decrease in pain in 50% (from 85% to 30%) of patients. An additional 162 failures were identified over the five years of follow-up; 129 veins were found to have recanalization, and 33 limbs had reflux in the groin. Logistic regression analysis (risk factors of gender, age, body mass index [BMI], vein diameter, and catheter pullback speed) showed that BMI was associated with long-term failure. The rate of pull-back speed of the catheter during treatment was associated with failure to occlude or recanalization.

Endovenous Laser Ablation

The 2012 RELACS study randomized 400 patients to EVLA performed by a surgeon at one site or to ligation and stripping performed by a different surgeon at a second location. At two-year follow-up, there was no significant difference between the groups for clinically recurrent varicose veins, medical condition on the Homburg Varicose Vein Severity Score, or disease-related quality of life. Saphenofemoral reflux was detected by ultrasonography more frequently after EVLT (17.8% vs. 1.3%). The follow-up rate at 5 years was 81%. Same-site recurrences were more frequent in the endovenous laser ablation group (18% with endovenous laser ablation vs 5% with surgery, p=0.002), but different-site recurrences were more frequent in the surgically treated group (50% with surgery vs 31% with endovenous laser ablation, p=0.002). Overall, there was no significant difference in recurrence rates between the groups. There were also no significant differences between groups in disease severity or QOL at 5 years.

Christenson et al (2010) compared EVLA with ligation and stripping in 200 limbs (100 in each group). At one-year follow-up, 98% of the limbs were reported to be free of symptoms. At two-year follow-up, the EVLA group had two veins completely reopened and five partially reopened, which was significantly greater than in the ligation and stripping group. In the 2013 MAGNA trial, 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or foam sclerotherapy. At one- year follow-up, the anatomic success rates were similar between EVLA and stripping (88.5% and 88.2%, respectively), which were superior to foam sclerotherapy (72.2%). Ten percent of the stripping group showed neovascularization. Health-related quality of life improved in all groups. The CEAP classification improved in all groups with no significant difference between the groups. Grade I neovascularization was higher in the conventional surgery group (27% vs 3%, p<0.001), while grade II neovascularization was similar in the two groups (17% vs 13%).

Literature on isolated treatment of the anterior accessory saphenous vein is limited. In a 2009 study, outcomes from a cohort of 33 patients who underwent EVLA of the anterior accessory saphenous vein were compared with 33 matched controls undergoing EVLA of the great saphenous vein. In 21 of the patients (64%) in the accessory saphenous vein group, there had

been no previous treatment of the great saphenous vein. At 12-month follow-up, there was no evidence of reflux in these patients, and the treated accessory saphenous vein was not visible with ultrasound. The Aberdeen Varicose Vein Symptom Severity Score had improved in both groups, with no significant difference between the two groups. Patient satisfaction scores were also similar.

Section Summary: Endovenous Thermal Ablation (Laser or Radiofrequency)
There are a number of large RCTs and systematic reviews of RCTs on endovenous ablation with radiofrequency or laser energy of the saphenous veins. Comparison with ligation and stripping at 2- to 5-year follow-up has indicated similar recurrence rates for the different treatments. Evidence has suggested that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization, resulting in similar outcomes for endovenous thermal ablation and surgery.

Sclerotherapy
Physician-Compounded Sclerotherapy
In the 2013 MAGNA trial (previously described), 223 consecutive patients (240 legs) with great saphenous vein reflux were randomized to EVLA, ligation and stripping, or physician compounded foam sclerotherapy (1cc aethoxysclerol 3%: 3cc air). At one-year follow-up, the anatomic success rate of foam sclerotherapy (72.2%) was inferior to both EVLA and stripping (88.5% and 88.2%, respectively). Twenty-one patients in the sclerotherapy group had partial occlusion with reflux, though the clinical complaint was completely relieved. At five year follow-up, obliteration or absence of the great saphenous vein was observed in only 23% of patients treated with sclerotherapy compared with 85% of patients who underwent conventional surgery and 77% of patients who underwent EVLA. Thirty-two percent of legs treated initially with sclerotherapy required one or more reinterventions during follow-up compared with 10% in the conventional surgery and EVLA groups. However, clinically relevant grade II neovascularization was higher in the conventional surgery and EVLA groups (17% and 13%, respectively) compared with the sclerotherapy group (4%). EuroQol-5D scores improved equally in all groups. A 2012 study was a non-inferiority trial of foam sclerotherapy versus ligation and stripping in 430 patients. Analysis was per protocol. Forty patients (17%) had repeat sclerotherapy. At two-years, the probability of clinical recurrence was similar in the two groups (11.3% sclerotherapy vs. 9.0% ligation and stripping), although reflux was significantly more frequent in the sclerotherapy group (35% vs. 21%). Thrombophlebitis occurred in 7.4% of patients after sclerotherapy. There were two serious adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within one week of treatment.

Microfoam Sclerotherapy
In 2013, Varithena™ microfoam was approved under a new drug application (NDA) for the treatment of varicose veins. Efficacy data were from two randomized, blinded, multicenter studies. One evaluated Varithena™ at 0.5%, 1.0%, and 2.0% polidocanol and the second evaluated Varithena™ at 0.5% and 1.0% polidocanol compared with endovenous placebo or a subtherapeutic dose of polidocanol foam. The primary end point was improvement in symptoms at week eight, as measured by the Varicose Vein Symptoms Questionnaire. The improvement in symptoms was greater in the pooled Varithena™ treatment group ($p<0.0001$) and in each of the individual dose-concentration groups compared with vehicle alone. Secondary and tertiary end

points (appearance, duplex ultrasound response, quality of life) were also significantly better for the Varithena™ groups compared with controls. This second study, called VANISH-2, was published in 2014. At the eight-week assessment, there was elimination of reflux and/or occlusion of the previously incompetent vein in 85.6% of the combined 0.5% and 1.0% groups, 59.6% of patients in the 0.125% group, and 1.8% of the placebo group. Analysis of data from both studies showed a dose response from 0.5% to 2.0% for improvement in appearance and from 0.5% to 1.0% for Duplex responders. The 1.0% dose of Varithena™ was selected for the FDA approval. Safety analysis found deep vein thrombosis detected by ultrasound in 2.8% of Varithena™ -treated patients with 1% of patients having proximal symptomatic thrombi; these were treated with anticoagulants. There was no signal of an increase in neurological adverse events, and there were no adverse cardiac or cardiopulmonary effects following treatment with Varithena™ injectable foam. Rates of occlusion with Varithena™ are similar to those reported for EVLA or stripping. A randomized trial comparing EVLA and stripping with this new preparation of foam sclerotherapy is needed to evaluate its comparative effectiveness. Evaluation out to five years is continuing.

Section Summary: Sclerotherapy
For physician-compounded sclerotherapy, there is high variability in success rates of the procedure and some reports of serious adverse events. By comparison, rates of occlusion with the FDA-approved microfoam sclerotherapy (polidocanol 1%) 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 2 years are similar to those of ligation and stripping.

Mechanochemical Ablation
Early results of an RCT and several prospective cohort studies have been reported.

One prospective multicenter series (2014) evaluated the efficacy of mechanochemical ablation (MCA) of the great saphenous vein in 126 patients in a community setting. Veins were selected that were greater than 4mm and less than 12mm in diameter, with an average diameter of 7.3mm. Closure rates were 100% at one week, 98% at three months, and 94% at six months. The venous clinical severity score decreased from a score of approximately nine pretreatment to about three at six months. In 2012, Elias and Raines reported an industry-sponsored safety and efficacy study of the ClariVein® system. Thirty greater saphenous veins in 29 patients were treated with this device. Great saphenous veins with diameters greater than 12mm were excluded. At six-month follow-up, one vein had recanalized, for a primary closure rate of 96.7%. No pain during the procedure or adverse events were reported. Another prospective series (2013) evaluated MCA of the small saphenous vein in 50 consecutive patients. Only patients with a vein diameter of 2.5 to 11mm were included. The dose of sclerosant was increased after the first 15 patients. At the six-week assessment, all treated veins were occluded and at one-year follow-up, 94% remained occluded. The median visual analog scale (VAS) score for pain during the procedure was two of ten. There were no major complications.

In 2017, Lane et al reported on results from an RCT of 170 patients that compared ClariVein with RFA. Maximum visual analog scale (VAS) pain scores (out of 100) during the procedure were significantly lower in the mechanochemical ablation group (median, 15 mm) than in the

RFA group (median, 34 mm; p=0.003). Average VAS pain scores during the procedure were also significantly lower in the mechanochemical ablation group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific QOL, and generic QOL scores were similar between the groups at 1 and 6 months. However, only 71% of patients were available for follow-up at 6 months, limiting the evaluation of closure rates at this time point.

Section Summary: Mechanochemical Ablation
The evidence on mechanochemical ablation includes an RCT with short-term results and case series. Mechanochemical ablation is a combination of liquid sclerotherapy plus mechanical abrasion. One RCT with short-term follow-up has been published. These short-term results suggest that intraprocedural pain is slightly 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 the efficacy and durability of this procedure compared to established procedures.

Cyanoacrylate Adhesion
The VenaSeal™ pivotal study (VeClose) was a multicenter noninferiority trial with 222 patients that compared VenaSeal™ versus RFA for the treatment of venous reflux. The primary end point, the proportion of patients with complete closure of the target great saphenous vein at three months measured by ultrasound, was noninferior to RFA, with a 99% closure rate for VenaSeal™ compared with 96% for RFA. The secondary end point of intraoperative pain was similar for the two groups (2.2 on a ten point scale for VenaSeal™ and 2.4 for RFA, p=0.11). Ecchymosis at day three was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA (p<0.01). Scores on the Aberdeen Varicose Veins Questionnaire (AVVQ) and Venous Clinical Severity Score improved to a similar extent in the two groups.

Twenty-four-month follow-up was reported for 24 of 38 patients enrolled in a study by Almeida et al (2015). Thirty-three-month follow-up was reported in 467 veins out of a series of 795 veins (58.7%) treated at one institution in Germany. An inflammatory reddening of the skin was observed at approximately one week after treatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins reexamined, the sealing rate was 97.7%. This series is limited by the high loss to follow-up.

Section Summary: Cyanoacrylate Adhesive
Evidence on cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with 3 months of follow-up and case series with longer follow-up. The short-term efficacy of cyanoacrylate adhesive has been shown to be non-inferior to RFA at 3 months. Longer follow-up in trials with a larger number of patients is needed to determine durability of this treatment.

Endovenous Cryoablation
Klem and colleagues (2009) reported a randomized trial that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins. The percentage of patients with great saphenous vein remaining was 44% in the

endovenous cryoablation group and 15% in the conventional stripping group. The Aberdeen Varicose Vein Questionnaire also showed better results for conventional stripping (score of 11.7) in comparison with cryoablation (score of 8.0). There were no differences between the groups in Short-Form-36 (SF-36) subscores, and neural damage was the same (12%) in both groups.

Disselhoff and colleagues (2008, 2011) reported two and five year outcomes from a randomized trial that compared cryoablation with EVLA. Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP C2) with saphenofemoral incompetence and greater saphenous vein reflux. At ten days after treatment, EVLA had better results than cryoablation with respect to pain score over the first ten days (2.9 vs. 4.4), resumption of normal activity (75% vs. 45%) and induration (15% vs. 52%). At two year follow-up, freedom from recurrent incompetence was observed in 77% of patients after EVLA and 66% of patients after cryostripping (not significantly different). At five years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization was found in 62% of patients treated with EVLA and 51% of patients treated with cryostripping (not significantly different). Neovascularization was more common after cryostripping, but incompetent tributaries were more common after EVLA. There was no significant difference between groups in the Venous Clinical Severity Score or Aberdeen Varicose Vein Severity Score at either two or five years.

Section Summary: Cryoablation
Two RCTs have suggested that cryotherapy is not as effective as available alternatives.

Section Summary
There are a number of large randomized trials on endovenous ablation of the saphenous veins. Comparison with ligation and stripping at two-year follow-up supports use of both RFA and EVLT. Evidence suggests that ligation and stripping may lead to neovascularization, while thermal ablation may lead to recanalization. Controlled studies with longer follow-up are needed to determine the long-term efficacy of these treatments with greater certainty. Two randomized controlled trials suggest that cryotherapy is not as effective as available alternatives. For physician compounded sclerotherapy, there is high variability in success rates of the procedure and reports of serious adverse events. Rates of occlusion with the FDA-approved microfoam sclerotherapy are similar to those reported for EVLA or stripping. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared to thermal ablation techniques is that it does not require tumescent anesthesia and may result in less post-operative pain. To date, the ClariVein procedure has been assessed in relatively few patients and for short durations. Thus, there is insufficient evidence to permit conclusions regarding the safety and efficacy of mechanochemical ablation. Short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RF in a large multicenter RCT at three months. Longer term follow-up is needed to determine durability of this treatment.

Tributary Varicosities
Sclerotherapy and Phlebectomy
Early studies established ligation and stripping as the gold standard for the treatment of saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A 2006 Cochrane Review, based primarily on RCTs from the 1980s, concluded that, “The evidence supports the current place of

sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins." Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system, e.g., post- or adjunctive treatment to other procedures such as surgery. In 2014, El-Sheikha et al reported a small randomized trial of concomitant or sequential (if needed) phlebectomy following EVLA for varicose veins. Quality of life and clinical severity scores were similar between the groups by one year, with 16 of 24 patients (67%) in the sequential phlebectomy group receiving a secondary intervention.

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. For example, of 1,009 patients recruited for an RCT, 64 patients were found to have minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. At baseline, 92% had symptoms of heaviness, 69% had cosmetic concerns, 53% reported itching, and 30% reported relief of symptoms through the use of compression hosiery. At one year follow-up, there was an improvement in clinicians' assessment of the anatomical extent of varicose veins, with 85% of patients in the sclerotherapy group improved compared to 29% of patients in the conservative-therapy group. Symptoms of aching were better or eliminated in 69% of the sclerotherapy group and 28% of the group treated with conservative therapy. Cosmetic concerns were improved in 85% of the sclerotherapy patients and 14% of controls.

The bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. In 2012, Yamaki et al reported a prospective randomized controlled trial that compared visual foam sclerotherapy vs. ultrasound-guided foam sclerotherapy of the great saphenous vein together with visual foam sclerotherapy for varicose tributary veins. A total of 51 limbs in 48 patients were treated with ultrasound-guided foam sclerotherapy plus visual foam sclerotherapy of the varicose tributaries, and 52 limbs in 49 patients were treated with foam sclerotherapy alone. At six-month follow-up, complete occlusion was found in 23 limbs (45.1%) treated with ultrasound-guided and visual-guided foam sclerotherapy and in 22 limbs (42.3%) treated with visual sclerotherapy alone. Reflux was absent in 30 limbs (58.8%) treated with ultrasound and visual guidance and in 37 (71.2%) treated with visual guidance alone (not significantly different). The authors note that for the treatment of tributary veins in clinical practice, most patients receive direct injection of foam without ultrasound guidance.

Transilluminated Powered Phlebectomy (TIPP)

A 2008 meta-analysis included five studies that compared TIPP with conventional surgery. Results showed a significant advantage of TIPP over the conventional treatment for number of incisions, mean cosmetic score, and duration of the procedure. However, TIPP also increased the incidence of hematoma and resulted in worse mean pain scores. Included in the meta-analysis was a randomized clinical trial by Chetter et al that compared TIPP (n=29) with a multiple stab incision procedure (n=33). A single surgeon performed all but two of the procedures, and there was no difference in operating time. Patients treated with TIPP had an average of five incisions, compared with 20 for the multiple stab procedure. However, blinded evaluation revealed that bruising or discoloration was higher for the TIPP group at both one and six weeks after surgery. At six weeks after surgery, patients in the TIPP group showed no improvement in pain (-2 points

on the Burford pain scale), while patients in the multiple stab incision group had a significant improvement in pain score compared with presurgical baseline (-20 points). At six weeks after surgery, quality-of-life measures had improved in the multiple-stab incision group but not in the TIPP group. Thus, although TIPP had the advantage of fewer surgical incisions, in this single-center study, it was associated with a more prolonged recovery due to more extensive bruising, prolonged pain, and reduced early postoperative quality of life.

Section Summary: Tributary Varicosities

The evidence includes RCTs and systematic reviews of RCTs. The literature has indicated that sclerotherapy is effective for the treatment of 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). TIPP is effective at removing varicosities; outcomes are comparable with available alternatives such as stab avulsion and hook phlebectomy. However, there is limited evidence that TIPP is associated with more pain, bruising, discoloration, and a longer recovery, and the current literature does not show an advantage of TIPP over conventional treatment.

Perforator Reflux

A systematic literature review published in 2008 indicates insufficient evidence for the role of incompetent perforator vein surgery. These conclusions were based on four RCTs published since 2000 that compared superficial vein surgery with conservative therapy in advanced chronic venous insufficiency (CEAP category C5/6). The four trials included two Level I (large subject population) and two Level II (small subject population) studies. Two of the trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other two treated the greater saphenous vein alone. The two randomized studies in which the greater saphenous vein alone was treated (including the ESCHAR trial) showed a significant reduction in ulcer recurrence in comparison with conservative therapy. A 2011 community hospital-based multicenter, double-blind, randomized trial found no clinical benefit (self-reported symptoms) from adding subfascial endoscopic perforator surgery (SEPS) to saphenous surgery in 75 patients with varicose ulcers (CEAP C5 or C6) and incompetent perforators.

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, one study (2005) showed that reversal of perforator vein incompetence (41% of 68 previously incompetent perforators) was more common than new perforator vein incompetence (22% of 183 previously competent perforators) following superficial vein surgery. O'Donnell (2008) discusses additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

Subfascial Endoscopic Perforator Surgery (SEPS)

In 2004, Tenbrook and colleagues published a review of the literature of SEPS, which included 19 case series and one randomized trial. In total, the reviewed studies included 1031 patients

with 1140 treated limbs. The authors concluded that SEPS was associated with excellent results in terms of ulcer healing and prevention of recurrence. However, the authors also noted that randomized trials are required to define the relative contributions of compression therapy, superficial venous surgery, and SEPS in the management of severe venous disease. In 2015, Van Gent et al reported ten year follow-up of a randomized trial that compared conservative treatment versus SEPS for venous leg ulcers. Patients (196 legs) returned to the clinic on an annual basis and analysis was conducted with the last-observation-carried-forward. The primary outcome, incidence ulcer-free, was significantly higher in the surgical group than in the conservative treatment group (58.9% vs 39.6%, p=0.007). The number of incompetent perforator veins at follow-up was a risk factor for not being ulcer free (OR=18.5, p<0.001). The relatively high rate of recurrence of the surgically treated group may be due to limited/no stripping of the superficial veins at the time of SEPS.

A 2009 meta-analysis of SEPS for chronic venous insufficiency concludes that "Its [SEPS] use should not be employed routinely and could only be justified in patients with persistent ulceration thought to be of venous origin, and in whom any superficial reflux has already been ablated and post-thrombotic changes excluded." The authors also state that "introduction of less invasive techniques for perforator vein ablation, such as ultrasound-guided sclerotherapy or radiofrequency ablation may diminish the role of SEPS in the future."

Other Treatments

A 2008 review of procedures for management of varicose veins recommends duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short RF catheter for the treatment of symptomatic residual perforator vein incompetence. Ablation of incompetent perforator veins with laser or RFA had been shown to be technically feasible, although no studies had been identified that showed an improvement in clinical outcomes (e.g., ulcer healing or recurrence). The 2010 literature update identified one study of EVLA for perforating veins in 33 patients with a CEAP classification of four (skin changes), five (healed ulcer), or six (active ulcer). All incompetent saphenous trunks were treated simultaneously (63% of limbs). At three-month follow-up, occlusion was achieved in 78% of the perforating veins. Five patients (15%) had active ulcers at baseline; four of the five ulcers had healed by six weeks after EVLA. Evidence regarding the treatment of perforator veins with ultrasound-guided sclerotherapy is limited, and there is a risk of deep venous occlusion.

Section Summary

The literature indicates that the routine ligation/ablation of incompetent perforator veins is not medically 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). Therefore, treatment of incompetent perforator veins may be considered medically necessary in this specific situation.

Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. SEPS has been shown to be as effective as the Linton procedure with a reduction in adverse events. Only one small study has been identified showing an

improvement in health outcomes using EVLA. In addition, endoluminal ablation with specialized radiofrequency probes has also been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity in comparison with surgical interventions. However, there is not sufficient evidence to ensure positive net health outcomes and longer term data is needed. For sclerotherapy, concerns have been raised about the risk of deep vein occlusion, and evidence is currently insufficient to evaluate the safety or efficacy of this treatment for incompetent perforator veins.

Summary

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 2- to 5-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 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 2 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 2 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 3 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. Only 1 case series has been identified showing an improvement in health outcomes using endovenous ablation with specialized laser or radiofrequency probes. While results of the case series are

promising, additional studies are needed. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

Society for Vascular Surgery and the American Venous Forum

The Society for Vascular Surgery and the American Venous Forum published clinical practice guidelines in 2011. The recommendations are rated as strong=1 or weak=2, based on a level of evidence that is either high quality=A, moderate quality=B, or low quality=C, and include the following:

Compression therapy for venous ulcerations and varicose veins:

- Compression therapy is recommended as the primary treatment to aid healing of venous ulceration (GRADE 1B, strong recommendation, moderate quality evidence).
- To decrease the recurrence of venous ulcers, they recommend ablation of the incompetent superficial veins in addition to compression therapy is recommended (GRADE 1A, strong recommendation, high quality evidence).
- Use of compression therapy for patients with symptomatic varicose veins is recommended (GRADE 2C, weak recommendation, low-quality evidence)
- Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended (GRADE 1B, strong recommendation, moderate quality evidence).

Treatment of the incompetent great saphenous vein:

Endovenous thermal ablation (radiofrequency or laser) is recommended over:

- Chemical ablation with foam (GRADE 1B, strong recommendation, moderate quality evidence) or
- High ligation and stripping (GRADE 1B, strong recommendation, moderate quality evidence) due to reduced convalescence and less pain and morbidity. Cryostripping is a technique that is new in the United States, and it has not been fully evaluated.

Varicose tributaries:

- Phlebectomy or sclerotherapy are recommended to treat varicose tributaries (GRADE 1B, strong recommendation, moderate quality evidence).
- Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy (GRADE 2C, weak recommendation, low quality evidence).

Perforating vein incompetence:

- Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended (CEAP class C2; GRADE 1B, strong recommendation, moderate quality evidence),
- Treatment of pathologic perforating veins (outward flow of > 500 ms duration, with a diameter of > 3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6) is recommended (GRADE 2B,weak recommendation, moderate quality evidence)

Society of Interventional Radiography (SIR)
In 2003, the (SIR) published a position statement that considered endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins under the following conditions:

1. The endovenous treatment of varicose veins may be medically necessary when one of the following indications (a-e) is present:
    a) Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching, and/or swelling during activity or after prolonged standing.
    b) Significant recurrent attacks of superficial phlebitis
    c) Hemorrhage from a ruptured varix
    d) Ulceration from venous stasis where incompetent varices are a contributing factor
    e) Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above);

    And;
2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings; **And**;
3. The patient's anatomy is amenable to endovenous ablation.

In a joint statement published in 2007, the American Venous Forum and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency. The document recommended that reporting in clinical studies should include the symptoms of venous disease, history of disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation may include patients with reflux in an incompetent GSV or small saphenous vein (SSV) or in a major tributary branch of the GSV or SSV such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory GSV. The presence of reflux in these veins is important to document using duplex ultrasound imaging, and the ultrasound criteria used to define reflux should be indicated. It was also stated that in current practice, most vascular laboratories consider the presence of venous flow reversal for >0.5 to 1.0 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

National Institute for Health and Clinical Excellence (NICE)
NICE issued updated guidance on ultrasound-guided foam sclerotherapy for varicose veins in 2013. The guidance states that:

> "1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but significant risks of foam embolization (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.
> 1.2 During the consent process, clinicians should inform patients that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischemic attacks and stroke."

NICE issued guidance on endovenous mechanochemical ablation in 2016, concluding that current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure provided that standard arrangements are in place for consent, audit and clinical governance."

In 2013, NICE published practice guideline on the diagnosis and management of varicose veins in the leg. NICE recommends a study of the clinical and cost effectiveness of

- Concurrent phlebectomies or foam sclerotherapy for varicose tributaries during truncal endothermal ablation for varicose veins
- Truncal endothermal ablation without concurrent phlebectomies or foam sclerotherapy
- Truncal endothermal ablation with phlebectomies or foam sclerotherapy, if needed, six to twelve weeks later.

In 2015, NICE published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation, and surgery for varicose veins. Cost-effectiveness was based on a large multicenter randomized trial comparing treatments for varicose veins (described previously). Five-year trial results are currently being evaluated.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force has not addressed the treatment of varicose veins/venous insufficiency.

Key Words:

Varicose vein, varicosity, telangiectasia, venous insufficiency, spider veins, sclerotherapy, ultrasound guided sclerotherapy, echosclerotherapy, greater saphenous vein, VNUS Closure System, radiofrequency ablation, Endovenous Laser Ablation, SEPS, Subfascial Endoscopic Perforator Surgery, GSV, COMPASS technique, Linton procedure, EVLT, Trivex*, Trivex* System, transilluminated power phlebectomy, TIPP, stab avulsion, phlebectomy, ambulatory phlebectomy, foam sclerotherapy, perforator, ClariVein, endomechanical, VenaCure, Varithena

Approved by Governing Bodies:

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 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 RFS*Flex*™ 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."
- 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

***NOTE*: For sclerotherapy treatment only, make sure it is not treatment for spider veins.**

Current Coding:

CPT codes:

Prior to 01/01/18, there is no specific CPT for microfoam sclerotherapy (Varithena™). Use the unlisted vascular surgery procedure code 37799. Use of codes 36475-36476 would be inappropriate as the procedure is not ablation therapy.

Prior to 01/01/17, mechanochemical ablation should be reported with the unlisted vascular surgery procedure code 37799.

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) **(Effective 01/01/18)**
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 **(Effective 01/01/18)**
36468	~~Single or multiple~~ Injection(s) of sclerosant ~~sclerosing solutions~~ for spider veins (telangiectasia), limb or trunk
36470	Injection of ~~sclerosing solution~~ sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of ~~sclerosing solution~~ sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated. **(Effective 01/01/17)**
36474	; subsequent vein(s) treated in a single extremity, each through separate access sites **(Effective 01/01/17)**
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	; 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	; subsequent veins treated in a single extremity, each through separate access sites
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 **(Effective 01/01/18)**
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) **(Effective 01/01/18)**
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous

	malformations, venous and capillary hemangiomas, varices, varicoceles) **(Effective 01/01/2014)**
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 veins(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division and/or excision varicose veins cluster(s), one leg
37799	Unlisted procedure, vascular surgery
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study

HCPCS:

S2202	Echosclerotherapy

ICD-9-CM:

454.0-454.8	Varicose veins of lower extremities, code range
459.81	Venous (peripheral) insufficiency, unspecified

ICD-10-CM (effective 10/01/15)

I83.001-I83.899	Varicose veins of lower extremities, code range
I87.2	Venous, insufficiency (chronic, peripheral)

Previous Coding:

CPT code:

36469	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face **(Deleted 01/01/15)**
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 **(Deleted effective 01/01/2014)**

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