Clinical Policy Title: Varicose vein treatments and therapies

Clinical Policy Number: 16.03.06

Effective Date: January 1, 2014
Initial Review Date: August 20, 2014
Most Recent Review Date: August 17, 2016
Next Review Date: August 2017

Policy contains:
- Varicose veins.
- Treatments and therapies.

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers varicose vein treatments and therapies to be clinically proven and, therefore, medically necessary when the following criteria are met:

- The patient has documented varicose veins, which are symptomatic (e.g., aching and/or edema, not responsive to elevation and/or analgesics).

- Compression stockings are the initial treatment for varicose veins.
  - Graded compression stockings may be indicated for all of the following:
    - Venous stasis ulcer.
    - Following an invasive procedure on a saphenous vein, for example:
      - Saphenous vein stripping.
      - Laser ablation of the saphenous vein.
      - Radiofrequency ablation (RFA) of saphenous vein.
      - Deep venous thrombosis of a lower extremity.
    - Prevention or treatment of post-thrombotic syndrome.
  - Contraindications have been excluded, including all of the following:
    - Untreated cellulitis.
    - Arterial insufficiency.
    - Severe cardiac failure.

- Compression therapy (pressure 20–30 mm Hg) is a second order therapy under the following conditions:
- For patients with symptomatic varicose veins.
- As the primary treatment to aid healing of venous ulceration.
- In addition to ablation of incompetent superficial veins to decrease the recurrence of venous ulcers.
- Not recommended as the primary treatment if the patient is a candidate for saphenous vein ablation.
- Prior to consideration of ablative or surgical approaches, an ultrasound or duplex scan must be performed to determine the extent and configuration of varicose veins. Documentation from the studies must demonstrate both of the following:
  - Absence of deep venous thrombosis.
  - Greater and/or lesser saphenous vein valvular incompetence/reflux that correlates with the patient’s symptoms.
- Varicose vein ablative and stripping procedures that fail conservative therapy, including:

<table>
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<tr>
<th>Invasive procedure</th>
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| Endovascular laser ablation, radiofrequency ablation, stripping, ligation and excision of the great saphenous vein and small saphenous | • Saphenofemoral valve incompetence documented by duplex scan or ultrasound test.  
  • The saphenofemoral junction.  
  • The great saphenous vein in the thigh.  
  • The saphenopopliteal junction.  
  - The small saphenous vein in the calf.  
  - Perforators that remain incompetent only after ablation of the incompetent saphenous system and all the following criteria are met:  
    ▪ Perforator vein size is 3.5 mm or greater.  
    ▪ Outward flow duration is ≥500 milliseconds.  
    ▪ Perforating vein is located underneath a healed or active venous stasis ulcer (CEAP class C-5-C6). (See glossary.) | • Deep venous thrombosis ruled out by duplex ultrasound or other imaging test.  
  • No evidence of clinically significant lower extremity arterial disease.  
  • Symptoms of saphenous venous insufficiency causing a clinically significant functional impairment, including one or more of the following:  
    - Leg pain.  
    - Leg fatigue.  
    - Leg edema.  
    - Persistent or recurrent venous stasis ulcer.  
    - Persistent or recurrent superficial thrombophlebitis.  
  • No significant symptomatic improvement in response to a three-month trial of fitted elastic support hose. |
| Ambulatory phlebectomy or transilluminated powered phlebectomy | • Symptomatic saphenous veins, varicose tributaries, accessory, and perforator veins 2.5 mm or greater in diameter for persons who meet the medical necessity criteria for varicose vein treatment in sections I and II above and who are being treated or have previously been treated by one or more of the procedures noted in sections I and II above for incompetence (i.e., reflux) at the saphenofemoral junction or |
### Liquid or foam sclerotherapy (endovenous chemical ablation)

- Symptomatic saphenous veins, varicose tributaries, accessory, and perforator veins 2.5 mm or greater in diameter for persons who meet medical necessity criteria for varicose vein treatment in sections I and II above and who are being treated or have previously been treated by one or more of the procedures noted in section II above for incompetence (i.e., reflux) at the saphenofemoral junction or saphenopopliteal junction.
- No evidence of saphenofemoral valve incompetence documented by duplex ultrasound or other imaging test.
- One or more of the following is or are present:
  - Recurrent or residual symptomatic superficial varicosities after vein stripping.
  - Superficial varices from venous malformations for which surgery is not advisable.
  - Emergency treatment for bleeding, ruptured superficial varicose veins.
  - Large superficial varices around skin ulcer.

The number of medically necessary sclerotherapy injection sessions varies with the number of anatomical areas that have to be injected, as well as the response to each injection. Usually one to three injections are necessary to obliterate any vessel, and 10 to 40 vessels, or a set of up to 20 injections in each leg, may be treated during one treatment session. Initially, up to two sets of injections of sclerosing solution in multiple veins in each affected leg (i.e., four sets of injections if both legs are affected) are considered medically necessary when criteria are met. (A set of injections is defined as multiple sclerotherapy injections during a treatment session.) Additional sets of injections of sclerosing solution are considered medically necessary for persons with persistent or recurrent symptoms.

### Subfascial endoscopic perforator vein surgery (SEPS)

Medically necessary for the treatment of members with advanced chronic venous insufficiency secondary to primary valvular incompetence of superficial and perforating veins, with or without deep venous incompetence, when conservative management has failed.

### Valvular reconstruction

Is considered medically necessary for chronic venous insufficiency.

### Limitations:

All other uses of therapies and/or treatments for varicose veins are not medically necessary. Keystone First considers any of the following varicose vein therapies and/or treatments to be cosmetic and not clinically proven, therefore not medically necessary:

- Sclerotherapy or various laser treatments (including tunable dye or pulsed dye laser like PhotoDerm®, VeinLase®, or VascuLight®) of the telangiectatic dermal veins (e.g., reticular, capillary, or venule), which may be described as "spider veins" or "broken blood vessels."
- Endoluminal radiofrequency ablation and endoluminal laser ablation, which are considered investigational and not medically necessary for all other uses in the lower extremities including but not limited to:
  - As an alternative to perforator vein ligation.
  - As treatment of saphenous vein tributaries or extensions (e.g., anterolateral thigh, anterior accessory saphenous, and Giacomini veins).
As an alternative to adjunctive sclerotherapy or echosclerotherapy of symptomatic varicose tributaries.

- Endoluminal cryoablation, which is investigational and not medically necessary.
- Mechanochemical ablation of any vein, which is investigational and not medically necessary because it has not been proven to be as effective as established alternatives.
- Sclerotherapy or echosclerotherapy, which are considered investigational and not medically necessary:
  - As the sole* treatment of symptomatic varicose tributary or extension or perforator veins in the presence of valvular incompetence of the greater or lesser saphenous veins (by Doppler or duplex ultrasound scanning).
  - As the sole treatment of symptomatic varicose tributary or perforator veins in the absence of saphenous vein reflux or major saphenous vein tributary reflux.
  - For the treatment of secondary varicose veins resulting from deep-vein thrombosis or arteriovenous fistulae when used to treat valvular incompetence (i.e., reflux) of the greater or lesser saphenous veins, with or without associated ligation of the saphenofemoral junction.
  - When performed as part of other protocols for sclerotherapy, including, but not limited to, the COMPASS protocol, for the treatment of valvular incompetence (i.e., reflux) of the greater or lesser saphenous veins.
- Photothermal sclerosis (also referred to as an intense pulsed light source, like PhotoDerm Vasculight, or VeinLase), used to treat small veins such as small varicose veins and spider veins, which is considered cosmetic because such small veins do not cause pain, bleeding, ulceration or other medical problems.
- Transdermal laser treatment, which is considered experimental and investigational for the treatment of large varicose veins because it has not been proven in direct comparative studies to be as effective as sclerotherapy and/or ligation and vein stripping in the treatment of the larger varicose veins associated with significant symptoms (pain, ulceration, inflammation). (Note: Although transdermal Nd:YAG laser has been shown to be effective for the treatment of telangiectasias and reticular veins, treatment of these small veins is considered cosmetic.)
- Polidocanol injection (Asclera), which is considered cosmetic. It has been approved by the U.S. Food and Drug Administration for the treatment of telangiectasias and reticular veins less than 3 mm in diameter (treatment of these small veins is considered cosmetic).
- Subfascial endoscopic perforator vein surgery (SEPS), which is considered experimental and investigational for the treatment of patients with postthrombotic syndrome, varicose veins, and other indications because its effectiveness has not been established.
- Ambulatory phlebectomy or transilluminated powered phlebectomy, which is considered experimental and investigational for treatment of junctional reflux as these procedures have not been proven to be effective for these indications. Ambulatory phlebectomy is considered cosmetic for veins less than 2.5 mm in diameter and all other indications.
- Repeated procedures for venous ablation (e.g., VNUS, ELAS), performed more than twice, on the same area of the same vein, in separate surgical procedures; considered not medically necessary.

*Note for patients receiving anticoagulant therapy: If the decision is made to proceed with the service, the medical record should clearly support that the benefit outweighs the risk and the justification to proceed with the service should be given.
Contraindications:
- Pregnant women.
- Patients on anticoagulant therapy.*
- Patients unable to tolerate compressive bandages or stockings.
- Patients with severe distal arterial occlusive disease.
- Patients undergoing obliteration of the deep venous system.
- Patients who are allergic to the sclerosant.

Alternative covered services:
Consultation with treating physician or specialist.

Background
Varicose veins are widened veins that twist and turn and are visible under the skin of the leg. These abnormally enlarged vessels develop when the thin flaps of the venous valves no longer meet in the midline, which allows blood to reflux, or flow backwards away from the heart, causing discoloration. Backward blood flow introduces increased pressure into veins that are intended to function as a low-pressure system, which leads to progressive distension, dilation, and tortuosity of the vein. Since the superficial veins lack muscle support and lie close to the surface of the skin, they become visible with increased intravascular pressure. The condition is further aggravated as the walls of the affected vein weaken. Larger varicose veins are found most often on the back of the calf or on the inside of the leg between the groin and ankle, and are commonly the result of reflux through the valve at the junction between the great saphenous vein (GSV) and the common femoral vein, but can also result from enlargements of the perforating veins. Some form of venous disorder affects approximately 80 million Americans. Women are more likely to suffer from varicose veins than men, with as many as 50 percent affected.

Varicose veins generally do not cause medical problems, although many sufferers seek medical advice as they are often a cosmetic concern. Symptoms that may occur include pain, ankle swelling, tired legs, restless legs, night cramps, heaviness, and itching. Initially, these symptoms may not warrant medical intervention but they can become clinically important when symptoms such as cramping, throbbing, burning, swelling, feeling of heaviness or fatigue, and alterations in skin pigmentation become pronounced. Severe varicosities may be associated with dermatitis, ulceration, and thrombophlebitis, which result when metabolic waste products are no longer removed due to pooling of venous blood and increased hydrostatic pressure.

The four main causes of these abnormalities are heredity, female sex, gravitational hydrostatic forces, and hemodynamic muscular compartment pressure. There are clear indications and goals for intervention. Genetic predisposition is the primary contributing factor causing varicose veins. Hormonal factors associated with puberty, pregnancy, menopause, the use of birth control pills, estrogen, and progesterone may also contribute to the condition. Varicose veins may also be the result of increased hydrostatic pressure from: standing occupations, obesity, ultraviolet or chronic X-ray exposure, thrombophlebitis or deep vein thrombosis, chronic lower extremity infection, anoxia, or traumatic injury. The degeneration of smooth muscles and loss of elastic support, which is associated with advanced age, is also a contributing factor.
Another common cause is chronic venous insufficiency (CVI), a venous disorder affecting at least 25 million Americans. CVI is a disorder in which veins fail to pump blood back to the heart adequately. It can cause varicose veins, skin ulcers, and superficial or deep vein thrombosis in the legs. GSV reflux, a form of CVI, is most commonly responsible for the development of varicose veins.

Traditionally, varicose veins are first treated with conservative management techniques that attempt to treat the underlying cause of the defect. Conservative therapies may include: weight reduction, elevation of the legs, walking, or compression hosiery. Compression stockings are often the first line of treatment and come in a variety — knee-length to full tights — and apply different pressures to support the flow of blood in the veins. There are three types of compression stockings that offer increasing levels of pressure, including support pantyhose, over-the-counter compression hose, and prescription-strength compression hose. Although compression stockings may not prevent the emergence of varicose veins, they can reduce the risk of GSV reflux and the worsening of symptoms.

Varicose veins are often treated with surgery to remove the veins by stripping them to the level of the knee (so-called high ligation and stripping), particularly if there is severe discomfort, ulceration, thrombosis, ligation, or excision, or if ablation of the affected veins may be indicated. New less invasive treatments seal the main leaking vein in the thigh using laser (endovenous laser therapy), RFA, or foam sclerotherapy. These techniques may result in less pain after the procedure, fewer complications, and a quicker return to work and normal activities, with improved patient quality of life, as well as avoiding the need for general anesthesia.

**Saphenous vein ablation, radiofrequency:**

RFA, also called obliteration, is a form of endovenous thermal ablation. Under duplex (Doppler) scan guidance, radiofrequency energy is directed at the specified varicose vein. This controlled heating of the vein wall results in closure of the vein due to contraction of collagen in the wall. Providing saphenous vein closure rates around 85 percent to 90 percent, RFA may have a somewhat lower closure rate when directly compared with vein stripping and ligation. Possible complications include vessel perforation, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, and skin burns. RFA has been shown in a prospective nonrandomized trial to be more effective than foam sclerotherapy for closure of the GSV at one-year follow-up. RFA offers a less invasive alternative to surgical stripping and ligation for patients with symptomatic varicose veins. Post-RFA patients can return to work sooner with less pain and fewer infections.

**Sclerotherapy:**

Injection sclerotherapy can be used for superficial, residual, or recurring varicose veins following surgery and thread veins to obliterate veins. An irritant liquid such as sodium tetradecyl sulphate (STD) is injected into the faulty blood vessel. The solution obliterates the lumen through irritating the vein until it shrinks, becoming scar tissue and fading. Possible complications of sclerotherapy include formation of blood clots, skin staining, inflammation, ulcers and tissue damage, and reactions to the sclerosing agent. Currently sclerotherapy is usually limited to treatment of recurrent varicose veins following surgery and thread veins.

**Varicose vein and venous insufficiency/ligation tripping cryostripping:**

Ligation is a surgical technique where veins are tied off proximally; this usually results in atrophy of veins. This prevents the pooling of blood or backwards flow that can lead to discoloration. Ligation is
sometimes performed in conjunction with stripping of the vein, which is actual removal of the specified vein. The stripping technique surgically removes the truncal vein. This is used for both the initial treatment and for the prevention of future varicose veins. Usually performed as an outpatient procedure, these surgical treatment options of varicose veins are consistently successful.

Cryoablation uses extreme cold to injure the vessel. Cryoablation of the GSV may be considered an alternative approach to traditional ligation and stripping. During this procedure, a cryoprobe is passed through the GSV, the probe attaches to the GSV, and stripping is performed by pulling back the probe. Results of cryotherapy procedures for treatment of varicose veins in the published scientific literature are mixed and do not lend strong support to improved clinical outcomes when compared to more conventional methods of varicose vein treatment. Further studies are needed to demonstrate safety, efficacy, and the clinical utility of cryoablation.

Ambulatory phlebectomy/stab phlebectomy:

Ambulatory phlebectomy is also widely accepted as an alternative to sclerotherapy, performed for the treatment of secondary branch varicose veins. It is also referred to as miniphlebectomy, hook phlebectomy, or stab avulsion. In ambulatory phlebectomy, multiple small incisions are made, and the varicose veins are grasped with a small hook or hemostat. The entire varicosity can be extracted with multiple small incisions. Effectiveness is dependent on the type of vein treated. Phlebectomy is a treatment of choice for smaller veins such as the lateral accessory veins; for larger veins, such as the saphenous veins, phlebectomy may not provide the same level of success as sclerotherapy.

Transilluminated powered phlebectomy (TIPP):

TIPP, which is similar to ambulatory phlebectomy, is another minimally invasive alternative to standard surgery for the treatment of symptomatic varicosities. Also known as the TriVex™ procedure, TIPP involves endoscopic resection and ablation of the superficial varicosity.

Subcutaneous transillumination and tumescent anesthesia help visualize and locate the varicosity, while subcutaneous vein ablation is performed using a powered resector to obliterate the vein. Tumescent anesthesia involves the infusion of large amounts of saline and lidocaine to reduce hemorrhage and of epiinephrine to delay absorption of the lidocaine. TIPP is intended for patients who are suitable candidates for conventional ambulatory phlebectomy and may also be used as an adjunctive method to other varicose vein treatments (e.g., ligation and stripping). Several treatment options are available for the treatment of symptomatic varicose veins, including ligation and stripping, subfascial endoscopic surgery, and ablative procedures. Procedures such as sclerotherapy and phlebectomy are effective for treatment of secondary varicose tributaries when performed either at the same time or following an initial invasive procedure. The peer-reviewed scientific literature supports safety and efficacy of these procedures, with most patients obtaining improvement in clinical outcomes. While varicose vein surgery is a very common surgical procedure, there is no general consensus regarding the best surgical approach.

Additionally, recurrences have been reported requiring second treatment sessions for some procedures. Evidence in the medical literature evaluating procedures such as transilluminated powered phlebectomy, endomechanical ablative approaches, and cryoablative procedures is primarily in the form of case series, lack randomization and controls, and involve small sample populations evaluating short-term outcomes. Strong evidence-based conclusions cannot be made regarding safety, efficacy, and
improvement of net health outcomes. Further clinical studies are needed to support the safety and efficacy of these procedures.

**Searches**

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches in July 13, 2016. Search terms were: "varicose veins" or free-text terms “varicose”[Mesh].

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

A review of available randomized, controlled trials that compared the new techniques such as RFA to surgery in the treatment of varicosities in the great saphenous vein found only five trials, with a combined total of 450 patients, which met inclusion criteria. Three trials compared laser therapy with surgery and two trials compared RFA with surgery. Laser therapy was associated with less technical failure but a trend to higher rates of reopening of the treated vein (recanalization) compared with surgery. No results were available to compare the rates of recurrence. It was found that RFA was associated with trends for fewer technical failures and less new vein growth (neovascularization) compared with surgery; the trend was for more recanalization within four months with no demonstrated difference in recurrence of varicose veins. The results in the study reports were presented as either the number of legs or number of patients, where some patients had varicose veins in both legs. The outcomes were also measured at different times after the procedures for the different trials. This limited the findings of our review. Currently available clinical trial evidence suggests RFA and endovenous laser ablation (EVLT) are at least as effective as surgery in the treatment of (GSV). There is insufficient data to comment on ultrasound-guided sclerotherapy (USGS). Further randomized trials are needed.

Seventeen randomized controlled trials involving over 3,300 people were included in the review. One study comparing sclerotherapy to compression stockings in pregnancy found that sclerotherapy improved symptoms and cosmetic appearance. There was no overall benefit from using alternative agents to STD, or any evidence that a foam was superior to liquid. Adding local anesthetic to the sclerosing agent reduced the pain of injection in one study. Neither the type, nor duration of elastic
compression, nor type of pressure pad after sclerotherapy had any clear effect on the effectiveness of sclerotherapy on varicose vein recurrence rates, cosmetic appearance, symptomatic improvement, or complications. There were no controlled trials comparing sclerotherapy for thread veins with either laser treatment or simple observation; hypertonic dextrose had similar efficacy in terms of sclerosis to STD in one study.

Given its success rates and minimally invasive approach in an outpatient setting, UGFS may offer an attractive, alternative treatment option for patients before conventional surgical stripping and ligation (phlebectomy), which are inherently more invasive procedures that carry greater morbidity.

Evidence from a number of randomized comparative trials and prospective studies suggests that EVLA effectively provides venous occlusion to treat symptomatic varicose veins due to GSV reflux in adult patients. Several studies of moderate-to-good quality that evaluated the relative efficacy of EVLA compared with conventional surgical techniques report comparable or superior clinical results of EVLA, with rates of recurrence generally less than 5 percent. The evidence also suggests that patients who underwent EVLA experienced less postoperative morbidity, with less need for extended analgesics to address pain, and experienced faster recovery compared with conventional surgical techniques. Patient-reported health outcomes, including cosmesis, quality of life, and overall patient satisfaction, were generally comparable between EVLA and conventional surgical treatments.

**Policy updates:**

**2016**

NICE guideline CG168 for varicose veins. Review decision: February 2016. We checked this guideline and decided that it should not be updated at this time. For details, see the update decision, decision matrix, and the process for deciding if an update is needed. Next review date: 2017.

Added new Randomized Trial Comparing the Effectiveness of Elastic Compression in Treating Chronic Venous Disease to the clinical trials section.

**2015**

Keystone First found one randomized controlled study comparing treatments on cost effectiveness c of vascular surgery (Brittenden, 2014; Mandavia, 2015). These studies confirm current practice guidelines and would not change current policy.

**Summary of clinical evidence:**

<table>
<thead>
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<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Wright, et al. (2006)</td>
<td><strong>Key points:</strong></td>
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</table>
| Comparing the safety and efficacy of USGS using polidocanol 1% microfoam formulation (Varisolve) with surgery for the treatment of primary or recurrent varicose veins and trunk vein incompetence (n=710) |  - Patients had either GSV or SSV incompetence, and were assigned to receive either surgery (n=311) or sclerotherapy (n=399) based on the severity of the disease and physician preference. Within the surgery group, patients were randomized to receive Varisolve (n=210) or surgery (n=101); within the sclerotherapy group, patients were randomized to receive Varisolve (n=274) or conventional sclerotherapy (n=125).  
  - The primary outcome measure was treatment response at three months of follow-up, defined as the complete occlusion of the incompetent trunk veins viewed on duplex scanning.  
  - Secondary outcomes included postprocedure pain (measured using a visual analog scale), time to return to normal activity, the number of treatment sessions required, and the response rate at 12 months. |
<table>
<thead>
<tr>
<th>Key points:</th>
<th>Rasmussen, et al. (2011) Comparing four treatments for varicose GSVs (n=500 consecutive patients; 580 legs).</th>
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| - Patients were randomized to EVLA, RFA, USGS, or surgical stripping with local anesthesia with light sedation. Patients treated by foam sclerotherapy experienced the highest failure rate (GSV that was open and refluxing) (16%) compared with EVLA (6%), RFA (5%), and surgical stripping (5%) (P<0.001 for each comparison). Secondary outcomes included pain, return to activity, VCSS, AVVSS, and SF-36.  
- Foam sclerotherapy resulted in a significantly greater number of patients with phlebitis (n=17) compared with EVLA postoperative pain than patients treated with EVLA or stripping (P<0.001 for each comparison). |

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<th>Key points:</th>
<th>Lurie, et al. (2003) This study was designed as a randomized comparison of procedure-related complications, patient recuperation and quality of life outcomes between patients undergoing vein stripping with high ligation and patients (SandL) undergoing GSV obliteration with temperature-controlled radiofrequency ablation (RFO).</th>
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| - Success was reported for 95% of limbs in the RFO group and 100% of limbs in the SandL group. In 16.3% RFO limbs, a scan after the procedure showed flow in the proximal GSV. Five of these segments had reflux in the open segment. At one week, two closed, and an additional segment closed at three weeks. In no cases did flow reappear after complete occlusion of the GSV.  
- RFO groups had shorter recovery times and better global and pain scores than the SandL group.  
- There are significant early advantages to endovascular obliteration of the GSV compared with conventional vein stripping. |

- Treatment was more cost effective than conservative management options including compression stockings.  
- Endovenous treatment is most cost-effective option including ELVA and RFA compared to compression and surgical treatment. |

| Key points: | Brittenden (2014) Randomized trial with 798 patients comparing results of foam sclerotherapy, laser endovenous treatment, and surgical stripping.  
- Efficacy of treatment options similar, lower rate of complications in laser group.  
- Foam sclerotherapy produced slightly worse quality of life scores (P=0.006) and was less successful at complete ablation of saphenous vein. |

**Glossary**

**Ablation** — The removal of tissue, a part of the body, or an abnormal growth, usually by cutting.

**Ambulatory phlebectomy** — A surgical technique to remove superficial varicosities, usually involving an instrument that pierces the skin adjacent to the varicosity, hooks under it, and pulls the varicosity from the skin. Also known as avulsion, hook avulsion, stab avulsion, or micro-extraction phlebectomy.

**Avulsion** — A surgical technique to remove superficial varicosities.
**Chronic venous insufficiency (CVI)** — A disorder in which veins fail to pump blood back to the heart appropriately, causing varicose veins, skin ulcers, and superficial or deep vein thrombosis in the legs.

**Crossectomy** — Division of a truncal vein and ligation of tributaries.

**Doppler ultrasound** — A device utilizing Doppler ultrasound that permits color-coded visualization of blood flow in the superficial, perforating, and deep veins, as well as gray-scale imaging of the veins and surrounding tissue. It can also be used to image blood flow in arteries.

**Duplex** — A device utilizing Doppler ultrasound that permits color-coded visualization of blood flow in the superficial, perforating, and deep veins, as well as gray-scale imaging of the veins and surrounding tissue.

**Endothermal** — A specialized form of endovenous treatment that ablates via thermal damage to the inner lumen of the vein.

**Endovenous** — Indicates within the vein.

**Endovenous thermal ablation** — Also called laser therapy endovenous laser ablation therapy (EVLAT), a newer technique that uses a laser or high-frequency radio waves to create intense local heat in the varicose vein or incompetent vein to close vein with minimal damage.

**Foam sclerotherapy** — Sclerotherapy using a sclerosant that has been mixed with a gas to make a foam.

**Great saphenous vein (GSV)** — Previously also called the long saphenous vein, a large, subcutaneous, superficial vein of the leg. It is the longest vein in the body running along the length of the leg.

**Laser ablation** — An endothermal ablation technique that uses laser energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein.

**Ligation** — A surgical technique where veins are tied off proximally; this usually results in atrophy of the vein.

**Liquid sclerotherapy** — Sclerotherapy using a liquid sclerosant.

**Phlebectomy** — A surgical technique to remove superficial varicosities, usually involving an instrument that pierces the skin adjacent to the varicosity, hooks under it, and pulls the varicosity from the skin. Also known as avulsion, hook avulsion, or ambulatory phlebectomy.

**Radiofrequency ablation** — An endothermal ablation technique that uses radio wave electromagnetic energy to cause venous ablation and closure by raising the temperature of the inner lumen of the vein.

**Sclerotherapy** — The injection of chemical substances into a truncal or tributary vein that causes closure of the vein.

**Spider veins/dermal telangiectasias** — A localized collection of distended blood capillary vessels which may be obliterated through various procedures, such as laser photocoagulation or sclerotherapy.
**Stripping** — A surgical technique of truncal vein removal, where the vein is stripped from surrounding tissues and removed.

**Transilluminated powered phlebectomy (TIPP)** — Transilluminated powered phlebectomy performed with an illuminator and a motorized resector aiming to reduce the risk associated with stab avulsion.

**Ultrasound-guided sclerotherapy** — The injection of a sclerosing agent into a vein guided by real-time ultrasound imaging.

**Vein ligation and stripping** — A surgical approach to the treatment of varicose veins. Also called phlebectomy.

**References**

**Professional society guidelines/other:**


Hayes Directory, Ultrasound-Guided Foam Sclerotherapy (UGFS) for Varicose Veins, November 4, 2011.


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on July 14, 2016, using terms “varicose veins treatment.” | Open Studies. 101 studies found, four relevant.


Additional resource information on clinical trials is at [http://clinicaltrials.gov/info/resources](http://clinicaltrials.gov/info/resources).

**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.
Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>36475</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, includes of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated.</td>
<td></td>
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<tr>
<td>36476</td>
<td>Second and subsequent veins treated in a single extremity, each through separate access sites.</td>
<td>Add-on code</td>
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<tr>
<td>36478</td>
<td>Endovenous ablation therapy of an incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated.</td>
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<td>36479</td>
<td>Second and subsequent veins treated in a single extremity; each through separate access sites.</td>
<td>Add-on code</td>
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<tr>
<td>37735</td>
<td>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 the lower leg, with excision of deep fascia.</td>
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<tr>
<td>37760</td>
<td>Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, one leg.</td>
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<tr>
<td>37761</td>
<td>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance when performed; one leg.</td>
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<tr>
<td>37765</td>
<td>Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions.</td>
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<tr>
<td>37766</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; more than 20 stab incisions.</td>
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<tr>
<td>37780</td>
<td>Ligation and division of short saphenous vein at saphenopopliteal junction.</td>
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<tr>
<td>37785</td>
<td>Ligation, division, and/or excision of varicose vein cluster(1), one leg.</td>
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<td>Varicose veins, lower extremities</td>
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