FEP 7.01.124 Treatment of Varicose Veins/Venous Insufficiency

Effective Date: January 15, 2019
Related Policies: None

Medical Policy Title

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

OBJECTIVE

The objective of this evidence review is to evaluate the safety and efficacy of ablative, chemical, and adhesive technologies used to treat varicose veins/venous insufficiency arising from reflux in the saphenous, tributary, and perforator veins.

POLICY STATEMENT

Saphenous Veins

Great or Small Saphenous Veins
Treatment of the great or small saphenous veins by surgery (ligation and stripping), endovenous radiofrequency or laser ablation, or microfoam sclerotherapy may be considered medically necessary for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater; AND
- There is documentation of 1 or more of the following indications:
  - Ulceration secondary to venous stasis; OR
  - Recurrent superficial thrombophlebitis; OR
  - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
  - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least 3 months has not improved the symptoms.

Treatment of great or small saphenous veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy that does not meet the criteria described above is considered cosmetic and not medically necessary.
Accessory Saphenous Veins

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

- Incompetence of the accessory saphenous vein is isolated, OR the great or small saphenous veins had been previously eliminated (at least 3 months); AND
- there is demonstrated accessory saphenous reflux; AND
- there is documentation of 1 or more of the following indications:
  - Ulceration secondary to venous stasis; OR
  - Recurrent superficial thrombophlebitis; OR
  - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
  - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least 3 months has not improved the symptoms.

Treatment of accessory saphenous veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy that does not meet the criteria described above is considered cosmetic and not medically necessary.

Symptomatic Varicose Tributaries

The following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment (surgical, radiofrequency, or laser) of the saphenous veins (none of these techniques has been shown to be superior to another):

- Stab avulsion
- Hook phlebectomy
- Sclerotherapy
- Transilluminated powered phlebectomy.

Treatment of symptomatic varicose tributaries, when performed either at the same time or following prior treatment of saphenous veins using any other techniques than those noted above is considered investigational.

Perforator Veins

Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when the following conditions have been met:

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

Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary.
Telangiectasia

Treatment of telangiectasia such as spider veins, angiomata, and hemangiomata is considered cosmetic.

Other Veins

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

- Sclerotherapy techniques, other than microfoam sclerotherapy, of great, small, or accessory saphenous veins
- Sclerotherapy of perforator veins
- Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
- Stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator, great or small saphenous, or accessory saphenous veins
- Endovenous radiofrequency or laser ablation of tributary veins
- Mechanochemical ablation of any vein
- Cyanoacrylate adhesive of any vein
- Endovenous cryoablation of any vein.

POLICY GUIDELINES

The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. Table PG1 provides is the Clinical portion of the CEAP.

Table PG1. Clinical Portion of the CEAP Classification System

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>C0</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>C1</td>
<td>Telangiectasies or reticular veins</td>
</tr>
<tr>
<td>C2</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>C3</td>
<td>Edema</td>
</tr>
<tr>
<td>C4a</td>
<td>Pigmentation and eczema</td>
</tr>
<tr>
<td>C4b</td>
<td>Lipodermatosclerosis and atrophie blanche</td>
</tr>
<tr>
<td>C5</td>
<td>Healed venous ulcer</td>
</tr>
<tr>
<td>C6</td>
<td>Active venous ulcer</td>
</tr>
<tr>
<td>S</td>
<td>Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>A</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>


CEAP: Clinical, Etiologic, Anatomic, Pathophysiologic classification system.

It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. When ultrasound guidance is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2015, the VenaSeal® Closure System (Sapheon, part of Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (P140018) process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation. The
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VenaSeal® Closure System seals the vein using a cyanoacrylate adhesive agent. FDA product code: PJQ.

In 2013, Varithena™ (formerly Varisolve®), a sclerosant microfoam made with a proprietary gas mix, was approved by FDA under a new drug application (205-098) for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.

The following devices were cleared for marketing by FDA through the 501(k) process for endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ System, a radiofrequency device, was cleared by FDA through the 510(k) process for “endovascular coagulation of blood vessels in patients with superficial vein reflux.” In 2005, the VNUS RFS™ and RFSFlex™ devices were cleared by FDA for “use in vessel and tissue coagulation including treatment of incompetent (ie, refluxing) perforator and tributary veins.” In 2008, the modified VNUS® ClosureFast™ Intravascular Catheter was cleared by FDA through the 510(k) process. FDA product code: GEI.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit was cleared by FDA through the 510(k) process “…for use in the endovascular coagulation of the great saphenous vein of the thigh in patients with superficial vein reflux.” FDA product code: GEX.
- In 2005, a modified Erbe Erbokryo® cryosurgical unit (Erbe USA) was approved by FDA for marketing. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.
- In 2003, the Trivex® system (InaVein), a device for transilluminated powered phlebectomy, was cleared by FDA through the 510(k) process for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.” FDA product code: DNQ.
- In 2008, the ClariVein® Infusion Catheter (Vascular Insights) was cleared by FDA through the 510(k) process (K071468) for mecanochemical ablation. FDA determined that this device was substantially equivalent to the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock, and syringe, and is intended for the infusion of physician-specified agents in the peripheral vasculature. FDA product code: KRA.

RATIONALE

Summary of Evidence

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive endovenous thermal ablation (radiofrequency or laser), the evidence includes 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 the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead 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 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 less pain during the procedure. One RCT with high loss to follow-up has been published, and a larger RCT is 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, liquid sclerotherapy is not as effective as thermal ablation techniques for saphenous veins, and mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in larger RCTs is needed to evaluate its efficacy and durability compared with 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 (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, 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 (eg, subfascial endoscopic perforator surgery) of perforator veins, 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 (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, 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. Although only 1 case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Society for Vascular Surgery and American Venous Forum
The Society for Vascular Surgery and the American Venous Forum published joint clinical practice guidelines in 2011. Table 3 provides the recommendations.

Table 3. Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade*</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression therapy for venous ulcerations and varicose veins</td>
<td>Compression therapy is recommended as the primary treatment to aid healing of venous ulceration</td>
<td>1B</td>
<td>Strong</td>
</tr>
<tr>
<td>To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended</td>
<td>1A</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>Use of compression therapy for patients with symptomatic varicose veins is recommended</td>
<td>2C</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Treatment of the incompetent great saphenous vein</td>
<td>Endovenous thermal ablation (radiofrequency or laser) is recommended over chemical ablation with foam or high ligation and stripping due to reduced convalescence and less pain and morbidity. Cryoablation is a technique that is new in the United States, and it has not been fully evaluated.</td>
<td>1B</td>
<td>Strong</td>
</tr>
<tr>
<td>Phlebectomy or sclerotherapy are recommended to treat varicose tributaries</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy</td>
<td>2C</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended</td>
<td>1B</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>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</td>
<td>2B</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

QOE: quality of evidence; SOR: strength of recommendation.

* Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.

Society of Interventional Radiography
In 2003, the Society of Interventional Radiology 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:

"The endovenous treatment of varicose veins may be medically necessary when:
1. one of the following indications (A - E) is present:

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A. Persistent symptoms interfering with activities of daily living in spite of conservative/nonsurgical 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, nonoperative 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, American Venous Forum and Society of Interventional Radiography recommended reporting standards for endovenous ablation for the treatment of venous insufficiency. They recommended that reporting in clinical studies should include the symptoms of venous disease, history of the disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation might include patients with reflux in an incompetent great saphenous vein or smaller saphenous vein or a major tributary branch of the great or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory great saphenous vein. 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 greater than 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 Care Excellence

The National Institute for Health and Care Excellence (NICE) updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins in 2013. NICE stated 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 ischaemic attacks and stroke."

NICE revised its 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..." In 2013, NICE published guidance on the diagnosis and management of varicose veins in the leg. 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. Five-year trial results are currently being evaluated.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
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REFERENCES


20. Todd KL, 3rd, Wright D, for the Vanish-Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0%
compared with placebo for the treatment of saphenofemoral junction incompetence. Phlebology. Oct 2014;29(9):608-618. PMID 23864535


32. Zierau UT. Sealing veins with the VenaSeal Sapheon Closure System: results for 795 treated truncal veins after 1000 days. Vasomed. 2015;27:124-127. PMID


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td></td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, References added, renumbered or removed. New information added to policy regarding endovenous mechanochemical ablation and policy statement under “Other” as considered investigational. Addition to policy statement under Accessory Saphenous Veins: “Incompetence of the accessory saphenous vein is isolated, OR”. New product information added under Regulatory Status on ClarVein® Infusion Catheter.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review, references added, policy</td>
</tr>
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<thead>
<tr>
<th>Date</th>
<th>Update Policy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 8-9, 18, 24, 33 added and some references removed; microfoam sclerotherapy considered medically necessary.</td>
</tr>
<tr>
<td>March 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through July 7, 2015; references 15, 25-28, 47, and 61 added; reference 52 updated; clinical input reviewed. The requirement of failure of compression therapy was removed from the policy statements on ulceration secondary to venous stasis and recurrent superficial thrombophlebitis; terminology was changed from greater and lesser to great and small saphenous veins.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Update Policy</td>
<td>Policy updated with literature review through March 5, 2018; references 9, 12, 18, 20-21, 24-27, and 30-31 added; references 52, 54 and 56 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2018</td>
<td>Update Policy</td>
<td>Removed &quot;not medically necessary&quot; from policy statement: &quot;Treatment of telangiectasia such as spider veins, angioma, and hemangiomata is considered cosmetic.&quot;</td>
</tr>
</tbody>
</table>