Introduction

Varicose veins are swollen, twisted veins that are visible just below the skin. They most often occur in the legs but can develop in other parts of the body. Veins have valves that keep the blood moving toward the heart. If the valves are weak or damaged, blood can pool in the veins. It’s this pooling that causes the veins to swell and appear twisted. Most varicose veins do not result in physical symptoms. On occasion, they can cause symptoms such as pain, an achy feeling, bleeding, or skin ulcers (sores). Varicose veins usually can be treated without surgery by activities such as exercising, raising the legs, or wearing compression stockings. This policy describes when varicose vein surgery or other procedures may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Documentation Requirements

Review of this procedure requires the provider to specifically indicate the following in the clinical notes submitted with the request:

- The CPT codes for the procedures being requested

AND

- The name of the vein to be treated with each CPT code

<table>
<thead>
<tr>
<th>Vein(s)</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater or lesser (small) saphenous veins</td>
<td>Treatment of the greater or lesser (small) saphenous veins by surgery (ligation and stripping), endovenous radiofrequency ablation, laser ablation or microfoam sclerotherapy (eg, Varithena) may be considered medically necessary for symptomatic varicose veins/venous insufficiency when the following criteria have been met:</td>
</tr>
<tr>
<td></td>
<td>• There is moderate to severe (greater than 0.5 second) saphenous reflux documented on venous studies and CEAP [Clinical-Etiology-Anatomy-Pathophysiology] class C2 or greater (see Definition of Terms)</td>
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<tr>
<td></td>
<td>AND</td>
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<td></td>
<td>• There is documentation of one or more of the following four indications:</td>
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<tr>
<td></td>
<td>o Ulceration secondary to venous stasis</td>
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<tr>
<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>o Recurrent superficial thrombophlebitis</td>
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<td></td>
<td>OR</td>
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<td></td>
<td>o Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity</td>
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<td></td>
<td>OR</td>
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<td></td>
<td>o Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux</td>
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<td></td>
<td>AND</td>
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<td></td>
<td>• These symptoms significantly interfere with activities of daily living</td>
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<td>AND</td>
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<tr>
<td>Vein(s)</td>
<td>Medical Necessity</td>
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<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>- Conservative management, including compression therapy (see Definition of Terms) for at least 3 months, has not improved the symptoms</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work.</td>
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</tbody>
</table>

**Treatment of the greater or lesser (small) saphenous veins using the following techniques is considered investigational, including, but not limited to:**

- Cyanoacrylate adhesive/cyanoacrylate embolization (CAE) (eg, VenaSeal System)
- Endovenous cryoablation
- Endovenous mechanochemical ablation (MCA) (eg, MOCA ClariVein)
- Stab avulsion
- Stab/Hook/Micro-phlebectomy
- Transilluminated powered phlebectomy (TIPP) (eg, TRIVEX System)

**Accessory saphenous veins**

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

- The greater or lesser (small) saphenous veins have been previously eliminated (at least 3 months) when the greater or lesser (small) saphenous veins had reflux
  **OR**
  - There is no reflux documented in both the greater and lesser (small) saphenous veins
  **AND**
  - There is moderate to severe (greater than 0.5 second) accessory saphenous reflux documented on venous studies
<table>
<thead>
<tr>
<th>Vein(s)</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td></td>
<td>• There is documentation of one or more of the following 4 indications:</td>
</tr>
<tr>
<td></td>
<td>o Ulceration secondary to venous stasis</td>
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<tr>
<td></td>
<td>OR</td>
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<td></td>
<td>AND</td>
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<td></td>
<td>▪ These symptoms significantly interfere with activities of daily living</td>
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<tr>
<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>▪ Conservative management, including compression therapy (see <strong>Definition of Terms</strong>) for at least 3 months, has not improved these symptoms.</td>
</tr>
</tbody>
</table>

**Note:** If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work.

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

**Treatment of the accessory saphenous veins using the following techniques is considered investigational, including, but not limited to:**

- Cyanoacrylate adhesive/cyanoacrylate embolization (CAE) (eg, VenaSeal System)
- Endovenous cryoablation
- Endovenous mechanochemical ablation (MCA) (eg, MOCA)
<table>
<thead>
<tr>
<th>Vein(s)</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| ClariVein)                  | • Stab avulsion  
|                            | • Stab/Hook/Micro-phlebectomy  
|                            | • Transilluminated powered phlebectomy (TIPP) (eg, TRIVEX System)  |

### Symptomatic varicose tributaries

The following treatments are considered medically necessary as a component of the treatment of symptomatic varicose tributaries when performed concurrently with or within 10 days of treatment (surgical, radiofrequency or laser) of the saphenous veins (none of these techniques has been shown to be superior to another):

- Sclerotherapy  
- Stab avulsion  
- Stab/Hook/Micro-phlebectomy  
- Transilluminated powered phlebectomy (TIPP) (eg, TRIVEX System)

When stab avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy (TIPP) is requested more than 10 days following a prior surgical, radiofrequency or laser treatment, it may be considered medically necessary when there is documentation of one or more of the following 4 indications:

- Ulceration secondary to venous stasis  
- Recurrent superficial thrombophlebitis  
- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity  
- Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux

**AND**

- These symptoms significantly interfere with activities of daily living

**AND**

- Conservative management, including compression therapy
<table>
<thead>
<tr>
<th>Vein(s)</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(see Definition of Terms) for at least 3 months, has not improved these symptoms</td>
</tr>
</tbody>
</table>

**Note:** If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work.

**Treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment of saphenous veins using any other techniques than noted above is considered investigational, including, but not limited to:**

- Cyanacrylate adhesive/cyanacrylate embolization (CAE) (eg, VenaSeal System)
- Endovenous cryoablation
- Endovenous mechanochemical ablation (MCA) (eg, MOCA ClariVein)
- Endovenous radiofrequency or laser ablation

**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 active or healed leg ulcers with documented persistent reflux when ALL of the following conditions have been met:

- The superficial saphenous veins (greater, lesser, or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated

**AND**

- Three months after superficial vein treatment and compression therapy (see Definition of Terms), the perforator veins have BOTH an outward flow of greater than or equal to 500 ms duration AND a diameter of greater than or equal to 3.5mm

**AND**

- The perforator veins are located underneath healed or active ulcers
<table>
<thead>
<tr>
<th>Vein(s)</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AND</strong></td>
<td>The venous insufficiency is not secondary to deep venous thromboembolism</td>
</tr>
<tr>
<td></td>
<td>Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is not medically necessary.</td>
</tr>
<tr>
<td></td>
<td>Treatment of incompetent perforator veins using any other techniques than noted above is considered investigational, including, but not limited to:</td>
</tr>
<tr>
<td></td>
<td>- Cyanoacrylate adhesive/cyanoacrylate embolization (CAE) (eg, VenaSeal System)</td>
</tr>
<tr>
<td></td>
<td>- Endovenous mechanochemical ablation (MCA) (eg, MOCA ClariVein)</td>
</tr>
<tr>
<td></td>
<td>- Sclerotherapy</td>
</tr>
<tr>
<td></td>
<td>- Stab avulsion</td>
</tr>
<tr>
<td></td>
<td>- Stab/Hook/Micro-phlebectomy</td>
</tr>
<tr>
<td></td>
<td>- Transilluminated powered phlebectomy (TIPP) (eg, TRIVEX System)</td>
</tr>
</tbody>
</table>

| Telangiectasia | Treatment, by any method, of small telangiectasia such as spider veins (1mm or less), superficial reticular veins (1-2 mm), angiomata, and hemangiomata is considered cosmetic. |

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultrasound guidance</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

Written documentation in the medical record must include:

1. CPT codes for the procedures being requested, and the name of the vein to be treated with
Documentation Requirements

- each CPT code
- Copy of the venous studies (ultrasound studies evaluating blood flow in the veins)
- CEAP (Clinical-Etiology-Anatomy-Pathophysiology) class C2 or greater (Clinical classification, large varicose veins)
- One or more indications:
  - Ulceration secondary to venous stasis (leg ulcers caused by poor blood flow in the veins)
  - Recurrent superficial thrombophlebitis (recurrent blood clots or inflammation in a small veins near the surface of the skin)
  - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity (bleeding from a varicose vein)
  - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux (pooling of the blood caused by valves that don’t work correctly)

  AND
  - These symptoms significantly interfere with activities of daily living
  - Conservative management including compression therapy for at least 3 months has not improved the symptoms

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>36465</td>
<td>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) (new code effective 1/1/18)</td>
</tr>
<tr>
<td>36466</td>
<td>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 (new code effective 1/1/18)</td>
</tr>
<tr>
<td>36468</td>
<td>Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk</td>
</tr>
<tr>
<td>36470</td>
<td>Injection of sclerosing solution; single vein</td>
</tr>
<tr>
<td>36471</td>
<td>Injection of sclerosing solution; multiple veins, same leg</td>
</tr>
<tr>
<td>36473</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>36474</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>36475</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated</td>
</tr>
<tr>
<td>36476</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>36478</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated</td>
</tr>
<tr>
<td>36479</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>36482</td>
<td>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 (new code effective 1/1/18)</td>
</tr>
<tr>
<td>36483</td>
<td>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) (new code effective 1/1/18)</td>
</tr>
<tr>
<td>37500</td>
<td>Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)</td>
</tr>
<tr>
<td>37700</td>
<td>Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions</td>
</tr>
<tr>
<td>37718</td>
<td>Ligation, division, and stripping, short saphenous vein</td>
</tr>
<tr>
<td>37722</td>
<td>Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below</td>
</tr>
<tr>
<td>37735</td>
<td>Ligation and division and complete stripping of long and 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</td>
</tr>
<tr>
<td>37760</td>
<td>Ligation of perforator veins, subfascial, radical (Linton type) including skin graft, when performed, open, 1 leg</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>37761</td>
<td>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg</td>
</tr>
<tr>
<td>37765</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; 10–20 stab incisions</td>
</tr>
<tr>
<td>37766</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; more than 20 stab incisions</td>
</tr>
<tr>
<td>37780</td>
<td>Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)</td>
</tr>
<tr>
<td>37785</td>
<td>Ligation, division, and/or excision of varicose vein cluster(s), one leg</td>
</tr>
<tr>
<td>37799</td>
<td>Unlisted procedure, vascular surgery (eg, MOCA ClariVein, Varithena, TRIVEX System)</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

**Definition of Terms**

**Accessory saphenous veins:** Veins that travel in parallel with the greater and lesser saphenous veins and are generally 2 to 2.5 mm in their normal state.

**Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification:** Considers the clinical, etiologic, anatomic, and pathologic (CEAP) characteristics of venous insufficiency. See table below.

<table>
<thead>
<tr>
<th>Class</th>
<th>Clinical Classification</th>
</tr>
</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, and other</td>
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<tr>
<td>Class</td>
<td>Clinical Classification</td>
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<td>-------</td>
<td>-----------------------------------------------------------------------------------------</td>
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<tr>
<td></td>
<td>complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>A</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>C0</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
</tbody>
</table>

**Compression Therapy:** Compression hosiery or stockings are often the first line of treatment for varicose veins. Compression stockings are generally thought to be effective in a range of 20 mmHg to 40mmHg. The Society for Vascular Surgery/American Venous Forum recommends compression therapy of 20-30 mmHg for patients with symptomatic varicose veins. Compression stockings of 20-30mmHg are available over the counter without a prescription.

**Greater/long saphenous vein:** Superficial vein running the entire length of the leg and is generally 3 mm in its normal state. A typical GSV contains an average of 7 valves throughout its entire length, and it is the most common superficial vein to develop venous reflux.

**Lesser (small)/short saphenous veins:** Superficial vein of the calf and is generally 2.5 mm in its normal state. The small saphenous vein originates at the back of the ankle near the outer malleous bone, and usually runs up the back of the lower leg to the popliteal vein behind the knee.

**Moderate to severe reflux:** In current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

**Perforator veins:** These connect superficial veins to deep veins. They contain one-way valves to direct the blood from the superficial system to the deep system and are generally less than 3mm in their normal state.

**Stab avulsion:** This technique is also known as stab/hook phlebectomy. Stab avulsion results in removal of the varicose veins through incisions that are 2-3 mm in length. The veins are hooked with a tiny hook-like instrument and pulled out. The wounds are closed with tapes, not sutures, and the leg is wrapped in elastic compression support. Once healed, the incision sites are almost invisible.

**Telangiectasia/spider veins:** Very small (≤1 mm in diameter) thread veins found commonly just under the surface of the skin, usually not distorting skin or surrounding tissues.

**Tributary veins:** Veins that empty into a larger vein
Evidence Review

Description

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

Based on the available evidence, clinical input and clinical practice guidelines, the use of endovenous radiofrequency, laser ablation, and microfoam sclerotherapy are considered to improve outcomes when used in the saphenous veins. For treatment of saphenous tributaries at the same time or following treatment of the saphenous vein, stab avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy improve outcomes.

Background

The venous system of the lower extremities consists of the superficial veins (this includes the greater and lesser saphenous and accessory, or duplicate, veins that travel in parallel with the greater and lesser saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins with visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification considers the clinical, etiologic, anatomic, and pathologic (CEAP) characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment of venous reflux/venous insufficiency is aimed at reducing abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of elevation of the extremities, graded compression, and wound care when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the
saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or in the deep venous system. The competence of any single valve is not static and may be pressure-dependent. For example, accessory saphenous veins may have independent saphenofemoral or saphenopopliteal junctions that become incompetent when the greater or lesser saphenous veins are eliminated and blood flow is diverted through the accessory veins.

**Saphenous Veins and Tributaries**

Saphenous veins include the greater and lesser saphenous and accessory saphenous veins that travel in parallel with the greater or lesser (small) saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux typically includes the following:

- Identification by preoperative Doppler ultrasonography of the valvular incompetence
- Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
- Removal of the superficial vein from circulation, for example by stripping of the greater and/or lesser saphenous veins
- 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 radiowaves (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
sclerosants are commonly produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment. Varithena (previously known as Varisolve, BTG PLC, London) is a proprietary microfoam sclerosant that is dispersed from a canister with a controlled density and more consistent bubble size.

**Endovenous Mechanochemical Ablation (MCA)**

Endovenous mechanochemical ablation (MOCA™) 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 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without need for the tumescent anesthesia used with thermal endovenous ablation techniques (radiofrequency ablation [RFA] and endovenous laser treatment [EVLT]).

**Thermal Ablation**

Radiofrequency (RFA) 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 lesser saphenous vein.
**Cyanoacrylate Adhesive for Embolization (CAE)**

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 (TIPP)**

Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or hook phlebectomy. This procedure uses 2 instruments: an illuminator which also provides irrigation, and a resector, which has an oscillating tip and can perform suction. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of the varicosity. The resector is then inserted under the skin from the opposite direction, and the oscillating tip is placed directly beneath the illuminated veins to fragment and loosen the veins from the supporting tissue. Irrigation from the illuminator is used to clear the vein fragments and blood through aspiration and additional drainage holes. The illuminator and resector tips may then be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or hook phlebectomy. It has been proposed that TIPP might result in decreased operative time, decreased complications such as bruising, and faster recovery compared to the established procedures.

**Treatment of Perforator Veins**

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally addressed with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified
Linton procedure may occasionally be used for the closure of incompetent perforator veins that cannot be reached by less invasive procedures. Subfascial endoscopic perforator surgery is a less-invasive surgical procedure for treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin, and the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and RFA has also been reported.

**Other**

Deep vein valve replacement is being investigated. Outcomes of interest for venous interventions include healing and recurrence, recannulation of the vein, and neovascularization. Recannulation (recanalization) is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques. Neovascularization is the proliferation of new blood vessels in tissue and occurs more frequently following vein stripping. Direct comparisons of durability for endovenous and surgical procedures are complicated by these different mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

**Review of Evidence**

**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 8 trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. In addition, multicomponent 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 2 months, while the median time to healing in other reports was 3 to 5 months.

A Cochrane review on compression stockings for the initial treatment of varicose veins in patients without venous ulceration was published in 2011.\textsuperscript{3} Included in the review were 7 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.

This Cochrane review was updated in 2013.\textsuperscript{64} The authors stated: “Conclusions from the individual studies regarding the optimum pressure provided by stockings were conflicting, although the results of one study suggested that lower pressured stockings (20 mmHg) may be as effective as higher pressured stockings (30 to 40 mmHg) for relieving symptoms. Conclusions regarding the optimum length of the stockings were inconclusive. No severe or long lasting side effects were noted.”

The Clinical Practice Guidelines for the Society for Vascular Surgery and the American Venous Forum (Gloviczki, 2011) includes the following recommendations for compression therapy:

- We suggest compression therapy using moderate pressure (20-30 mm Hg) for patients with symptomatic varicose veins (GRADE 2C)
- We recommend against compression therapy as the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation (GRADE 1B)
- We recommend compression as the primary therapeutic modality for healing venous ulcers (GRADE 1B).
- We recommend compression as an adjuvant treatment to superficial vein ablation for the prevention of ulcer recurrence (GRADE 1A).\textsuperscript{52}
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.\textsuperscript{4, 5} In general, recurrence rates after ligation and stripping are estimated at around 20%. Jones et al 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.\textsuperscript{6} At 1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy.\textsuperscript{7} At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

Comparison of Endovenous Ablation and Sclerotherapy with Ligation and Stripping

An updated Cochrane review from 2014 compared endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus ligation/stripping for saphenous vein varices.\textsuperscript{8} 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<0.001; and OR=0.29, p<0.001, 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.

In 2014, Brittenden et al. reported a multicenter randomized trial that compared foam sclerotherapy, EVLA, and surgical treatment in 798 patients.\textsuperscript{9} 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 6-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. Six months after treatment, mean disease-specific quality of life was slightly worse after sclerotherapy than after surgery (p=0.006), and there were more residual varicose veins, although the differences were small. 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%). The rate of complications at 6 months (primarily lumpiness and skin staining), was highest for the sclerotherapy group.

**Endovenous Radiofrequency Ablation (RFA)**

In 2008, Luebke et al. reported a meta-analysis of 8 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 2 treatments. There were significant reductions in tenderness and ecchymosis at 1 week and fewer hematomas at 72 hours, 1 week, and 3 weeks with RFA. Quality-of-life results, including return to normal activity and return to work, favored RFA 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 5-year data (406 limbs). The registry included data on the treatment of 52 lesser saphenous veins and 16 accessory saphenous veins. Follow-up at 1 week showed a 97% anatomic success rate and a decrease in pain in 50% (from 85% to 30%) of patients. An additional 162 failures were identified over the 5 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 sex, 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 (EVLA)**

The largest trial on EVLA is the 2012 RELACS study, which was a practical design that randomized 400 patients to EVLA performed by a surgeon at 1 site or to ligation and stripping performed by a different surgeon at a second location. At 2-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 endovenous laser treatment (EVLT) (17.8% vs. 1.3%). This study will follow patients for 5 years. Another trial compared EVLA with ligation and stripping in 200 limbs (100 in each group). At 1-year follow-up, 98% of the limbs were reported to be free of symptoms. At 2-year follow-up, the EVLA group had 2 veins completely reopened and 5 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 1-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. Transient adverse events were reported in 11 patients after stripping, 7 after EVLA, and 5 after sclerotherapy. At 5-year follow-up, Kaplan-Meier analysis showed obliteration or absence of the great saphenous vein in 85% of patients who underwent conventional surgery and 77% of patients who underwent EVLA (not significantly different). Grade I neovascularization was higher in the conventional surgery group (27% vs 3%, p<0.001), while grade II neovascularization was similar in the 2 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 greater saphenous vein. In 21 of the patients (64%) in the accessory saphenous vein group, there had been no previous treatment of the greater 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 2 groups. Patient satisfaction scores were also similar.

**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 (1 cc aethoxysclerol 3%: 3 cc air). At 1-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 5-year follow-up,
obliteration or absence of the greater saphenous vein was observed in only 23% of patients treated with sclerotherapy compared to 85% of patients who underwent conventional surgery and 77% of patients who underwent EVLA.\textsuperscript{15} Thirty-two percent of legs treated initially with sclerotherapy required 1 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 noninferiority trial of foam sclerotherapy versus ligation and stripping in 430 patients.\textsuperscript{17} Analysis was per protocol. Forty patients (17%) had repeat sclerotherapy. At 2 years, the probability of clinical recurrence was similar in the 2 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 2 serious adverse events in the sclerotherapy group (deep venous thrombosis and pulmonary emboli) that occurred within 1 week of treatment.

In 2013, Varithena™ microfoam was approved under a new drug application for the treatment of varicose veins. Efficacy data were from 2 randomized, blinded, multicenter studies.\textsuperscript{18} 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 8, as measured by the Varicose Vein Symptoms Questionnaire. The improvement in symptoms was greater in the pooled Varithena™ treatment group (p<0.001) 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.\textsuperscript{19} At the 8-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 5 years is continuing.
Mechanochemical Ablation (MCA)

Several prospective series and cohort studies have been reported. One prospective multicenter series evaluated the efficacy of mechanochemical ablation (MCA) of the great saphenous vein in 126 patients in a community setting.\textsuperscript{20} Veins were selected that were greater than 4 mm and less than 12 mm in diameter, with an average diameter of 7.3 mm. Closure rates were 100\% at 1 week, 98\% at 3 months, and 94\% at 6 months. The venous clinical severity score decreased from a score of approximately 9 pretreatment to about 3 at 6 months. In 2012, Elias and Raines reported an industry-sponsored safety and efficacy study of MCA with the ClariVein\textsuperscript{®} system.\textsuperscript{21} Thirty greater saphenous veins in 29 patients were treated with this device. Greater saphenous veins with diameters greater than 12 mm were excluded. At 6-month follow-up, 1 vein had recanalized, for a primary closure rate of 96.7\%. No pain during the procedure or adverse events was reported. Another prospective series evaluated MCA of the small saphenous vein in 50 consecutive patients.\textsuperscript{22} Only patients with a vein diameter of 2.5 to 11 mm were included. The dose of sclerosant was increased after the first 15 patients. At the 6-week assessment, all treated veins were occluded and at 1-year follow-up, 94\% remained occluded. The median visual analog scale score for pain during the procedure was 2 of 10. There were no major complications. Controlled studies with a greater number of subjects and longer follow-up are needed.

A 2013 review of MCA notes that a 5-year 840 patient randomized trial comparing ClariVein with RFA began in 2012 in Europe.\textsuperscript{23} This trial will provide needed data on the comparative effectiveness of MCA, measured at a longer duration and in a larger population. Early results from this trial (119 patients) indicate that intra-procedural pain is slightly lower with MCA (13.4 mm on a 100-mm scale) compared with RFA (24.4, p=0.001).\textsuperscript{24}

Cyanoacrylate Adhesion

The VenaSeal\textsuperscript{™} pivotal study (VeClose) was a multicenter noninferiority trial with 222 patients that compared VenaSeal\textsuperscript{™} versus RFA for the treatment of venous reflux.\textsuperscript{25, 26} The primary endpoint, the proportion of patients with complete closure of the target GSV at 3 months measured by ultrasound, was non-inferior to RFA with a 99\% closure rate for VenaSeal\textsuperscript{™} compared with 96\% for RFA. The secondary endpoint of intraoperative pain was similar for the 2 groups (2.2 on a 10-point scale for VenaSeal\textsuperscript{™} and 2.4 for RFA, p=0.11). Ecchymosis at day 3 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 AVVQ and
Venous Clinical Severity Score improved to a similar extent in the 2 groups. Longer term follow-up is needed to permit conclusions regarding the durability of this procedure.

Twenty-four-month follow-up was reported for 24 of 38 patients enrolled in a study by Almeida et al.Thirty-three month follow-up was reported in 467 veins out of a series of 795 veins (58.7%) treated at 1 institution in Germany. An inflammatory reddening of the skin was observed at approximately 1 week after treatment in 11.7% of cases. No permanent skin responses were observed. Of the 467 veins re-examined, the sealing rate was 97.7%. This series is limited by the high loss to follow-up.

**Endovenous Cryoablation**

Klem et al. reported a randomized trial in 2009 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 greater 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, 11.7) in comparison with cryoablation (score, 8.0). There were no differences between the groups in SF-36 subscores, and neural damage was the same (12%) in both groups.

Disselhoff et al. reported 2 and 5 year outcomes from a randomized trial that compared cryostripping with EVLA. Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP C2) with saphenofemoral incompetence and greater saphenous vein reflux. At 10 days after treatment, EVLA had better results than cryostripping with respect to pain score over the first 10 days (2.9 vs. 4.4), resumption of normal activity (75% vs. 45%) and induration (15% vs. 52%). At 2-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 5 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 2 or 5 years.
Other Treatments

Both steam injection and microwave ablation for endovenous treatment of varicose veins were reported outside of the United States.\textsuperscript{32-34} These procedures have not been approved or cleared for marketing by FDA.

Section Summary

There are a number of large randomized trials on endovenous ablation of the saphenous veins. Comparison with ligation and stripping at 2-year follow-up supports use of both RFA and EVLA. 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 RCTs 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. MCA is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared with thermal ablation techniques is that it does not require tumescent anesthesia and may result in less postoperative 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 MCA. Short-term efficacy of cyanoacrylate adhesion has been shown to be noninferior to RF in a large multicenter RCT. Longer term follow-up is needed to determine durability of this treatment.

Treatment of Tributary Varicosities

\textit{Sclerotherapy and Phlebectomy}

Early studies established ligation and stripping as the criterion 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."\textsuperscript{35} Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system, eg, 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 1 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 1009 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 1-year follow-up, there was an improvement in clinicians’ assessment of the anatomic extent of varicose veins, with 85% of patients in the sclerotherapy group improved compared with 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 RCT that compared visual foam sclerotherapy versus ultrasound-guided foam sclerotherapy of the greater 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 6-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 5 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 an RCT
by Chetter et al. that compared TIPP (n=29) with a multiple stab incision procedure (n=33). A single surgeon performed all but 2 of the procedures, and there was no difference in operating time. Patients treated with TIPP had an average of 5 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 1 and 6 weeks after surgery. At 6 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). 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. The current literature does not show an advantage of TIPP over conventional treatment.

Section Summary

The literature indicates that sclerotherapy of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins may be considered medically necessary. Evidence is insufficient to evaluate the health benefit of sclerotherapy as a sole treatment of varicose tributaries without prior or concurrent treatment of the saphenous veins. No studies have been identified that compare RF or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy (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.

Treatment of 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 4 RCTs published since 2000 that compared superficial vein surgery with conservative therapy in advanced chronic venous insufficiency (CEAP category C5 to C6). The 4 trials included 2 level I (large subject population) and 2 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 2 treated the greater saphenous vein alone. The 2 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.\textsuperscript{42, 43} 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.\textsuperscript{44}

Treatment of the great saphenous vein alone has been reported to improve perforator function. For example, 1 study 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.\textsuperscript{45} O'Donnell discusses additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency.\textsuperscript{5} 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 et al. published a review of the literature of SEPS, which included 19 case series and 1 randomized trial.\textsuperscript{46} In total, the reviewed studies included 1,031 patients with 1,140 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 10-year follow-up of a randomized trial that compared conservative treatment versus SEPS for venous leg ulcers.\textsuperscript{47} 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 compared with 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 postthrombotic changes excluded."\textsuperscript{48} 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 RFA 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 (eg, ulcer healing or recurrence). The 2011 literature update identified 1 study of EVLA for perforating veins in 33 patients with a CEAP classification of 4 (skin changes), 5 (healed ulcer), or 6 (active ulcer). All incompetent saphenous trunks were treated simultaneously (63% of limbs). At 3-month follow-up, occlusion was achieved in 78% of the perforating veins. Five patients (15%) had active ulcers at baseline; 4 of the 5 ulcers had healed by 6 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.

**Summary of Evidence**

Although randomized controlled trials (RCTs) with longer follow-up are needed to evaluate long-term durability, and repeat treatments may be required, evidence indicates that endovenous treatment of saphenous veins with radiofrequency or laser ablation improves short-term clinical outcomes (eg, pain and return to work) in comparison with surgery. Ultrasound-guided foam sclerotherapy (physician compounded) leads to success rates that approach that of surgery. There are no trials comparing the recently U.S. Food and Drug Administration (FDA) approved microfoam sclerotherapy with other treatments of varicose veins. Results from a recent RCT of cryoablation indicate that this therapy is inferior to conventional stripping. There is insufficient evidence on mechanochemical ablation.

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; treatment of perforator vein reflux may be as beneficial as any alternative (eg, 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. 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 in comparison with surgical interventions. 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01807585&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Randomized Control Trial Comparing VenaSeal Sapheon Closure System With Radiofrequency Ablation (Pivotal Study)</td>
<td>244</td>
<td>Sep 2016</td>
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<tr>
<td>NCT01459263</td>
<td>Mechanochemical Endovenous Ablation of Great Saphenous Vein Incompetence Using the ClariVein™ Device: a Prospective Study</td>
<td>100</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NTR4613&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial)</td>
<td>160</td>
<td>Apr 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial. NTR: Netherlands Trial Registry.
<sup>a</sup> Denotes industry-sponsored or cosponsored trial

Summary of Evidence

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

Practice Guidelines and Position Statements

The Society for Vascular Surgery and the American Venous Forum (AVF)

The Society for Vascular Surgery and the American Venous Forum (AVF) 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 (GRADE 1A, strong recommendation, high quality evidence). They recommend use of compression therapy for patients with symptomatic varicose veins (GRADE 2C, weak recommendation, low-quality evidence) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (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), but there is a GRADE 2B recommendation (weak recommendation, moderate quality evidence) for 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) by subfascial endoscopic perforating vein surgery, sclerotherapy, or thermal ablations (GRADE 1C, weak recommendation, low quality evidence).

**American College of Radiology (ACR)**

In 2012 the American College of Radiology published their latest version of appropriateness criteria for the treatment of lower-extremity venous insufficiency. The following is a summary of treatment options:

- **Compression stockings**: Graduated compression stockings are routinely used to control venous insufficiency symptoms. They provide external support that can constrict dilated veins and restore competence to incompetent valves. Compression stockings are particularly helpful during pregnancy, and they are frequently used following venous ablation treatment.

- **Surgery**: Great saphenous vein (GSV) stripping with branch ligation had historically been the primary treatment option for venous insufficiency. The GSV is ligated near the groin. Ligation alone can preserve the vein for subsequent harvesting in case of arterial bypass; however, ligation alone has proven unsatisfactory for preventing the occurrence of reflux, so it is often supplemented by vein stripping. Ambulatory phlebectomy is primarily used to treat surface varicose veins. It can be performed as an adjunct to endovenous ablation or stripping. This procedure involves making tiny punctures or incisions through which the varicose veins are removed. Other surgical methods to treat venous insufficiency have been described, including SEPS for treating venous ulcers and valvular surgery for treating reflux caused by incompetent valves of the deep veins.

- **Injection sclerotherapy**: Injection sclerotherapy is a common treatment for telangiectasias and can be used to treat smaller varicose veins. The sclerotherapy solution can be in liquid form or can be injected as “foam” (mixed with a gas such as air). Sclerotherapy has not been shown to have long-term effectiveness for large veins, such as the GSV.

- **Endovenous ablation**: Endovenous ablation is a minimally invasive alternative to surgery. It is a percutaneous procedure that can be used to treat the GSV, small saphenous vein (SSV), and other superficial veins. Endovenous ablation uses RFA or laser energy (EVLA) applied
inside the vein to cause occlusion. Small prospective trials comparing EVLA and RFA with conventional surgery in patients with GSV reflux have shown favorable results. One study demonstrated that EVLA is comparable to surgery in abolishing reflux and improving disease-specific quality of life and that it allows earlier return to normal activity. A recent systematic literature review comparing the safety and efficacy of EVLA and surgery involving saphenous ligation and stripping as treatments for varicose veins showed few differences in clinical effectiveness outcomes, although long-term follow-up was lacking. A meta-analysis suggested that EVLA and RFA are at least as effective as surgery in treating lower-extremity varicose veins. After 3 years, the estimated pooled success rates for treatment were 78% for surgical stripping, 77% for foam sclerotherapy, 84% for RFA, and 94% for laser therapy.

- **Adjunctive treatments**: Adjunctive treatments may be required to help eliminate venous insufficiency. Patients with venous insufficiency and associated venous occlusion or stenosis of the common iliac vein (e.g., May-Thurner syndrome) may require venous recanalization with angioplasty and stenting to achieve a patent conduit for venous return. Patients with pelvic venous insufficiency may require percutaneous embolization of the ovarian veins. Patients with deep venous thrombosis are typically treated with anticoagulation to reduce the risk of thrombus propagation, embolization, and post-thrombotic syndrome. One study suggested that endovenous ablation of the saphenous vein can be considered as a viable treatment alternative in patients with venous insufficiency and previous deep venous thrombosis.

- **Complications**: All forms of lower-extremity venous insufficiency treatment are subject to recurrence. Additional risks of vein ligation and stripping surgery include: anesthetic risk, scarring, pain, bleeding, deep venous injury or thrombosis, nerve injury, and infection. Complications of the endovenous ablation procedure include bruising, swelling, transient numbness, and rarely deep venous thrombosis.

**Society of Interventional Radiography (SIR)**

In 2003, the Society of Interventional Radiography (SIR) published a position statement\textsuperscript{53} 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/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, AVF 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 greater saphenous vein or smaller saphenous vein or in a major tributary branch of the greater or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory greater 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 (NICE)**

In 2003 and 2004, the U.K.’s National Institute for Health and Care Excellence (NICE) published guidance on radiofrequency ablation of varicose veins and on endovenous laser treatment of the long saphenous vein. NICE concluded that the evidence on the safety and efficacy
appeared adequate to support the use of these procedures provided that the normal arrangements were in place for consent, audit, and clinical governance. The evidence on efficacy at this time was limited to case series with limited follow-up. Clinicians were encouraged to collect longer-term follow up data.

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 ischaemic attacks and stroke.”

NICE issued guidance on endovenous mechanochemical ablation in 2013, concluding that current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

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, 6-12 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.
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.

Regulatory Status

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) is a sclerosant microfoam made with a proprietary gas mix. It was approved by the FDA in 2013 under a new drug application (NDA) 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 RFSFlex devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (ie, refluxing) perforator and tributary veins. The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008. FDA product code: GEI.

- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit received FDA clearance through the 510(k) process, "... for use in the endovascular coagulation of the greater 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) received FDA clearance for marketing. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.
In October 2003 the Trivex system received FDA clearance through the 510(k) process. The manufacturer, LeMaitre Vascular, describes it as a transilluminated powered phlebectomy system (TIPP). According to the label, the intended use is for “ambulatory phlebectomy procedures for the resection and ablation of varicose veins.” FDA product code: DNQ.

In 2008 The ClariVein® Infusion Catheter (Vascular Insights) received marketing clearance through the 510(k) process (K071468). It is used for mechanochemical ablation. Predicate devices were listed as the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature. FDA product code: KRA.

References


19. Todd KL, 3rd, Wright D, for the V-IG. 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 sapheno-femoral junction incompetence. Phlebology. Oct 2014;29(9):608-618. PMID 23864353


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/11/12</td>
<td>Replace policy. Formatting changed to now organize procedures by type of vein. Policy statement extensively revised with additional medically necessary criteria for each</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
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<tr>
<td>04/08/13</td>
<td>Policy statement clarification. In criteria for sclerotherapy of accessory saphenous veins when not done concurrently with other listed treatments, the moderate to severe saphenous reflux criterion has been removed. To clarify the definition of “symptomatic” for treatment of tributaries not done concurrently with other listed treatments, specific criteria added for stab avulsion, hook phlebectomy, sclerotherapy or transilluminated powered phlebectomy treatment of tributaries. Tributary criterion for moderate to severe saphenous reflux, when not done concurrently with other listed treatments, has been removed.</td>
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<tr>
<td>06/14/13</td>
<td>Minor clarification. Hook phlebectomy clarified to indicate that it is also known as stab phlebectomy or micro-phlebectomy.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. CPT codes for sclerotherapy (36468, 36469, 36470, 36471), TIPP (37765 or 37766, stab avulsion (37765, or 37799), etc. added to Policy Guidelines section.</td>
</tr>
<tr>
<td>02/27/14</td>
<td>Update Related Policies. Add 10.01.514.</td>
</tr>
<tr>
<td>06/09/14</td>
<td>Interim update. Criteria for vein size removed from policy statement. Minor edit to change definition of “moderate to severe reflux” to greater than 0.5 second. Coding update: ICD-9 and ICD-10 diagnosis and procedure codes removed – these are not utilized for adjudication.</td>
</tr>
<tr>
<td>02/10/15</td>
<td>Annual Review. Policy updated with literature review through September 23, 2014; reference 8-9, 18, 24 33 added and some references removed; policy statement revised to allow sclerotherapy as medically necessary when criteria are met. Information added regarding FDA approval of Varithena sclerotherapy. Documentation requirements added to Policy Guidelines.</td>
</tr>
<tr>
<td>05/12/15</td>
<td>Interim Update. Policy statement clarified: Treatment of tributaries by sclerotherapy, stab avulsion, stab/hook phlebectomy or transilluminated powered phlebectomy may now be considered medically necessary up to 10 days after saphenous veins have been treated. Definition of moderate to severe saphenous reflux and abbreviation &quot;TIPP&quot; added to the policy statement.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Interim Update. Policy statement clarified: TRIVEX listed as an example of TIPP. Exercises and pain relievers removed from conservative management requirement. TRIVEX manufacturer website added to Reference section. CPT codes 76942, 93970-71 and HCPCS code S2202 removed; these are not reviewed.</td>
</tr>
<tr>
<td>11/10/15</td>
<td>Interim Update. Policy updated with clarification to coverage criteria for the accessory saphenous vein, indicating parameters around treatment of the greater or lesser saphenous veins and the presence of reflux.</td>
</tr>
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<td>01/12/16</td>
<td>Annual Review. Added statement that cyanoacrylate adhesive/embolization (CAE) (eg, VenaSeal closure system) and endovenous mechanochemical ablation (MOCA) (eg ClariVein) of any vein is considered investigational. The failure of compression therapy</td>
</tr>
</tbody>
</table>
removed from the policy statements on venous stasis and thrombophlebitis. References added. Policy updated with literature review through July 7, 2015.

Interim Update, approved September 13, 2016. Perforator vein criteria revised: Requirement of active ulcers changed to “healed or active ulcers” and “demonstrated perforator reflux” is more clearly defined with measurements of outward flow and vein diameter.

Policy moved to new format. Policy statements unchanged. Added Prior Authorization Requirements section.

Coding update, added CPT codes 36473 and 36474 effective 1/1/17.

Annual Review, approved February 14, 2017. No change to policy statement. Compression Therapy added to Definition of Terms. Reference 64 added. Removed CPT code 36469 from policy as it terminated as of 01/01/2015.

Minor formatting edits made.

Minor edit, added Documentation Requirements table to the Policy Coverage Criteria section.

Coding update, added CPT codes 36465, 36466, 36482, and 36483 (new codes effective 1/1/18).

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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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