Varicose Vein Treatments

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

<table>
<thead>
<tr>
<th>Type</th>
<th>Title</th>
<th>Jurisdiction Medicare Administrative Contractors (MACs)</th>
<th>Applicable States/Territories</th>
</tr>
</thead>
</table>
Varicose Vein Treatments

Description

Varicose veins are abnormally enlarged and tortuous vessels greater than three millimeters (3 mm) in diameter that usually result from reflux of blood caused by incompetent valves in the venous system. Rather than flowing forward, blood refluxes (flows backward) across the faulty valve and the resulting increased pressure causes the vein to dilate. The condition is further aggravated with the weakening of the affected vein's walls. Abnormal dilation may affect small reticular or feeder veins as well as superficial veins, located within or just below the skin. Reflux greater than or equal to 500 milliseconds (0.5 seconds) is generally considered clinically significant when combined with other symptoms.

Perforator veins penetrate the deep fascia of muscles to form a connection between a deep venous system and a superficial one. They, or other larger veins that may communicate with the saphenous system, may become dilated and tortuous as their valves fail. This may occur anywhere on the leg between the groin and ankle and is commonly the result of reflux through the valve at the junction between the great saphenous vein (GSV) and the common femoral vein (saphenofemoral junction [SFJ]), or as a result of reflux through the valve at the junction between the small saphenous vein (SSV) and the popliteal vein (saphenopopliteal junction [SPJ]).

Recommendations for noninvasive management of varicose vein symptoms generally include daily exercise (walking), leg elevation (3 times daily for 30 minutes), leg exercises (ankle flexion) when seated and weight management. Prescriptions may be needed for venoactive medication and/or prescription compression hose.

Proposed treatments for varicose veins include, but may not be limited to:

- **Catheter-assisted venous sclerotherapy (KAVS catheter)** uses an intravascular catheter with a balloon at the distal end to temporarily block blood flow to the segment of the vein being targeted for sclerotherapy. May also be referred to as **endovenous catheter-directed chemical ablation with balloon isolation**.

- **Cryoablation** (cryofreezing, cryostripping, cryosurgery, cryotherapy) involves the use of liquid nitrogen or argon gas at extreme cold temperatures to destroy venous tissue.

- **Cyanoacrylate closure (CAC)** (eg, VenaSeal closure system) delivers medical adhesive using ultrasound guidance via a catheter inserted into the target vein. The catheter is withdrawn, and pressure is applied to the vein.

- **Endovenous thermal ablation** techniques use heat energy to seal veins:
  - Endovenous laser ablation or therapy (EVLA or EVLT) utilizes a percutaneous catheter to deliver high-intensity laser light to induce photocoagulation of blood and occlusion of the vein.
  - **Radiofrequency ablation (RFA), endovascular occlusion or endoluminal radiofrequency ablation (eg, ClosureFast [formerly known as Venefit or VNUS Closure system])** involves the delivery of controlled
radiofrequency (RF) energy through a catheter inserted into the affected vein. The heat generated by the RF energy causes the vein to contract and become occluded.

- **Ligation and stripping** consists of tying off and/or removing the varicose veins just under the skin, through several small incisions made along the veins. Once the veins are tied off and/or removed, the blood will flow through the deep veins back to the heart. Compression wrap to the leg(s) is used to limit bruising and swelling postoperatively.

- **Phlebectomy (ambulatory phlebectomy, microphlebectomy, miniphlebectomy, stab phlebectomy)** is the surgical removal of veins through a small incision.

- **Sclerotherapy (endovenous chemical ablation)** involves injecting a liquid or foam sclerosing agent into the targeted varicose vein, which causes irritation to the inner lining of the vein thereby causing it to collapse. After injecting the sclerosing agent, the extremity is tightly wrapped to keep the vein closed and enhance permanent closure. The body then absorbs the sclerotic tissue. Examples of types of sclerosants include chemical irritants, detergents, and osmotic agents. Sclerotherapy delivered by a specialized catheter with a rotating tip is called endomechanical or mechanochemical ablation (MOCA) (eg, ClariVein). The rotation action is thought to facilitate dispersing the infused medication into the bloodstream and to the targeted treatment area on the vessel wall. Sclerotherapy delivered using a drug/device combination product that dispenses a liquid sclerosant and low-nitrogen gas under pressure, from a proprietary canister is called polidocanol endovenous microfoam (PEM) (Varithena).

- **Subfascial endoscopic perforator vein surgery (SEPS)** is a less invasive alternative to traditional open surgical treatment of chronic venous insufficiency. An endoscope is inserted into a small incision away from an ulcer site and balloon dissection is performed, with clips or scalpel interrupting incompetent perforator veins in the calf.

- **Transilluminated powered phlebectomy (TIPP)** involves endoscopic resection and ablation of superficial varicosities using an illuminator for vein identification and a powered resector that ablates the vein from underneath.

### Coverage Determination

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

When multiple procedures are requested, the criteria for each must be met.
The use of ultrasound to guide catheter, device or needle placement during a procedure is considered integral to the primary procedure and not separately reimbursable.\textsuperscript{19,26}

Duplex ultrasound or Doppler imaging studies necessary for a procedure-related complication MAY be considered separately reimbursable.

**General Requirements for Varicose Vein Treatments**
The general criteria for varicose vein treatments apply to all requests for treatment except sclerotherapy, phlebectomy for recurrent varicosities. Please see specific treatments for additional requirements.

**Varicose vein treatment** will be considered medically reasonable and necessary when the following general requirements are met:

- Duplex ultrasound or Doppler imaging study report shows clinically significant varicose veins AND documentation in the clinical records of at least one of the following:
  - Hemorrhage from venous varicosity;
  - Venous stasis dermatitis;
  - Venous stasis ulceration;
  - Symptoms of venous insufficiency of the lower extremities (ache, pain, muscle cramps, heaviness, edema, tightness) which interferes with activities of daily living,

AND

- Documentation in the clinical record of a discussion of personalized conservative therapy* options, specific to the individual’s health needs, including but not limited to:
  - Compression therapy with surgical grade stockings providing a minimum of 20 – 30 mm Hg pressure
  - Exercise plan with prescribed physical activity (eg, cycling, treadmill, walking)
  - Periodic leg elevation
  - Weight reduction

*Conservative therapy may be waived for individuals with any of the following:
  - Hemorrhage
  - Recurrent superficial thrombophlebitis
  - Skin changes attributable to venous disease, active or healed venous leg ulceration

**Procedures Without Additional Criteria**
The following will be considered medically reasonable and necessary when the above General Requirements for Varicose Vein Treatments are met. There are no additional criterion requirements for:

- Cyanoacrylate closure (CAC), (eg, VenaSeal closure system)
- EVLA, EVLT, RFA of Great or Small Saphenous Veins
Criteria for Specific Treatments
Unless noted otherwise, the following treatments must meet the above General Requirements for Varicose Vein Treatments for varicose vein treatments in addition to the individual criteria outlined below for each treatment.

Sclerotherapy, Phlebectomy for Recurrent Varicosities
(General Criteria for Varicose Vein Treatments does NOT apply)

Sclerotherapy OR phlebectomy OR a combination thereof, to treat recurrent symptomatic varicose tributary, perforator or accessory veins will be considered medically reasonable and necessary when the following requirements are met:

- Duplex scan report provides evidence of recurrent and clinically significant varicose veins AND at least one of the following:
  - Hemorrhage from venous varicosity; OR
  - Venous stasis ulceration; OR
  - Symptoms of venous insufficiency of the lower extremities (eg, ache, pain, edema, heaviness, muscle cramps, tightness)

Subfascial Endoscopic Perforator Vein Surgery (SEPS)
SEPS to treat symptomatic varicose perforator veins will be considered medically reasonable and necessary when all the following requirements are met:

- Duplex ultrasound or Doppler imaging study report shows clinically significant reflux where the outward flow of duration is greater than or equal to 500 ms (0.5 seconds); AND
- Perforator vein diameter is greater than or equal to 3.5 mm; AND
- The vein to be treated is located beneath a healed or open venous ulcer (Clinical, Etiology, Anatomy and Pathology [CEAP] classification of chronic venous disorders, class C5 - C6)

Telangiectasias
(General Criteria for Varicose Vein Treatments does NOT apply)
The treatment of telangiectasias (spider veins, venules, reticular veins, superficial capillaries) will be considered medically reasonable and necessary ONLY in cases involving spontaneous hemorrhage.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The treatment of telangiectasias (spider veins, venules, reticular veins, superficial capillaries) for any indication other than those listed above is considered cosmetic and is not considered medically reasonable and necessary.

Cosmetic surgery or expenses incurred in connection with such surgery is not a covered Medicare benefit. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (ie, as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. These treatments and services fall within the Medicare program’s statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury ($1862(a)(1) of the Act).

Note: This exclusion does not apply to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.26

The following service will not be considered medically reasonable and necessary for the treatment of varicose veins:

- Catheter-assisted venous sclerotherapy (KAVS catheter) (also referred to as endovenous catheter-directed chemical ablation with balloon isolation)

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following services will not be considered medically reasonable and necessary for the treatment of varicose veins:

- Cryoablation (also referred to as cryofreezing, cryostripping, cryosurgery, cryotherapy)
• **TIPP**

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

**Summary of Evidence**

*Cryoablation (cryofreezing, cryostripping, cryosurgery, cryotherapy)*

Studies have shown this treatment to be inferior to both conventional stripping and RFA. A randomized clinical trial with outcomes 5 years after treatment showed no significant difference between EVLA and cryostripping. A 2011 professional society guideline reported that the technique was new to the US, experience was limited, had not been fully evaluated and therefore no recommendation could be made. The same organization published a systematic review in 2023 and chose not to analyze cryostripping.

*Transilluminated Powered Phlebectomy (TIPP)*

The TIPP procedure using the TRIVEX System (FDA-approved 2003), was intended as a less invasive alternative to standard varicose vein surgery. In the twenty years since inception, the published literature has failed to show a clear advantage to the procedure, other than requiring fewer and smaller incisions. While some studies showed results to be equivalent, others described patients experiencing more pain and/or bruising. Potential disadvantages to providers also include equipment requirements and a steep learning curve to mastery, despite the development of next-generation systems and techniques. TIPP has largely been replaced by more effective, less invasive techniques with high quality published evidence supporting their safety and efficacy.

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<thead>
<tr>
<th>CPT® Code(s)</th>
<th>Description</th>
<th>Comments</th>
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<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)</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<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</td>
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<td>36468</td>
<td>Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk</td>
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<tr>
<td>36470</td>
<td>Injection of sclerosant; single incompetent vein (other than telangiectasia)</td>
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<tr>
<td>36471</td>
<td>Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg</td>
<td></td>
</tr>
<tr>
<td>36473</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated</td>
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<tr>
<td>36474</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
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<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>
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<td>36476</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
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<td>36478</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated</td>
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<td>36479</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
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<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</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<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)</td>
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<td>37241</td>
<td>Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)</td>
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<td>37500</td>
<td>Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)</td>
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<td>37700</td>
<td>Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions</td>
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<td>37718</td>
<td>Ligation, division, and stripping, short saphenous vein</td>
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<tr>
<td>37722</td>
<td>Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below</td>
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<tr>
<td>37735</td>
<td>Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia</td>
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<tr>
<td>37760</td>
<td>Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg</td>
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<td>37761</td>
<td>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg</td>
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<td>37765</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions</td>
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<td>37766</td>
<td>Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions</td>
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<td>37780</td>
<td>Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)</td>
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<td>37785</td>
<td>Ligation, division, and/or excision of varicose vein cluster(s), 1 leg</td>
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<td>37799</td>
<td>Unlisted procedure, vascular surgery</td>
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<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
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<tr>
<td>93970</td>
<td>Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study</td>
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<td>Comments</td>
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<tr>
<td>0524T</td>
<td>Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring</td>
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**References**


55. UpToDate. Approach to treating symptomatic superficial venous insufficiency. 


57. UpToDate. Clinical manifestations of lower extremity chronic venous disease. 

58. UpToDate. Comparison of methods for endovenous ablation for chronic venous disease. 


60. UpToDate. Injection sclerotherapy techniques for the treatment of telangiectasias, reticular veins 
    2023.

61. UpToDate. Laser and light therapy of lower extremity telangiectasias, reticular veins and small 

62. UpToDate. Medical management of lower extremity chronic venous disease. 

63. UpToDate. Nonthermal, nontumescent ablation techniques for the treatment of lower extremity 


67. UpToDate. Superficial vein thrombosis and phlebitis of the lower extremity veins. 

68. UpToDate. Techniques for endovenous laser ablation for the treatment of lower extremity chronic 

### Appendix

**Appendix A**

**CEAP Classification**

<table>
<thead>
<tr>
<th>Clinical classification</th>
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<tbody>
<tr>
<td>C0</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>C1</td>
<td>Telangiectasias, reticular veins, malleolar flares</td>
</tr>
<tr>
<td>C2</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>C2r</td>
<td>Recurrent varicose veins</td>
</tr>
<tr>
<td>C3</td>
<td>Edema without skin changes</td>
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<tr>
<td>C4</td>
<td>Changes in skin and subcutaneous tissue due to chronic venous insufficiency</td>
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<td>Description</td>
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<td>--------------------------------------------------</td>
</tr>
<tr>
<td>C4a</td>
<td>Pigmentation or eczema</td>
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<td>C4b</td>
<td>Lipodermatosclerosis or atrophie blanche</td>
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<tr>
<td>C4c</td>
<td>Corona phlebectatica (abnormally dilated veins around ankle)</td>
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<td>C5</td>
<td>Healed venous ulcer</td>
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<td>C6</td>
<td>Active venous ulcer</td>
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<td>Recurrent active venous ulcer</td>
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**Change Summary**

- 01/01/2024 New Policy.