Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

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➲ Instructions for Use

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Related Commercial/Individual Exchange Policies
- Cosmetic and Reconstructive Procedures
- Outpatient Surgical Procedures – Site of Service

Community Plan Policy
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

Medicare Advantage Policy
- Varicose Veins Treatment and Other Vein Embolization Procedures

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Thermal and Nonthermal Treatments for Venous Insufficiency and Varicose Veins

Endovenous Ablation of the lower extremity superficial truncal or perforator veins for the treatment of Venous Insufficiency and Varicose Veins is reconstructive and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Procedures, Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein (Custom) – UHG.

Click here to view the InterQual® criteria.

The following procedures for the treatment of Venous Insufficiency and Varicose Veins are considered unproven and not medically necessary due to insufficient evidence of efficacy:
- Endovenous mechanochemical ablation (MOCA)
- Endovenous Ablation of incompetent perforator veins using endovenous foam Sclerotherapy (e.g., noncompounded foam sclerosant)
- Endovenous Ablation of recurrent or residual perforator vein following a prior vein procedure

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Ligation Procedures

Ligation and division, with or without stripping or excision of lower extremity Superficial Veins, is reconstructive and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein.

Click here to view the InterQual® criteria.

Sclerotherapy of Superficial Veins

- Refer to the Applicable Codes section for Sclerotherapy (e.g., liquid, foam, ultrasound guided, endovenous chemical ablation, endovenous microfoam)
- Refer to the Benefit Considerations section for cosmetic Sclerotherapy

Other Procedures

Porcine bioprosthetic valve (e.g., VenoValve) implantation into the femoral vein for treatment of deep vein reflux associated with chronic Venous Insufficiency is unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

When applicable, refer to the member specific benefit plan document for definitions.

Accessory Vein: Accessory saphenous veins indicate a venous segment ascending parallel to the Great Saphenous Vein (GSV) and are located more superficially above the saphenous fascia, both in the leg and in the thigh. These can include the anterior and posterior GSVs and the circumflex veins (anterior or posterior). Additionally, before the Small Saphenous Vein penetrates the muscular fascia, it may branch out a cranial extension, known as the vein of Giacomini, which goes upward to join the GSV (Lee et al., 2017).

Axial Reflux: Axial Reflux of the GSV is defined as uninterrupted retrograde venous flow from the groin to the upper calf. Axial Reflux in the Small Saphenous Vein is defined as being from the knee to the ankle. Axial Reflux in the anterior accessory GSV and posterior accessory GSV is retrograde flow between two measurements, at least 5 cm apart (Gloviczki et al., 2023).

Duplex Ultrasonography: Noninvasive imaging that uses sound waves to assess blood flow through the vessels in the legs. It combines a B-mode scanner with built-in Doppler capability. B-mode imaging permits accurate placement of the pulsed Doppler sample volume, and the addition of color makes it easier to establish obstruction, turbulence, and the direction of venous and arterial flow [National Heart, Lung, and Blood Institute (NHLBI), 2014; updated 2023; Gloviczki et al., 2011].

Endovenous Ablation: A minimally invasive procedure that uses heat generated by radiofrequency or laser energy to seal off damaged veins (NHLBI, 2014; updated 2023).

Functional or Physical Impairment: A Functional or Physical or physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; and performing basic life functions (Medicare, 2023).

Great Saphenous Vein: A Superficial Vein that originates from the medial side of the dorsal pedal venous arch and ascends along the inside of the leg and thigh until it joins the common femoral vein at the saphenofemoral junction (Lee et al., 2017).

Ligation: Tying off a vein (NHLBI, 2014; updated 2023).

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Moderate to Severe Pain: The Venous Clinical Severity Score describes Moderate Pain to be daily pain or other discomfort interfering with but not preventing regular daily activities and Severe Pain to be daily pain or discomfort that limits most regular daily activities [Vasquez et al. (American Venous Forum), 2010].

Sclerotherapy: The injection of liquid or foam chemicals into the vein to create a plug that seals it shut (NHLBI, 2014; updated 2023).

Small Saphenous Vein: A Superficial Vein that ascends along the posterior calf to join the popliteal vein in the popliteal fossa in most cases (De Maeseneer et al., 2022).

Superficial Vein: Veins located above the muscular fascia (Lee et al., 2017).

Telangiectasias/Spider Veins: Dilated small Superficial Veins measuring less than 1 mm in diameter and occurring predominantly in the lower extremities (Gloviczki et al., 2023).

Tributary Vein: Small Superficial Veins in the legs that run close to the skin within the superficial plane of the subcutaneous layer (Caggiati et al., 2024).

Varicose Veins: Varicose Veins are dilated subcutaneous tributaries greater than or equal to 3 mm in diameter, and individuals with Varicose Veins belong to CEAP (Clinical, Etiology, Anatomy, and Pathophysiology) class C2 (Gloviczki et al., 2023).

Venous Reflux/Insufficiency: Gloviczki et al. (2023) defines Venous Reflux as reversed blood flow in the veins. Abnormal (pathological reflux) times exceed different thresholds, depending on the system of veins:
- Deep veins: 1 second
- Superficial Veins: 0.5 seconds
- Perforator veins: 0.5 seconds

Venous Stasis Dermatitis: A skin inflammation due to the chronic buildup of fluid (swelling) under the skin (MedlinePlus, 2022).

Venous Stripping: Surgical removal of Superficial Veins (NHLBI, 2014; updated 2023).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:
- Per AMA coding guidance for endovenous radiofrequency ablation (e.g., CPT code 36475), the initial incompetent vein treated may only be requested once per extremity. For endovenous radiofrequency ablation for the treatment of subsequent incompetent veins in the same extremity as the initial vein treated (e.g., CPT code 36476), only one add-on code per extremity may be requested, regardless of the number of additional vein(s) treated (CPT Assistant, November 2016). Therefore, only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated.
- **Sclerotherapy**:
  - Per AMA coding guidance, if the targeted vein is an extremity truncal vein and injection of a noncompounded foam sclerosant, with ultrasound-guided compression maneuvers to guide dispersion of the injectate, is performed, refer to CPT codes 36465 and 36466 (CPT Assistant, 2018).
  - CPT code 36468 for sclerosant treatment for Spider Veins/Telangiectasias is considered cosmetic and does not improve a Functional, Physical, or physiological Impairment (2019 Certificate of Coverage Amendment).
  - CPT codes 36470 and 36471 are covered for Sclerotherapy (nontruncal, nontelangiectasia) up to three sessions per leg within a year.
    - More than three sessions per leg within a year is considered cosmetic and does not improve a Functional, Physical, or physiological Impairment. Cosmetic Sclerotherapy is excluded (2019 Certificate of Coverage Amendment).

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- A session is defined as one date of service in which Sclerotherapy (CPT codes 36470 and 36471) is performed.
- A year is defined as a rolling 12 months (365 days).

CPT Code	Description
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (e.g., polyester, ePTFE, bovine pericardium), when performed
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein)
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg
36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	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)
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	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)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	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)
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., 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)
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous vein
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg

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Description of Services

Varicose Veins are enlarged veins that are swollen and raised above the surface of the skin. They can be dark purple or blue and look twisted and bulging. Varicose Veins usually occur in the legs. Veins have one-way valves that help keep blood flowing toward the heart. When the valves become weak or damaged and do not close properly, blood can back up and pool in the veins, causing them to get larger. The resulting condition is known as reflux. Varicose Veins may lead to complications such as pain, itching or burning, skin color changes around the veins, blood clots, or skin ulcers (National Heart, Lung, and Blood Institute, 2014; updated 2023).

Duplex ultrasound is considered the gold standard for diagnosis of superficial venous incompetence. The CEAP (Clinical, Etiology, Anatomy, Pathophysiology) classification system is used to describe the degree of varicosity. The "C" part of CEAP classification is more useful and practical in rating the severity of Varicose Veins:

- C0: No visible or palpable signs of venous disease
- C1: Telangiectasis (Spider Veins) or reticular veins
- C2: Varicose Veins (diameter of vein is > 3 mm)
- C3: Edema
- C4a: Pigmentation and eczema
- C4b: Lipodermatosclerosis and atrophie blanche
- C5: Healed venous ulcer
- C6: Active venous ulcer

(Lurie et al., American Venous Forum, 2020)

Preoperative venous duplex ultrasound is used to evaluate individuals for Venous Insufficiency symptoms or suspected deep vein thrombosis; it can provide a road map of vein anatomy similar to contrast venography as well as essential hemodynamic information about the presence of proximal obstruction, vein valve function, and Venous Reflux (Lin et al., 2015).

Varicose Veins are treated with lifestyle changes and medical procedures done either to remove the veins or to close them. Endovenous Ablation therapy uses lasers or radiofrequency energy to create heat to close off a Varicose Vein. Venous Stripping and Ligation involves tying shut and removing the veins through small cuts in the skin (National Heart, Lung, and Blood Institute, 2014; updated 2023).

Endovascular embolization using cyanoacrylate-based adhesive (e.g., VenaSeal™ closure system) is a minimally invasive, nonthermal, and nonsclerosant procedure that does not require tumescent anesthesia. The medical adhesive is used to close the lower extremity superficial truncal veins in individuals with symptomatic Venous Reflux disease (Hayes, 2022; updated 2024).

Endovascular embolization using endovenous foam Sclerotherapy with polidocanol endovenous microfoam [e.g., Varithena™ (Provensis Ltd.)] is a prescribed proprietary canister that generates a sterile, uniform, stable, low-nitrogen polidocanol 1% microfoam sclerosant intended for ultrasound-guided intravenous injection for treating venous incompetence and varicosities (Hayes, 2022). The aim of ultrasound-guided foam Sclerotherapy for Varicose Veins is to damage the endothelial surface of the vein causing scarring and leading to blockage of the treated Varicose Veins. Sclerosant, in the form of a foam, is intended to have good surface area contact with the vein walls (National Institute for Health and Care Excellence, 2013).

Endovenous mechanochemical ablation (e.g., ClariVein®) uses a flexible, steerable, infusion catheter equipped with a rotatable dispersion wire. The wire tip causes minimal mechanical damage to the vessel lining, then a sclerosing agent is distributed to the treatment area. The process induces sclerosis of the vein, activating the clotting system and leading to vessel occlusion (Hayes, 2022; updated 2024).

A porcine bioprosthetic valve (e.g., VenoValve) is currently under investigation for the treatment of deep vein reflux. The porcine aortic monocuspid valve leaflet attached to a nonexpandable stainless-steel frame is implanted into the femoral vein, and the leaflet is designed to act as a functional valve. VenoValve is intended to be a permanent implant that decreases the risk of venous hypertension developing in the leg affected by chronic Venous Insufficiency by preventing the backflow of blood (Hayes, 2022; updated 2024).

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Benefit Considerations

Coverage Limitations and Exclusions

The following procedures are excluded from coverage:

- Procedures that correct an anatomical congenital anomaly, without improving or restoring physiological function, are considered cosmetic procedures and therefore excluded from coverage. The fact that a covered person may experience psychological consequences or socially avoidant behavior as a result of an injury, sickness, or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.
- Any procedure that does not meet the criteria in the Coverage Rationale section.
- Treatments for Spider Veins and/or Telangiectasias are considered to be cosmetic and therefore excluded from coverage.
- Endovenous Ablation (radiofrequency and/or laser) of either reticular or Telangiectatic Veins is not reconstructive and not medically necessary and therefore excluded from coverage.

Sclerotherapy Treatment of Veins

- Cosmetic Sclerotherapy is excluded.

Clinical Evidence

Endovenous Mechanochemical Ablation

Evidence in the peer-reviewed literature evaluating mechanochemical ablation (MOCA) for the treatment of venous insufficiency and varicose veins is limited. Future robust randomized controlled trials (RCTs) are warranted, along with long-term outcomes, to establish the safety and efficacy of this procedure.

Lim et al. (2025) reported 5-year results from the LAMA trial, a randomized controlled study that compared endovenous laser ablation (EVLA) with MOCA using the ClariVein device. At 1 year, MOCA combined with ambulatory phlebectomy showed lower anatomical occlusion rates and no advantage in periprocedural pain compared with EVLA with phlebectomy. At 5 years, follow-up was completed by 69% of EVLA participants and 76% of MOCA participants. EVLA demonstrated significantly higher anatomical occlusion (91% vs 47%; $p < 0.001$) and a lower reintervention rate (8% vs 21%; $p = 0.031$). The absolute risk reduction for occlusion failure with EVLA was 45% (95% CI, 29%-60%). However, there were no significant differences between groups in quality-of-life (QOL) measures, including the Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) scores. The authors concluded that MOCA resulted in persistently lower occlusion rates and higher reintervention needs, but after additional procedures, long-term QOL outcomes were similar between the two treatments. A key limitation of this study is the relatively high loss to follow-up, with only 69% of EVLA participants and 76% of MOCA participants completing the 5-year assessment.

Bontinis et al. (2023) conducted a systematic review and meta-analysis, encompassing 14 studies and 4,177 individuals, to evaluate the effectiveness and safety of thermal and nonthermal endovenous ablation techniques for treating superficial venous insufficiency in the lower limbs. The primary end points were great saphenous vein (GSV) closure and VCSS improvement; the mean follow-up period was 25.7 months. Radiofrequency ablation RFA; odds ratio (OR, 3.99; 95% CI, 1.82-10.53), cyanoacrylate ablation (OR, 3.09; 95% CI, 1.35-8.37), and EVLA (OR, 2.72; 95% CI, 1.23-7.38) displayed increased odds for GSV closure compared with MOCA. MOCA inferiority compared with RFA [mean difference (MD), 0.96; 95% CI, 0.71-1.20], EVLA (MD, 0.94; 95% CI, 0.61-1.24), and cyanoacrylate ablation (MD, 0.89; 95% CI, 0.65-1.15) was also depicted regarding VCSS improvement. EVLA resulted in an increased risk of postoperative paresthesia compared with MOCA [risk ratio (RR), 9.61; 95% CI, 2.32-62.29], cyanoacrylate ablation (RR, 7.90; 95% CI, 2.44-38.16), and RFA (RR, 6.96; 95% CI, 2.31-28.04). Although the overall analysis identified nonstatistical significant differences for AVVQ score improvement, thrombophlebitis, ecchymosis, and pain, further investigation revealed an increased pain profile for EVLA at 1,470 nm compared with RFA (MD, 3.22; 95% CI, 0.93-5.47) and cyanoacrylate ablation (MD, 3.04; 95% CI, 1.05-4.97). A sensitivity analysis displayed a persistent underperformance of MOCA compared with RFA (OR, 4.33; 95% CI, 1.15-55.54) for GSV closure and both RFA (MD, 0.99; 95% CI, 0.22-1.77) and cyanoacrylate ablation (MD, 0.84; 95% CI, 0.08-1.65) regarding VCSS improvement. Although no regression model reached statistical significance, the GSV closure regression model revealed a trend for considerably decreased efficacy for both cyanoacrylate ablation and MOCA, with larger GSV diameters compared with RFA and EVLA. The authors concluded that the results of the study raised doubts on the mid-term effectiveness of MOCA for improving VCSS and achieving GSV closure rates. However, cyanoacrylate ablation demonstrated comparable results for both RFA and EVLA. Moreover, cyanoacrylate ablation was associated with a lower risk of postprocedural paresthesia, pigmentation, and induration than EVLA, and both RFA and cyanoacrylate ablation had a better pain profile than EVLA. The authors noted that nonthermal,

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nontumescent ablation methods for the treatment of large GSVs warrant further investigation. Limitations include the heterogeneity of the studies and limited long-term data.

Lim et al. (2023) conducted a meta-analysis to compare outcomes from RCTs regarding MOCA vs endovenous thermal ablation (EVTA) in the treatment of adult individuals with symptomatic or complicated superficial venous incompetence of CEAP (Clinical, Etiology, Anatomy, Pathophysiology) classes 2 to 6. The occlusion rate, QOL, procedural and postprocedural pain, and the rates of venous thromboembolism were the outcomes assessed. Four RCTs were included in the meta-analysis, comprising 654 individuals. The anatomical occlusion rate at 1 year was lower after MOCA than after EVTA (RR, 0.85; 95% CI, 0.78-0.91; p < 0.001). No significant differences were detected in procedural pain (MD, -3.25; -14.25 to 7.74; p = 0.560) or postprocedural pain (MD, -0.63; -2.15 to 0.89; p = 0.420). There were no significant differences in AVVQ score at 1 year (MD, 0.06; -0.50 to 0.62; p = 0.830) or in the incidence of venous thromboembolism (RR, 0.72; 95% CI, 0.14-3.61; p = 0.690). The authors concluded that there was no difference in procedural and postprocedural pain between the interventions but that the success rate of occlusion after MOCA was significantly lower than that after EVTA. Additionally, the authors noted that this study supports existing international guidelines, which advocate EVTA as the preferred first-line treatment for superficial venous incompetence in the majority of individuals. The authors stated that additional long-term studies are needed to evaluate the impact of the reduced vein occlusion rate on QOL and reinterventions. Mohamed et al. (2021), previously cited in this policy, is included in this review.

A systematic review and meta-analysis consisting of eight RCTs was conducted by Shahzad et al. (2023), who compared the technical success, complications, and QOL after thermal vs nonthermal EVLA for the treatment of superficial venous incompetence. The vein occlusion rate up to 4 weeks and 1 to 2 years from the procedure was the primary outcome. Periprocedural pain, nerve injury, endothermal heat-induced thrombosis, and QOL were the secondary outcomes measured. The study comprised a total of 1,956 individuals; EVTA was received by 1,042 individuals, and 915 underwent endovenous nonthermal ablation. There was no statistically significant difference in occlusion rate at all time points. The relative risk at 4 weeks and 1 to 2 years was 0.99 and 0.95, respectively. Nonthermal ablation was tolerated better and had less risk of nerve injury. There was no statistically significant difference in the risk of endothermal heat-induced thrombosis. There was improvement in QOL scores post procedure, but there was no statistically significant difference in thermal vs nonthermal ablation. The quality of evidence assessed using GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology showed high quality for occlusion rate at 4 weeks and 1 to 2 years; moderate quality for nerve injury and periprocedural pain; and low quality for endothermal heat-induced thrombosis. The authors concluded that there was no statistically significant difference in vein occlusion rates between thermal and glue ablation of truncal varicose veins; QOL after both thermal and nonthermal endovenous ablation was similar, and nonthermal endovenous ablation resulted in less pain and less risk of nerve injury. However, the occlusion rate using MOCA, considered in isolation, was statistically significantly worse than that with thermal ablation. Limitations include failure to explore the impact of stab phlebectomies and compression therapy to endovenous ablation; the lack of information on differences in heat energy and laser wavelengths used in trials; and individual modalities within each group that were not separately evaluated. Bootun et al. (2016), Holewijn et al. (2019), Mohamed et al. (2021), and Vähäaho et al. (2019), previously cited in this policy, are included in this review.

Belramman et al. (2022) conducted a multicenter RCT that compared MOCA with cyanoacrylate adhesive for treating varicose veins, focusing on postprocedure pain scores following truncal ablation. The study included participants with primary great or small saphenous varicose veins; those with recurrent varicose veins, active deep venous thrombosis, or significant arterial disease were excluded. A total of 392 participants were screened for the study, with 225 excluded and 167 randomized to receive either MOCA or cyanoacrylate adhesive for primary truncal vein incompetence. Four participants did not undergo the assigned intervention but were included in the intention-to-treat analysis. Follow-up assessments occurred at 2 weeks and at 3, 6, and 12 months. Among the 167 participants, 99 (59.3%) were women, and the mean age was 56 years (SD, 15.8 years). Of the treated truncal veins, 92.8% were GSVs, and baseline characteristics were similar across treatment groups. Nearly half of the participants (47%) received adjunctive varicosity treatment. The overall median maximum pain score after truncal ablation was 23 mm [interquartile range (IQR), 10-44 mm] on the visual analog scale (VAS) and 3 (IQR, 2-5) on the numeric scale, with no significant difference between the MOCA and cyanoacrylate adhesive injection (CAE) groups (VAS: 24 mm vs 20 mm; p = 0.23; numeric scale: 4 vs 3; p = 0.18). Both interventions resulted in significant and comparable improvements in clinical severity, QOL measures, and complete vein occlusion rates. Minor complications occurred in four CAE-treated participants, including superficial thrombophlebitis and thrombus extensions. The authors concluded that both MOCA and CAE demonstrated similar periprocedural pain outcomes. They emphasized the need for further well-designed, randomized trials, with extended follow-up, to evaluate the long-term efficacy of nonthermal, nontumescent techniques for treating saphenous vein reflux. The study's limitations include the inability to blind interventions due to differing device techniques, although this was partially addressed through blinded follow-up assessments. Additionally, the COVID-19 pandemic led to a 41% loss to follow-up (70 participants) by 12 months. However, dropout rates were similar across groups, and this limitation was mitigated by using an intention-to-treat analysis, with primary outcomes recorded at baseline.

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A Hayes Health Technology Assessment stated that MOCA with the ClariVein infusion catheter appears safe and effective over the short term but that the low-quality body of evidence does not allow conclusions to be drawn regarding the long-term durability of the procedure. The report stated that MOCA resulted in slightly poorer technical outcomes and higher rates of recanalization than thermal ablation and surgical procedures. The report recommended future well-designed trials, with larger sample sizes, that compare MOCA using the ClariVein infusion catheter with clinical alternatives, with long-term follow-up. The updated annual review included two newly published studies, but no change in the current rating was recommended (Hayes, 2022; updated 2025).

In an updated Cochrane review, Whing et al. (2021) compared interventions for treating varicosities of the GSV. The review included 24 RCTs, with 5,135 individuals who underwent EVLA, RFA, endovenous steam ablation, ultrasound-guided foam sclerotherapy (UGFS), cyanoacrylate glue, MOCA, or high ligation and stripping. The authors found that there was no clear difference in technical success or recurrence between RFA compared with MOCA; however, long-term data were not available, and the CIs of the combined data were broad, making these findings largely inconclusive. Additionally, the authors noted that all the trials had some risk-of-bias concerns. The authors determined that there was a relatively small number of studies for comparison, and the differences in outcome definitions and time points reported limited their conclusions. Future studies that provide more evidence on the breadth of treatments were recommended by the authors. Bootun et al. (2016), Lane et al. (2017), Holewijn et al. (2019), and Vähäaho et al. (2019), previously cited in this policy, are included in this review.

Kim et al. (2017) evaluated, in a case series, whether early efficacy in endovenous MOCA is maintained at 24 months. Individuals with reflux in the GSV involving the saphenofemoral junction and no previous venous interventions were included. The occlusion rate of treated veins was assessed with duplex ultrasound. Individual clinical improvement was assessed by CEAP class and VCSS. Of the initial 126 individuals, there were 65 individuals with 24-month follow-up. Of these 65 individuals, 70% were female, with a mean age of 70 ±14 years and an average body mass index of 30.5 ±6 kg/m^2. The mean GSV diameter in the upper thigh was 7.6 mm, and the mean treatment length was 39 cm. Adjunctive treatment of the varicosities was performed in 14% of individuals during the procedure. Closure rates were 100% at 1 week, 98% at 3 months, 95% at 12 months, and 92% at 24 months. There was one individual with complete and four with partial recanalization, ranging from 7 to 12 cm (mean length, 9 cm). There was significant improvement in CEAP and VCSS ($p < 0.001$) for all time intervals. An early high occlusion rate with MOCA was associated with significant clinical improvement, which was maintained at 24 months. According to the authors, this finding is suggestive of a good option for the treatment of GSV incompetence. Longer-term outcomes are needed to evaluate MOCA's efficacy. The study is limited by the lack of a comparison group and large loss to follow-up.

Vos et al. (2017) conducted a systematic review and meta-analysis to evaluate the efficacy of MOCA and cyanoacrylate vein ablation (CAVA) for GSV incompetence. Eligible articles were prospective studies that included individuals treated for GSV incompetence and described the primary outcome. The exclusion criteria were full text not being available, case reports, retrospective studies, small series ($n < 10$), reviews, abstracts, animal studies, and studies of small saphenous vein (SSV) incompetence or recurrent GSV incompetence. The primary outcome was anatomical success. The secondary outcomes were initial technical success, VCSS, AVVQ score, and complications. Fifteen articles met the inclusion criteria. The pooled anatomical success for MOCA and CAVA was 94.7% and 94.8% at 6 months and 94.1% and 89.0% at 1 year, respectively. VCSS and AVVQ score significantly improved after treatment with MOCA and CAVA. The authors concluded that both of these nonthermal techniques are promising and could serve as alternatives for thermal ablation techniques. However, to determine the exact role of MOCA and CAVA in clinical practice, high-quality RCTs comparing these novel modalities with well-established techniques are required. This study is limited by the inclusion of mostly uncontrolled studies to assess the efficacy and safety of MOCA. Elias and Raines (2012) and Bishawi et al. (2014), previously cited in this policy, are included in this meta-analysis.

Witte et al. (2017a) conducted a systematic review and meta-analysis of MOCA of the saphenous veins using ClariVein to report on the anatomical, technical, and clinical success. The literature search identified 759 records, of which 13 were included, describing 10 unique cohorts. A total of 1,521 veins (1,267 GSVs and 254 SSVs) were included, with cohort sizes ranging from 30 to 570 veins. The pooled anatomical success rate after short-term follow-up was 92% (95% CI, 90%-94%; n = 1,314 veins). After 6 and 12 months, these numbers were 92% (95% CI, 88%-95%; n = 284) and 91% (95% CI, 86%-94%; n = 228), respectively. The long-term anatomical success rates at 2 and 3 years were 91% (95% CI, 85%-95%; n = 136) and 87% (95% CI, 75%-94%; n = 48), respectively. Major complications and especially nerve injury were very rare (≤ 0.2%). All studies were of moderate or good quality using the Methodological Index for Nonrandomized Studies scoring scale. The authors concluded that MOCA using ClariVein, in combination with liquid sclerosant, is associated with an anatomical success rate ranging from 87% to 92% and good clinical success. However, they reported that no RCTs are available that study the anatomical success after MOCA compared with endothermal ablation.

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Witte et al. (2017b) reported the mid-term results of MOCA for treating GSV insufficiency. In a 1-year period, 85 consecutive individuals undergoing MOCA with polidocanol in 104 limbs were enrolled in a prospective registry. The individuals were evaluated at baseline and during follow-up (4 weeks and 1, 2, and 3 years) using duplex ultrasound, the CEAP classification, VCSS, the RAND Short Form 36-Item Health Survey, and the AVVQ. The primary outcome measures were clinical and anatomical success. The secondary outcome measures included general and disease-specific QOL and reinterventions. After a median follow-up of 36 months (IQR, 12.5-46.3 months), recanalization occurred in 15 of 102 (15%) successfully treated vein segments. Anatomical success was 92%, 90%, and 87% after 1, 2, and 3 years, respectively. The VCSS improved at all time intervals compared with the preprocedural median. The clinical success at 3 years was 83%. AVVQ and RAND Short Form 36-Item Health Survey scores showed an improvement at all time intervals compared with baseline values. However, between 12 and 36 months, a significant deterioration was observed in VCSS, which was accompanied by worsening of disease-specific and general QOL. Although the authors concluded that MOCA was shown to be an effective treatment modality for GSV insufficiency at the mid-term follow-up, clinical results seemed to drop over time. Additionally, these findings are limited by the lack of a comparison group undergoing a different treatment.

In a pilot study, van Eekeren et al. (2011) evaluated the feasibility and safety of endovenous MOCA for the treatment of GSV incompetence. Overall, 30 limbs in 25 individuals (18 women; mean age, 52 years) with GSV incompetence were treated with the ClariVein device. Initial technical success, complications, individuals' satisfaction, and classification by VCSS were assessed 6 weeks after the treatment. The initial technical success of MOCA was 100%. There were no major adverse events. Duplex ultrasonography at 6 weeks showed that 26 of 30 veins (87%) were completely occluded. Three veins showed partial recanalization in the proximal and distal GSV. One individual had full-segment recanalization and was successfully retreated. The VCSS significantly improved at 6 weeks. Individuals' satisfaction was high, with a median satisfaction of 8.8 on a 0-to-10 scale. The authors concluded that endovenous MOCA is feasible and safe in the treatment of GSV incompetence. Larger studies, with prolonged follow-up, are indicated to prove the efficacy of this technique. This study is limited by the lack of a comparison group undergoing a different treatment approach.

Endovenous Foam Sclerotherapy for Incompetent Perforator Veins

Evidence in peer-reviewed literature evaluating endovenous foam sclerotherapy for the treatment of perforator veins is limited and does not support a benefit compared with established therapies. Future robust RCTs are warranted, along with long-term outcomes, to establish the safety and efficacy of this procedure.

Hager et al. (2016) performed 296 perforator ablations in 112 individuals with advanced chronic venous insufficiency, comparing EVLA, RFA, and UGFS. The study concluded that RFA was the most reliable means of perforator closure and was significantly better than UGFS. The 2022 systematic review supporting the Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society guidelines on the management of varicose veins by Farah et al. did not address the role of perforator incompetence in individuals with venous ulcers. Lloret et al. (2015) conducted an observational cohort study to evaluate wound healing rates and recurrence rates in 180 individuals with venous leg ulcers treated with UGFS. Overall, 48 of the individuals had mixed GSV and perforator reflux, and 38 had isolated perforator reflux. The authors found that UGFS of superficial and perforator incompetent veins was well tolerated and an effective outpatient procedure, with a high healing rate and low mid-term recurrence rate. The study was limited by a small perforator vein sample size, short-term follow-up, and lack of a comparison group.

Endovenous Ablation of Recurrent or Residual Perforator Vein Following a Prior Vein Procedure

Evidence for the use of endovenous ablation to treat recurrent or residual perforator veins after a prior vein procedure is insufficient and limited, and its current clinical role remains uncertain, based on the existing peer-reviewed literature. Additional well-designed, long-term RCTs, along with comprehensive long-term outcome data, are needed to clearly determine the safety and efficacy of this procedure.

A systematic review by Farah et al. (2022) found that evidence supporting intervention in incompetent perforator veins in early chronic venous insufficiency (CEAP 2-3) is limited and inconsistent, yet many vascular laboratories routinely evaluate perforators during comprehensive duplex ultrasound examinations, which can prompt consideration of treatment when incompetence is identified. The review noted that perforator procedures are often performed in individuals with uncomplicated CEAP 2 varicose veins, either at the time of truncal ablation or afterward, based on the assumption that perforator incompetence contributes to persistent symptoms. Two randomized studies reported no significant differences in pain, mobility, or QOL outcomes between individuals who underwent perforator closure and those who did not, and an additional study found that residual below-knee reflux following saphenous ablation is not associated with perforator incompetence. According to the authors, current evidence provides minimal support for treating incompetent perforator veins in CEAP 2 disease, and no studies have specifically evaluated how these veins change following saphenous vein

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ablation. Study limitations include a high risk of bias in several included studies and a limited number of studies available to address each key question.

Ho et al. (2022) conducted a systematic review and meta-analysis that evaluated the safety and effectiveness of multiple treatments for incompetent perforator veins, including open ligation, subfascial endoscopic perforator surgery (SEPS), EVLA, ultrasound-guided sclerotherapy, and RFA. The review included English-language full-text studies reporting primary safety or efficacy data in adults with chronic venous insufficiency of incompetent perforator veins, excluding studies on pregnant or pediatric individuals as well as non–data-driven publications. A total of 81 studies met the criteria, representing 7,010 individuals, who had a mean age of 54.7 years and a CEAP score averaging 4.9; there was a slight female predominance. Most studies had single-arm observational designs, and the overall evidence quality ranged from low to intermediate, with a moderate to high risk of bias in comparative studies. Complications occurred in 11.3% of cases, with no reports of stroke or air embolism. Short-term efficacy outcomes showed high pooled wound-healing rates of 99.9% for ultrasound-guided sclerotherapy, 96.0% for SEPS, and 72.2% for open ligation, while SEPS demonstrated a 91.0% short-term freedom-from-recurrence rate. The authors emphasized that current evidence for treating incompetent perforator veins remains weak, largely because observational studies lack consistent reporting standards and comparative studies do not incorporate key methodological safeguards such as randomization, blinding, or allocation concealment. They concluded that more rigorous, well-designed, comparative research is needed to better inform clinical decision-making regarding invasive treatment options for incompetent perforator veins. The meta-analysis is limited by significant heterogeneity from the studies, which spanned 3 decades; inconsistent reporting of individuals' comorbidities; prior venous procedures that could not be analyzed; and an overall reliance on low-quality observational data, with notable bias in comparative studies.

Additionally, the clinical practice guidelines addressed below (Gloviczki et al., 2022; Gloviczki et al., 2023) note that for individuals with perforator-related varicosities and no saphenous involvement, either open or endovascular methods may be used, but the evidence base is minimal. They also emphasized that there is little to no randomized data to support a preferred perforator vein treatment in recurrent or persistent C2 disease. As a result, treating an incompetent perforator in these individuals should depend on clinician judgment, individuals' preferences, and available techniques. For those with C2 varicose veins who continue to have persistent or recurrent symptoms after previous complete ablation of incompetent superficial truncal veins, treatment of an incompetent perforator is suggested when it is identified as the source of symptomatic tributaries. This recommendation is considered weak (grade 2), and the quality of evidence is low to very low (grade C). Masuda et al. (2020) reported that the evidence for perforator vein treatment is inconsistent, making its benefits uncertain across many populations of individuals. While limited data support treating perforators in advanced chronic venous insufficiency (CEAP C5-C6), there is little evidence of benefit for earlier stages such as C4a and C4b. Edema related to venous disease is rarely caused solely by incompetent perforators, and treating these veins typically does not significantly improve swelling. Furthermore, perforator interventions for telangiectasia or varicose veins in symptomatic CEAP 1 to 2 individuals, particularly when veins show high outward flow or increased diameter, are considered rarely appropriate due to minimal demonstrated clinical benefit.

VenoValve

Evidence in peer-reviewed literature evaluating the VenoValve porcine bioprosthetic valve for the treatment of chronic venous insufficiency is limited. Future robust RCTs are warranted, along with long-term outcomes, to establish the safety and efficacy of this procedure.

Ochoa Chaar et al. (2026) conducted a prospective, single-arm, multicenter study that involved 75 adults with advanced deep chronic venous insufficiency who underwent VenoValve implantation. Eligible participants were ambulatory, aged 18 years or older, had CEAP C4b to C6 disease, had axial reflux of ≥ 1 second at the popliteal vein, had deep valvular incompetence on duplex ultrasound, and had not responded to at least 3 months of standard care. VenoValve implantation was successful in 73 participants; two could not receive the device due to femoral vein scarring. At 6 months, 34.3% of participants achieved at least a 30% improvement in reflux time. Revised VCSS scores showed significant and clinically meaningful improvement at 3, 6, and 12 months, with 84.6% of participants improving by an average of 7.9 points at 1 year. Pain and QOL measures also improved significantly through 12 months. Among C6 participants, 91.6% of ulcers lasting less than 12 months healed. No unexpected device-related adverse events occurred. The perioperative major adverse event rate was 30.7%, with no mortality, and most affected participants still experienced meaningful symptom improvement. The authors concluded that implanting the bioprosthetic venous valve provided significant clinical improvements and enhanced QOL in those with severe chronic venous insufficiency. Limitations include the lack of a control group, small patient population, and limited long-term data.

A 2022 Hayes Emerging Technology Report stated that published evidence is limited to publications reporting 6-month and 1-year outcomes in 11 individuals. The VenoValve will be the first porcine bioprosthetic valve to reach the market in the U.S. and the first device approved to treat chronic venous insufficiency, if it is eventually U.S. Food and Drug

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Administration approved. The VenoValve is currently under investigation in the SAVVE (Surgical Antireflux Venous Valve Endoprosthesis) trial (NCT04943172). The updated 2025 Hayes report stated that the U.S. Food and Drug Administration issued a "not approvable" letter in response to the premarket approval application submitted for VenoValve for the treatment of severe deep chronic venous insufficiency.

Ulloa and Glickman (2021) conducted a single-center, prospective, nonrandomized, first-in-human trial using a prosthetic venous valve, VenoValve, in participants with severe chronic venous insufficiency (C4b-C6 disease). Ten participants had the prosthetic valve surgically implanted into the femoral vein. Follow-up examinations were conducted post operation at 2 and 14 days and then every 30 days for 6 months to evaluate the feasibility, initial safety, and performance outcomes of the VenoValve. Six participants had required bovine patch angioplasty of the vein. Four adverse events occurred, including one case of hematoma at the incision site that was aspirated; two cases of superficial wound infection in C6 participants treated with antibiotics; and one case of a bleeding complication due to warfarin anticoagulation. One participant's VenoValve had thrombosed at 5 months due to nontherapeutic anticoagulation. Improvements in all five participants who had reached the 6-month follow-up mark with the VenoValve were demonstrated during the study period by decreases in VCSS (61% decrease from baseline), VAS for pain scores (57% decrease), and reflux time (40% decrease) and a statistically significant improvement in the VEINES-QOL/Sym questionnaire. The participant with the occluded VenoValve had experienced improvements in all areas, except for the reflux time. The authors concluded that VenoValve showed promising results, with improvements noted in QOL and clinical outcomes. The authors recommended further follow-up and larger studies in the future. In 2022, Ulloa and Glickman reported promising 1-year postimplantation results. Adverse events included one hematoma, three superficial wound infections, and one bleeding complication due to overanticoagulation. One VenoValve became occluded due to participant nonadherence with anticoagulation medication. One-year clinical outcomes included significant decreases in mean reflux times (54%) and significant improvements in mean disease severity Revised VCSS (56%), mean VAS pain scores (76%), and VEINES-QOL/Sym scores. Ulloa et al. (2023) reported on 2-year follow-up results and aimed to evaluate the long-term clinical safety in and performance of the 11 participants who were implanted with the VenoValve into the mid-thigh femoral vein. All 11 implant procedures were successful. Two-year follow-up data were obtained for eight participants; one participant died of non–device-related causes, one was lost to follow-up, and one refused to follow up due to the COVID-19 pandemic. No device-related adverse events occurred between the first and second years of follow-up. The reported 2-year clinical performance outcomes included significant decreases in mean reflux times of the mid-popliteal vein (61%) and significant improvements in mean scores for disease severity Revised VCSS (56%) and VAS pain (87%). The authors surmised that the long-term safety and performance of the VenoValve was sustained, as the participants obtained wound healing without ulcer recurrence. Additionally, there were significant improvements in reflux time, disease severity, and pain scores and diagnoses that were reclassified from severe to mild disease. The authors endorsed continued long-term follow-up and future larger, multicenter studies and noted that the clinical trial NCT04943172 is currently underway. Cifuentes et al. (2026) reported that at the 3-year follow-up, the VenoValve maintained a primary patency rate of 79%, with reflux times reduced by 62%, the Revised VCSS improving by seven points (52%), and pain levels decreasing by 84% on the VAS. Two cases of valve thrombosis occurred, one at 3 months and another at 3 years post implantation, both after discontinuation of anticoagulation therapy. No serious device-related adverse events were observed. The authors concluded that VenoValve implantation demonstrated mid-term safety and effectiveness in restoring deep venous competence in those with refractory postthrombotic syndrome, providing sustained improvement for 3 years.

Clinical Practice Guidelines

American Vein and Lymphatic Society (AVLS)

Blebea et al. (2025) assembled an expert panel for the AVLS to develop a position statement outlining recommendations for the appropriate use of MOCA in treating venous insufficiency. This document provides detailed recommendations regarding patient selection, procedural techniques, outcome evaluation, and potential complications. The statement concludes that MOCA is a safe and effective treatment option that alleviates symptoms while eliminating the need for tumescent anesthesia. It offers reduced procedural discomfort and minimizes the risk of thermal injury to nerves or skin, making it suitable for treating both below-knee segments of the GSV and the SSV. However, MOCA demonstrates lower vein closure rates and higher recanalization rates than thermal techniques such as RFA and EVLA. According to the authors, MOCA is best considered for those who are not candidates for thermal ablation.

European Society for Vascular Surgery (ESVS)

The ESVS released a guideline for the management of chronic venous disease (De Maeseneer et al., 2022). The guideline states that for patients with chronic venous disease requiring treatment of incompetent perforating veins, endovenous ablation, division, or ligation should be considered. Class of recommendation: IIa; level of evidence: C.

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National Institute for Health and Care Excellence (NICE)

In an updated guideline on endovenous MOCA for varicose veins, NICE (2016) states that the current evidence on the safety and efficacy of endovenous MOCA for varicose veins appears adequate to support the use of this procedure, provided that standard arrangements are in place for consent, audit, and clinical governance. Clinicians are encouraged to collect longer-term follow-up data.

Society for Vascular Surgery (SVS)/American Venous Forum (AVF)/American Vein and Lymphatic Society (AVLS)/Society of Interventional Radiology (SIR)

Gloviczki et al. (2023) published part II of the guidelines for the management of varicose veins of the lower extremities, which focuses on patients with compression, treatment with drugs and nutritional supplements, evaluation and treatment of varicose tributaries, superficial venous aneurysms, and the management of complicated varicose veins. Recommendations of the guideline are summarized as follows (not all inclusive):

- For patients with symptomatic telangiectasias and reticular veins, sclerotherapy with liquid or foam is recommended. Grade of recommendation: 1 (strong); quality of evidence: B (moderate).
- For the treatment of symptomatic varicose tributaries, miniphlebectomy or ultrasound-guided sclerotherapy using physician-compounded foam or polidocanol endovenous microfoam is recommended. Grade of recommendation: 1 (strong); quality of evidence: B (moderate).
- For patients with incompetent pathological perforators associated with symptomatic residual, recurrent, and rarely primary varicosities, without associated saphenous incompetence, either open or endovascular techniques can be used to treat the perforator veins. Consensus statement.

The SVS, AVF, and AVLS collaborated to update the 2011 SVS/AVF guideline to provide evidence-based recommendations for treating patients with varicose veins of the lower limbs (Gloviczki et al., 2022). Recommendations of the guideline are summarized as follows (not all inclusive):

- For patients with varicose veins (C2) and persistent or recurrent symptoms after previous complete ablation of incompetent superficial truncal veins, treatment of incompetent perforator veins, if they are the origin of symptomatic varicose tributaries, is suggested. Level of recommendation: grade 2 (weak); quality of evidence: C (low to very low).

The SVS, AVF, AVLS, and SIR developed the Appropriate Use Criteria for chronic lower extremity venous disease using the RAND/UCLA Appropriateness Method, incorporating best-available evidence with expert opinion and engaging a panel of experts in the field through a modified Delphi exercise (Masuda et al., 2020). The authors noted that treatment of nontruncal varicose veins, with or without telangiectasia, by sclerotherapy, ambulatory phlebectomy, or powered phlebectomy in a patient with symptomatic varicose veins, edema due to venous disease, skin or subcutaneous changes, or healed or active ulcers (CEAP classes 2-6) is considered appropriate.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Vein ligation surgery is a procedure and therefore not subject to FDA regulation.

The ClariVein infusion catheter (Vascular Insights) received FDA approval (K071468) on March 20, 2008. The device is designed to introduce physician-specified medicaments into the peripheral vasculature. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071468.pdf. (Accessed December 17, 2025)

The FDA has approved various sclerosing agents to treat varicose veins of the lower extremities. The two most commonly used include sodium tetradecyl sulfate and polidocanol. Asclera (polidocanol) is a sclerosing agent approved by the FDA in March 2010 and is indicated to treat small spider veins and uncomplicated reticular veins (varicose veins of 1-3 mm in diameter) in the lower extremity. It has not been studied in varicose veins larger than 3 mm in diameter. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. (Accessed December 17, 2025)

Varithena (polidocanol injectable foam; Provensis Ltd.) received FDA approval on November 25, 2013, as a sclerosing agent indicated for the treatment of incompetent great saphenous veins (GSVs), accessory saphenous veins, and visible varicosities of the GSV system above and below the knee. Refer to the following websites for more information:

- https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/205098Orig1s000ltr.pdf
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/205098s000lbl.pdf

(Accessed December 17, 2025)

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The VenaSeal Closure System received the FDA's premarket approval on February 20, 2015 (P140018). The device is indicated for the permanent closure of lower extremity superficial truncal veins, such as the GSV, through endovascular embolization with coaptation. VenaSeal is intended for use in adults with clinically symptomatic venous reflux, as diagnosed by duplex ultrasound. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id = P140018. (Accessed December 17, 2025)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2026	**Coverage Rationale** • Revised language to indicate: ***Thermal and Nonthermal Treatments for Venous Insufficiency and Varicose Veins*** ○ Endovenous Ablation of the lower extremity superficial truncal or perforator veins for the treatment of Venous Insufficiency and Varicose Veins is reconstructive and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Procedures, Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein (Custom) – UHG ○ The following procedures for the treatment of Venous Insufficiency and Varicose Veins are considered unproven and not medically necessary due to insufficient evidence of efficacy: ▪ Endovenous mechanochemical ablation (MOCA) ▪ Endovenous Ablation of incompetent perforator veins using endovenous foam Sclerotherapy (e.g., noncompounded foam sclerosant) ▪ Endovenous Ablation of recurrent or residual perforator vein following a prior vein procedure ***Ligation Procedures*** ○ Ligation and division, with or without stripping or excision of lower extremity Superficial Veins, is reconstructive and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein ***Other Procedures*** • Removed language indicating endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0447RR

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