Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only)

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Ü Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

Ü See Benefit Considerations

Varicose Vein Ablative and Stripping Procedures

Varicose Vein ablative and Stripping procedures are considered reconstructive, proven, and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein
- Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein

Click here to view the InterQual® criteria.

Ligation Procedures

The following procedure is proven and medically necessary:

- Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are intolerant of anticoagulation therapy

The following procedure is proven and medically necessary in certain circumstances:

- Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Subfascial Endoscopic Perforator Surgery (SEPS).

Click here to view the InterQual® criteria.

The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy:

- Ligation of the Great Saphenous Vein (GSV) at the saphenofemoral junction, as a stand-alone procedure
- Ligation of the Small Saphenous Vein (SSV) at the saphenopopliteal junction, as a stand-alone procedure
- Ligation of the accessory veins, as a stand-alone procedure
- Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins

Ambulatory Phlebectomy

Ambulatory phlebectomy for treating Varicose Veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Phlebectomy, Lower Extremity Superficial Tributary Varicose Vein.

Click here to view the InterQual® criteria.

Other Procedures

Sclerotherapy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:
- Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein
- Sclerotherapy, Lower Extremity Superficial Tributary Varicose Vein

Click here to view the InterQual® criteria.

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

Definitions

Refer to the federal, state, or contractual definitions that supersede the definitions below.

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

Great Saphenous Vein (GSV): A long vein that can be seen just in front of the anklebone. This vein travels along the inside of the leg and thigh (about one-half inch beneath the skin in the thigh) until it empties into the deep vein called the common femoral vein in the groin (American Vein & Lymphatic Society (AVLS), 2023).

Ligation: Tying off a vein (AVLS, 2023).

Reticular Vein: A network of veins parallel to the skin surface and lying between the saphenous fascia and dermis. These veins communicate with either saphenous tributaries or the deep veins through perforators (Meissner, 2005).

Small Saphenous Vein: (SSV) A superficial vein that starts at the outside of the foot and travels up the back of the calf where it empties into the deep vein (popliteal vein) in the crease of the knee (AVLS, 2023).

Spider Vein: Spider Veins/ Telangiectasias are dilated small superficial veins measuring less than 1.0 mm in diameter and occurring predominantly in the lower extremities (Nukano, 2021).

Superficial Thrombophlebitis: Inflammation of a vein due to a blood clot in a vein just below the skin's surface (AVLS,2023).

Varicose Veins: Varicose Veins are dilated subcutaneous tributaries ≥ 3 mm in diameter and patients with Varicose Veins belong to clinical stage, etiology, anatomy, pathology (CEAP) Class C2 (Gloviczki, 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 sec
- Superficial veins: 0.5 sec

- Perforator veins: 0.5 sec

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 federal, state, or contractual requirements 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 Clarification:

- According to the American Medical Association (AMA), CPT code 37241 is specific to venous embolization/occlusion and excludes lower extremity venous incompetency. Coding instructions state that 37241 should not be used to request treatment of incompetent extremity veins. For sclerosis of veins or Endovenous Ablation of incompetent extremity veins, refer to 36468-36479 (CPT Assistant, 2014).
- Adherence to AMA coding guidance is required when requesting Endovenous Ablation procedures.

Per AMA coding guidance, the initial incompetent vein treated (e.g., CPT code 36475) may only be requested once per extremity. For Endovenous Ablation, 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.

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)

CPT Code	Description
*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)
*37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
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
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
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
37799	Unlisted procedure, vascular surgery

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

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 are commonly found on the backs of the calves or on the inside of the leg. Veins have one-way valves that help keep blood flowing towards 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 Venous Insufficiency or Venous Reflux. Varicose Veins may lead to complications such as pain, blood clots or skin ulcers.

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: Telangiectasias (Spider Veins) or Reticular Veins
- C2: Varicose Veins (diameter of vein is > 3mm)
- 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 {AVF}, 2020]

Venous clinical severity scoring has been used to measure clinical improvement after treatment of Varicose Veins. Other venous severity scoring methods include Venous Severity Score, Venous Clinical Severity Score, Venous Segmental Disease Score [Lurie et al. (AVF), 2020].

Preoperative venous duplex ultrasound is used to evaluate patients for Venous Insufficiency symptoms or suspected DVT; 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. Vein Stripping and Ligation involves tying shut and removing the veins through small cuts in the skin [National Heart, Lung and Blood Institute (NHLBI), 2014].

Endomechanical ablation uses a specialized, rotating catheter (e.g., ClariVein) to close off a Varicose Vein by damaging the vessel lining prior to injecting a sclerosing agent. This technique is also referred to as mechanochemical ablation (MOCA), mechanochemical Endovenous Ablation (MCEA) and mechanically enhanced endovenous chemical ablation (MEECA).

Endovascular embolization using cyanoacrylate-based adhesive (e.g., VenaSeal™ Closure System) is a minimally invasive, non-thermal and non-sclerosant procedure that does not require tumescent anesthesia. The medical adhesive is used to close the lower extremity superficial truncal veins, such as the Great Saphenous Vein, in individuals with symptomatic Venous Reflux disease.

Endovascular embolization using endovenous foam sclerotherapy with polidocanol endovenous microfoam (PEM) [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 (IV) 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 of Health and Care Excellence (NICE), 2013].

Benefit Considerations

Coverage Limitations and Exclusions

The following procedures are excluded from coverage:

- 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.

Clinical Evidence

VenoValve

Evidence in peer review literature evaluating 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.

A 2022 Hayes Emerging Technology Report states published evidence is limited to publications reporting 6-month and 1-year outcomes for 11 patients. The VenoValve will be the first porcine bioprosthetic valve to reach the market in the U.S., and the first device approved to treat CVI, if eventually FDA-approved. VenoValve is currently under investigation in the Surgical Anti-Reflux Venous Valve Endoprosthesis (SAVVE) trial (NCT04943172).

Ulloa and Glickman (2021) conducted a single-center, prospective, non-randomized, first-in-human trial using a prosthetic venous valve, VenoValve, for patients with severe chronic venous insufficiency (C4b-C6 disease). Ten patients had the prosthetic valve surgically implanted into the femoral vein. Follow-up examinations were conducted postoperatively at two and 14 days and then every 30 days for six months to evaluate feasibility, initial safety, and performance outcomes of the VenoValve. Six patients 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 patients treated with antibiotics, and one case of a bleeding complication due to warfarin anticoagulation. One patient's VenoValve had thrombosed at five months due to nontherapeutic anticoagulation. Improvements in all five patients who had reached the 6-month follow-up mark with the VenoValve were demonstrated during the study period by decreases in the VCSS (61% decrease from baseline), visual analog scale for pain scores (57% decrease), and reflux time (40% decrease) and a statistically significant improvement in the VEINES-QOL/Sym questionnaire. The patient 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.

Ulloa et al. (2023) reported on two-year follow-up results aimed to evaluate the long-term clinical safety and performance of the eleven patients who were implanted with the VenoValve into the midthigh femoral vein. All eleven implant procedures were successful. Two-year follow-up data was obtained for eight subjects: one patient 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. Reported two-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 rVCSS (56%) and VAS pain (87%). The authors surmised the long-term safety and performance of the VenoValve was sustained as the patients obtained wound healing without ulcer recurrence. Additionally, there were significant improvements in reflux time, disease severity, pain scores and patients diagnosis were reclassified from severe to mild disease. The authors endorse continued long-term follow-up, future larger, multi-center studies, and note the clinical trial NCT04943172 currently underway.

Clinical Practice Guidelines

American College of Phlebology

The American College of Phlebology Guidelines Committee (Gibson et al.,2017c) performed a systematic review of the literature regarding the clinical impact and treatment of incompetent accessory saphenous veins. They developed a consensus opinion that patients with symptomatic incompetence of the accessory great saphenous veins (anterior and posterior accessory saphenous veins) be treated with EVTA (laser or radiofrequency) or UGFS to eliminate symptomatology (Recommendation Grade 1C).

The American College of Phlebology Guidelines Committee (2016) updated their evidence-based recommendations for treatment of superficial venous disease of the lower leg. They recommend that named veins (GSV, SSV, AAGSV, posterior accessory of the great saphenous vein [PAGSV], intersaphenous vein [Vein of Giacomini]) must have a reflux time > 500 msec regardless of the reported vein diameter (Grade 1A).

EVTA (laser and radiofrequency) is the Committee's preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence (Grade 1B). They suggest mechanical/chemical ablation may also be used to treat truncal venous reflux (Grade 2B). They further comment that open surgery is appropriate in veins not amenable to endovenous procedures but otherwise is not recommended because of increased pain, convalescent time, and morbidity (Grade 1B).

European Society for Vascular Surgery (ESVS)

The ESVS released a clinical practice guideline for management of chronic venous disease (De Maeseneer et al., 2022). The guidelines state that for patients with GSV and SSV incompetence requiring treatment endovenous thermal ablation is recommended as the first-choice treatment, in preference to high ligation/stripping and UGFS. However, UGFS may be considered for treating saphenous trunks with a diameter less than 6mm. The guidelines note that in long term follow up of comparative studies, treatment with UGFS has been substantially less effective than EVLA, RFA, and surgery in terms of occlusion or absence rates. Additionally, foam sclerotherapy is the technique of choice for anatomical configurations that make endovenous cannulation or advancing the ablation device challenging, and is suitable for treating tortuous, recurrent varicose veins. Mechanochemical ablation and cyanoacrylate adhesive closure may be considered when a non-thermal technique is preferred for patients with GSV incompetence. For patients with GSV incompetence, high ligation/stripping should be considered, if endovenous thermal ablation options are not available. Endovenous non-thermal non tumescent ablation methods may be considered for treatment of SSV incompetence. Additionally, endovenous thermal ablation and UGFS may be considered for anterior accessory saphenous vein requiring treatment.

National Institute for Health and Care Excellence (NICE)

In 2020, the National Institute for Health and Care Excellence (NICE) released an update to their guidance on Cyanoacrylate Glue Occlusion for Varicose Veins. The updated guidance states that current evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit. In addition, the guideline states physicians should: 1) only perform the procedure after appropriate training and experience in the use of venous ultrasound; 2) discuss the available options with the patient before making a decision; and 3) follow their hospital's policies regarding performing procedures and monitoring results.

In an updated guideline on endovenous MOCA for varicose veins, NICE (2016) states that 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.

The NICE 2013 interventional procedure guidance on UGFS specifies that if symptoms related to varicose veins are severe, the main treatment options include endovenous laser treatment and radiofrequency ablation, and surgery (ligation and stripping of the GSVs or ligation with or without stripping of the SSVs, and phlebectomy). The NICE 2013 clinical guideline on the diagnosis and treatment of varicose veins adds that if endovenous ablation is unsuitable, offer UGFS.

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 on the management of complicated varicose veins. Recommendations of the guideline are summarized as follows (not all-inclusive):

- In symptomatic patients with C2 disease suggestion is made against using truncal vein diameter to determine which patients need venous ablation. Grade of recommendation, 2 (weak), quality of evidence, B (moderate).
- 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 treatment of symptomatic varicose tributaries, miniphlebectomy or ultrasound-guided sclerotherapy using physician-compounded foam (PCF) or PEM is recommended. Grade of recommendation, 1 (strong), quality of evidence, B (moderate).
- For patients with symptomatic reflux in the GSV or SSV and associated varicosities, ablation of the refluxing venous trunk and concomitant phlebectomy or UGFS of the varicosities with PCF or PEM is recommended. Grade of recommendation, 1 (strong), quality of evidence, C (low to very low).
- For patients with symptomatic reflux in the AAGSV or PAGSV, suggestion is made for simultaneous ablation of the refluxing venous trunk and phlebectomy or UGFS of the varicosities with PCF or PEM. Grade of recommendation, 2 (strong), quality of evidence, C (low to very low).
- For patients with varicose veins (CEAP class C2) who have significant, symptomatic axial reflux of the GSV or SSV, recommendation is made against treatment of incompetent perforating veins concomitant with initial ablation of the saphenous veins. Grade of recommendation, 1 (strong), quality of evidence, C (low to very low).
- For patients with varicose veins (CEAP class C2) who have significant, symptomatic axial reflux of the AAGSV or PAGSV, suggestion is made against treatment of incompetent perforating veins concomitant with initial ablation of the superficial truncal veins. Grade of recommendation, 2 (weak), quality of evidence, C (low to very low).

The SVS, AVF, and AVLS collaborated to update the 2011 SFS/AVF clinical practice 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 CVD of the lower extremities, duplex ultrasound scanning is the diagnostic test of choice for evaluation of venous reflux.
- Reflux is defined as a minimum value > 500 ms of reversed flow in the superficial truncal veins and the tibial, deep femoral, and perforating veins.
- Axial reflux is defined as uninterrupted retrograde venous flow from the groin to the calf, and junctional reflux is limited to the SFJ or SPJ.
- Use of the 2020 upgraded CEAP classification of chronic venous disorders is recommended.
- “Pathologic” perforating veins in patients with varicose veins (CEAP clinical class C2) includes those with an outward flow duration of ≥ 500 ms and a diameter of ≥ 3.5 mm on duplex ultrasound.
- For patients with symptomatic varicose veins and axial reflux in the GSV and SSV, treatment with endovenous ablation over high ligation and stripping is recommended due to less post procedure pain and morbidity, and an earlier return to regular activity; if the technology or expertise in endovenous ablation is not available or the venous anatomy precludes endovenous treatment, ligation and stripping is recommended.
- For patients with symptomatic varicose veins and axial reflux in the AAGSV or PAGSV, treatment with ligation and stripping of the accessory saphenous vein, with additional phlebectomy, if needed, if technology or expertise in endovenous ablations is not available or if the venous anatomy precludes endovenous treatment is suggested.
- For patients with symptomatic varicose veins and axial reflux in the GSV, SSV, who place a high priority on the long-term outcomes of treatment (QoL and recurrence), treatment with EVLA, RFA, or high ligation and stripping over physician compounded UGFS is suggested.
- For patients with symptomatic axial reflux, both thermal and nonthermal ablation of the GSV and SSV are recommended depending on the available expertise of the treating physician and the preference of the patient.
- In patients with symptomatic reflux in the GSV or SSV and associated varicosities, ablation of the refluxing venous trunk, and concomitant phlebectomy, or UGFS of the varicosities with physician-compounded foam or commercial PEM is recommended.

- In patients with symptomatic reflux in the GSV or SSV, ablation of the refluxing venous trunk, and staged or UGFS of the varicosities is recommended only if anatomic or medical reasons are present.

The SVS, AVF, AVLS, and SIR developed the appropriate use criteria (AUC) 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 consensus does not appear to be based on a systematic review of the literature. One hundred and nineteen scenarios were rated on a scale of one to nine by an expert panel, with one being never appropriate and nine being appropriate. The panelists rated ablation for axial reflux of the GSV, with or without SFJ reflux, in symptomatic patients, CEAP classes 2-6 as appropriate. Per the AUC, when accompanied by no SFJ reflux (the junction is either assumed or proven to be competent or previously interrupted and communicates with the GSV through incompetent thigh perforators or other sources of collateral flow) the remaining refluxing GSV may be the source of recurrent symptoms. Therefore, for axial GSV reflux, ablating the GSV will likely lead to decreased recurrence even if the SFJ shows no reflux. The mean number of saphenous vein ablations per person ranges from 1.3 to 1.9. However, occasionally, treatment requiring three or more ablations in a limb is needed. The authors note that the AUC statements were intended to serve as a guide to patient care, particularly in areas where high quality evidence is lacking and was not meant to be a guide that addresses all clinical situations.

The SVS and AVF released joint clinical practice guidelines regarding the care of patients with venous leg ulcers (O'Donnell et al., 2014). For patients with a venous leg ulcer (C6), and incompetent superficial veins that have reflux to the ulcer bed in addition to pathological perforating veins (> 500 ms reflux duration and diameter of > 3.5 mm), that are located beneath or associated with the ulcer bed, the guideline recommends ablation of both the incompetent superficial veins and perforator veins in addition to standard compressive therapy to aid in ulcer healing and prevent recurrence. For patients who are at risk for a venous leg ulcer (C4b), or have a healed venous ulcer (C5), and have axial reflux directed to the bed of the affected skin/ulcer, the guidelines recommend ablation of the incompetent superficial veins in addition to standard compressive therapy.

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 15, 2023)

The VenaSeal™ Closure System received the FDA's pre-market approval (PMA) 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 (DUS). Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140018. (Accessed December 15, 2023)

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, 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 15, 2023)

Sclerotherapy

The U.S. Food and Drug Administration (FDA) has approved various sclerosing agents to treat varicose veins of the lower extremities. 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 1 to 3 mm in diameter) in the lower extremity. It has not been studied in larger varicose veins > 3 mm in diameter. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021201s000_Medr.pdf (Accessed December 15, 2023)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria for: ***Varicose Vein Ablative and Stripping Procedures*** o Added reference to the InterQual® CP: Procedures: § Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein § Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein o Removed reference to the InterQual® CP: Procedures: § Ablation, Endovenous, Varicose Vein § Ligation/Excision, Varicose Vein, +/- Stripping ***Ligation Procedures*** o Added reference to the InterQual® CP: Procedures, Subfascial Endoscopic Perforator Surgery (SEPS) o Removed reference to the InterQual® CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein ***Ambulatory Phlebectomy*** o Added reference to the InterQual® CP: Procedures, Phlebectomy, Lower Extremity Superficial Tributary Varicose Vein o Removed reference to the InterQual® CP: Procedures, Ambulatory Phlebectomy, Varicose Vein ***Other Procedures*** o Added reference to the InterQual® CP: Procedures: § Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein § Sclerotherapy, Lower Extremity Superficial Tributary Varicose Vein o Removed reference to the InterQual® CP: Procedures, Sclerotherapy, Varicose Vein • Revised list of unproven and not medically necessary procedures for treating Venous Reflux; removed: o Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive o Endovenous mechanochemical ablation (MOCA) of Varicose Veins **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS117IN.09

Instructions for Use

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UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.