



MASSACHUSETTS

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Medical Policy

Treatment of Varicose Veins/Venous Insufficiency

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Policy Number: 238

BCBSA Reference Number: 7.01.124 (For Plan internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

SAPHENOUS VEINS

Great or Small Saphenous Veins

Treatment of the great or small saphenous veins by surgery (ligation and stripping), endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy or cyanoacrylate adhesive may be considered **MEDICALLY NECESSARY** for symptomatic varicose veins/venous insufficiency when the following criteria have been met:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater, **AND**
- There is documentation of 1 or more of the following indications:
 - Ulceration secondary to venous stasis, **OR**
 - Recurrent superficial thrombophlebitis, **OR**
 - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity, **OR**
 - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, **AND**
 - Symptoms significantly interfere with activities of daily living, **AND**
 - A failure after the use of medical grade compression stockings (medical grade at least 20-30mmHg pressure).¹

Treatment of great or small saphenous veins by surgery, endovenous radiofrequency or laser ablation, or microfoam sclerotherapy or cyanoacrylate adhesive that does not meet the criteria described above is considered cosmetic and is considered **INVESTIGATIONAL**.

ACCESSORY SAPHENOUS VEINS

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

- Incompetence of the accessory saphenous vein is isolated, **AND**
- There is demonstrated accessory saphenous reflux, **AND**
- There is documentation of 1 or more of the following indications:
 - Ulceration secondary to venous stasis, **OR**
 - Recurrent superficial thrombophlebitis, **OR**
 - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity, **OR**
 - Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, **AND**
 - Symptoms significantly interfere with activities of daily living, **AND**
 - A failure after use of medical grade compression stockings (medical grade at least 20-30mmHg pressure).²

Concurrent treatment of the accessory saphenous veins along with the great or small saphenous veins may be considered **MEDICALLY NECESSARY** when criteria is met for each vein and there is documentation of anatomy showing that the accessory saphenous vein discharged directly into the common femoral vein.

Treatment of accessory saphenous veins by surgery or endovenous radiofrequency or laser ablation, microfoam sclerotherapy, or cyanoacrylate adhesive that does not meet the criteria described above is considered cosmetic and **NOT MEDICALLY NECESSARY**.

SYMPTOMATIC VARICOSE TRIBUTARIES

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

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

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

PERFORATOR VEINS

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

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

Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is **NOT MEDICALLY NECESSARY**.

TELANGIECTASIA

Treatment of telangiectasia such as spider veins, angiomas, and hemangiomas is considered cosmetic and **NOT MEDICALLY NECESSARY**.

OTHER VEINS

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

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <u>required</u> .
Commercial PPO	Prior authorization is <u>required</u> .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above **medical necessity criteria** **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
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 (eg, 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 (eg, great saphenous vein, accessory saphenous vein), same leg
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg

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; second and subsequent veins 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 (eg, 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 (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
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 and short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37760	Ligation of perforator veins, subfascial, radical (Linton type) including skin graft, when performed, open, 1 leg
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
37780	Ligation and division of short saphenous vein at saphenopopliteal junction
37785	Ligation, division, and/or excision of varicose vein cluster(s), one leg

HCPCS Codes

HCPCS codes:	Code Description
S2202	Echosclerotherapy

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
065M3ZZ	Destruction of Right Femoral Vein, Percutaneous Approach
065M4ZZ	Destruction of Right Femoral Vein, Percutaneous Endoscopic Approach
065N3ZZ	Destruction of Left Femoral Vein, Percutaneous Approach
065N4ZZ	Destruction of Left Femoral Vein, Percutaneous Endoscopic Approach
065P3ZZ	Destruction of Right Saphenous Vein, Percutaneous Approach
065P4ZZ	Destruction of Right Saphenous Vein, Percutaneous Endoscopic Approach

065Q3ZZ	Destruction of Left Saphenous Vein, Percutaneous Approach
065Q4ZZ	Destruction of Left Saphenous Vein, Percutaneous Endoscopic Approach
065T3ZZ	Destruction of Right Foot Vein, Percutaneous Approach
065T4ZZ	Destruction of Right Foot Vein, Percutaneous Endoscopic Approach
065V3ZZ	Destruction of Left Foot Vein, Percutaneous Approach
065V4ZZ	Destruction of Left Foot Vein, Percutaneous Endoscopic Approach
065Y3ZZ	Destruction of Lower Vein, Percutaneous Approach
065Y4ZZ	Destruction of Lower Vein, Percutaneous Endoscopic Approach
06BM0ZZ	Excision of Right Femoral Vein, Open Approach
06BM3ZZ	Excision of Right Femoral Vein, Percutaneous Approach
06BM4ZZ	Excision of Right Femoral Vein, Percutaneous Endoscopic Approach
06BN0ZZ	Excision of Left Femoral Vein, Open Approach
06BN3ZZ	Excision of Left Femoral Vein, Percutaneous Approach
06BN4ZZ	Excision of Left Femoral Vein, Percutaneous Endoscopic Approach
06BP0ZZ	Excision of Right Saphenous Vein, Open Approach
06BP3ZZ	Excision of Right Saphenous Vein, Percutaneous Approach
06BP4ZX	Excision of Right Saphenous Vein, Percutaneous Endoscopic Approach
06BQ0ZZ	Excision of Left Saphenous Vein, Open Approach
06BQ3ZZ	Excision of Left Saphenous Vein, Percutaneous Approach
06BQ4ZZ	Excision of Left Saphenous Vein, Percutaneous Endoscopic Approach
06BT0ZZ	Excision of Right Foot Vein, Open Approach
06BT3ZZ	Excision of Right Foot Vein, Percutaneous Approach
06BT4ZZ	Excision of Right Foot Vein, Percutaneous Endoscopic Approach
06BV0ZZ	Excision of Left Foot Vein, Open Approach
06BV3ZZ	Excision of Left Foot Vein, Percutaneous Approach
06BV4ZZ	Excision of Left Foot Vein, Percutaneous Endoscopic Approach
06DM0ZZ	Extraction of Right Femoral Vein, Open Approach
06DM3ZZ	Extraction of Right Femoral Vein, Percutaneous Approach
06DM4ZZ	Extraction of Right Femoral Vein, Percutaneous Endoscopic Approach
06DN0ZZ	Extraction of Left Femoral Vein, Open Approach
06DN3ZZ	Extraction of Left Femoral Vein, Percutaneous Approach
06DN4ZZ	Extraction of Left Femoral Vein, Percutaneous Endoscopic Approach
06DP0ZZ	Extraction of Right Saphenous Vein, Open Approach
06DP3ZZ	Extraction of Right Saphenous Vein, Percutaneous Approach
06DP4ZZ	Extraction of Right Saphenous Vein, Percutaneous Endoscopic Approach
06DQ0ZZ	Extraction of Left Saphenous Vein, Open Approach
06DQ3ZZ	Extraction of Left Saphenous Vein, Percutaneous Approach
06DQ4ZZ	Extraction of Left Saphenous Vein, Percutaneous Endoscopic Approach
06DY0ZZ	Extraction of Lower Vein, Open Approach
06DY3ZZ	Extraction of Lower Vein, Percutaneous Approach
06DY4ZZ	Extraction of Lower Vein, Percutaneous Endoscopic Approach
06LM0ZZ	Occlusion of Right Femoral Vein, Open Approach
06LM3ZZ	Occlusion of Right Femoral Vein, Percutaneous Approach
06LM4ZZ	Occlusion of Right Femoral Vein, Percutaneous Endoscopic Approach
06LN0ZZ	Occlusion of Left Femoral Vein, Open Approach
06LN3ZZ	Occlusion of Left Femoral Vein, Percutaneous Approach
06LN4ZZ	Occlusion of Left Femoral Vein, Percutaneous Endoscopic Approach
06LP0ZZ	Occlusion of Right Saphenous Vein, Open Approach
06LP3ZZ	Occlusion of Right Saphenous Vein, Percutaneous Approach
06LP4ZZ	Occlusion of Right Saphenous Vein, Percutaneous Endoscopic Approach
06LQ0ZZ	Occlusion of Left Saphenous Vein, Open Approach

06LQ3ZZ	Occlusion of Left Saphenous Vein, Percutaneous Approach
06LQ4ZZ	Occlusion of Left Saphenous Vein, Percutaneous Endoscopic Approach
06QM0ZZ	Repair Right Femoral Vein, Open Approach
06QM3ZZ	Repair Right Femoral Vein, Percutaneous Approach
06QM4ZZ	Repair Right Femoral Vein, Percutaneous Endoscopic Approach
06QN0ZZ	Repair Left Femoral Vein, Open Approach
06QN3ZZ	Repair Left Femoral Vein, Percutaneous Approach
06QN4ZZ	Repair Left Femoral Vein, Percutaneous Endoscopic Approach
06QP0ZZ	Repair Right Saphenous Vein, Open Approach
06QP3ZZ	Repair Right Saphenous Vein, Percutaneous Approach
06QP4ZZ	Repair Right Saphenous Vein, Percutaneous Endoscopic Approach
06QQ0ZZ	Repair Left Saphenous Vein, Open Approach
06QQ3ZZ	Repair Left Saphenous Vein, Percutaneous Approach
06QQ4ZZ	Repair Left Saphenous Vein, Percutaneous Endoscopic Approach
06QT0ZZ	Repair Right Foot Vein, Open Approach
06QT3ZZ	Repair Right Foot Vein, Percutaneous Approach
06QT4ZZ	Repair Right Foot Vein, Percutaneous Endoscopic Approach
06QV0ZZ	Repair Left Foot Vein, Open Approach
06QV3ZZ	Repair Left Foot Vein, Percutaneous Approach
06QV4ZZ	Repair Left Foot Vein, Percutaneous Endoscopic Approach
06QY0ZZ	Repair Lower Vein, Open Approach
06QY3ZZ	Repair Lower Vein, Percutaneous Approach
06QY4ZZ	Repair Lower Vein, Percutaneous Endoscopic Approach
0JBN0ZZ	Excision of Right Lower Leg Subcutaneous Tissue and Fascia, Open Approach
0JBP0ZZ	Excision of Left Lower Leg Subcutaneous Tissue and Fascia, Open Approach
0JUN07Z	Supplement of Right Lower Leg Subcutaneous Tissue and Fascia with Autologous Tissue Substitute, Open Approach
0JUP07Z	Supplement of Left Lower Leg Subcutaneous Tissue and Fascia with Autologous Tissue Substitute, Open Approach
3E033TZ	Introduction of Destructive Agent into Peripheral Vein, Percutaneous Approach

The following CPT code is considered not medically necessary for **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

CPT Codes

CPT codes:	Code Description
36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk

The following CPT codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

CPT Codes

CPT codes:	Code Description
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

The following CPT codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
0524T	Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring

Description

Venous Reflux/Venous Insufficiency

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

Treatment of Saphenous Veins and Tributaries

Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein.

Treatment of venous reflux has traditionally included the following:

- Identification by preoperative Doppler ultrasonography of the valvular incompetence
- Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction
- Removal of the superficial vein from circulation, eg, by stripping of the great and/or small saphenous veins.
- Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. They include forms of sclerotherapy, cyanoacrylate adhesive, and thermal ablation using cryotherapy, high-frequency radio waves (200-300 kHz), or laser energy.

Thermal Ablation

Radiofrequency ablation is performed using a specially designed catheter inserted through a small incision in the distal medial thigh to within 1 to 2 cm of the saphenofemoral junction. The catheter is slowly withdrawn, closing the vein. Laser ablation is performed similarly; a laser fiber is introduced into the great saphenous vein under ultrasound guidance; the laser is activated and slowly removed, along the course of the saphenous vein. Cryoablation uses extreme cold. The objective of endovenous techniques is to injure the vessel, causing retraction and subsequent fibrotic occlusion of the vein. Technical developments since thermal ablation procedures were initially introduced include the use of perivenous tumescent anesthesia, which allows successful treatment of veins larger than 12 mm in diameter and helps to protect adjacent tissue from thermal damage during treatment of the small saphenous vein.

Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately occluding the vessel. Treatment success depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not

considered good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). Physician-compounded foam is produced at the time of treatment. A commercially available microfoam sclerosant with a proprietary gas mix is available that is proposed to provide smaller and more consistent bubble size than what is produced with physician-compounded sclerosant foam.

Endovenous Mechanochemical Ablation

Endovenous mechanochemical ablation uses both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without the need for the tumescent anesthesia used with endovenous thermal ablation techniques (radiofrequency ablation, endovenous laser ablation).

Cyanoacrylate Adhesive

A cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material on contact with body fluids or tissue). The adhesive is gradually injected along the length of the vein in conjunction with ultrasound and manual compression. The acute coaptation halts blood flow through the vein until the implanted adhesive becomes fibrotically encapsulated and establishes chronic occlusion of the treated vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and surgical incisions or other skin wounds.

Transilluminated Powered Phlebectomy

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

Summary

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

Saphenous Veins

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive endovenous thermal ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins.

Comparison with the standard of ligation and stripping at 2- to 5-year follow-up has supported the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For physician-compounded sclerotherapy, there is high variability in success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration (FDA) are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that once occluded, recurrence rates at 2 years are similar to those of ligation and stripping. Together, this evidence indicates that the more consistent occlusion with the microfoam sclerotherapy preparation will lead to recurrence rates similar to ligation and stripping in the longer term. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive MOCA, the evidence includes 4 RCTs with 6 months to 2-year results that compared MOCA to thermal ablation, a prospective cohort with follow-up out to 5 years, and retrospective case series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. A potential advantage of this procedure compared with thermal ablation is that MOCA does not require tumescent anesthesia and may result in less pain during the procedure. Results to date have been mixed regarding a reduction in intraprocedural pain compared to thermal ablation procedures. Occlusion rates at 6 months to 2 years from RCTs indicate lower anatomic success rates compared to thermal ablation, but a difference in clinical outcomes at these early time points has not been observed. Experience with other endoluminal ablation procedures suggests that lower anatomic success in the short term is associated with recanalization and clinical recurrence between 2 to 5 years. The possibility of later clinical recurrence is supported by a prospective cohort study with 5-year follow-up following treatment with MOCA. However, there have been improvements in technique since the cohort study was begun, and clinical progression is frequently observed with venous disease. Because of these limitations of the single arm studies, longer follow-up in the more recently conducted RCTs is needed to establish the efficacy and durability of this procedure compared with the criterion standard of thermal ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive CAC, the evidence includes 2 RCTs and a prospective cohort. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Evidence includes a multicenter noninferiority trial with follow-up through 36 months, an RCT with follow-up through 24 months, and a prospective cohort with 30-month follow-up. The short-term efficacy of VenaSeal CAC has been shown to be noninferior to RFA at up to 36 months. At 24 and 36 months the study had greater than 20% loss to follow-up, but loss to follow-up was similar in the 2 groups at the long-term follow-up and is not expected to influence the comparative results. A second RCT (n=525) with the same active CAC ingredient (N-butyl cyanoacrylate) that is currently available outside of the U.S. found no significant differences in vein closure between CAC and thermal ablation controls at 24-month follow-up. The CAC procedure and return to work were shorter and pain scores were lower compared to thermal ablation, although the subjective pain scores may have been influenced by differing expectations in this study. A prospective cohort reported high closure rates at 30 months. Overall, results indicate that outcomes from CAC are at least as good as thermal ablation techniques, the current standard of care. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs and multicenter series. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Results from a

recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Varicose Tributary Veins

For individuals who have varicose tributary veins who receive ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy (TIPP) is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Perforator Veins

For individuals who have perforator vein reflux who receive ablation (eg, subfascial endoscopic perforator surgery) of perforator veins, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (ie, ulcers), treatment of perforator vein reflux may be as beneficial as an alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating or ablating incompetent perforator veins. Subfascial endoscopic perforator surgery is possibly as effective as the Linton procedure with a reduction in adverse events. Endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared with surgical interventions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
7/2022	Annual policy review. Minor editorial refinements to policy statement to update "not medically necessary" language to "investigational"; intent unchanged.
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
5/2022	Last criteria clarified under saphenous veins and accessory saphenous veins to state: A failure after the use of medical grade compression stockings (medical grade at least 20-30mmHg pressure). Effective 5/1/2022.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
7/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
10/2019	Annual policy review. Cyanoacrylate adhesive may be considered medically necessary. A medically necessary statement was added on concurrent treatment of the accessory saphenous veins. Effective 10/1/2019.
6/2019	Prior authorization is required. Clarified coding information. Effective 6/1/2019.
3/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	Clarified coding information.
7/2018	Annual policy review. Background and summary clarified. New references added.
1/2018	Clarified coding information.
10/2017	Clarified coding information.

6/2017	Annual policy review. New references added.
5/2017	Clarified coding information.
1/2017	Clarified coding information for the 2017 code changes.
4/2016	Annual policy review. The requirement of failure of compression therapy was removed from the policy statements on ulceration secondary to venous stasis and recurrent superficial thrombophlebitis; terminology was changed from greater and lesser to great and small saphenous veins. Effective 4/1/2016.
4/2015	Annual policy review. Clarified coding information. New medically necessary and investigational indications described. Effective 4/1/2015.
1/2015	Clarified coding information.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
4/2014	Annual policy review. New references added.
11/2013	Added HCPCS code S2202.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
12/2010	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
11/1/2010	Medical Policy 238 describing covered and non-covered indications. Effective 11/2/2010.

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Endnotes

¹ Based on expert opinion

² Based on expert opinion