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Treatment of Varicose Veins/Venous Insufficiency Corporate Medical Policy

File Name: Treatment of Varicose Veins/Venous Insufficiency
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Description/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.
The relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity (TRM). 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 a meaningful 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. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 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 two 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 a meaningful improvement in the net health outcome.

Based on the available evidence, clinical input obtained in 2015, and clinical practice guidelines, the use of endovenous RFA, endovenous laser ablation, and microfoam sclerotherapy are considered to improve outcomes when used in the saphenous veins. For treatment of saphenous tributaries at the same time or following treatment of the saphenous vein, stab avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy improve outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive MOCA, the evidence includes two RCTs and case series. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. MOCA is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that MOCA does not require multiple needle sticks with tumescent anesthesia and may result in less pain during the procedure. The evidence on MOCA includes an RCT that compared MOCA to thermal ablation with one year results, an RCT with short-term results that compared MOCA with RFA, and case series with follow-up out to three years. The short-term results of one RCT suggested that intraprocedural pain is slightly lower with MOCA than with RFA. However, the second RCT showed lower occlusion rates than thermal ablation. MOCA has been assessed in relatively few patients and for short durations. Longer follow-up in RCTs with a larger number of patients is needed to evaluate the efficacy and durability of this procedure compared with established procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive CAC, the evidence includes two RCTs and a prospective cohort. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 two 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 a meaningful 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. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 the effects of the technology on health outcomes.

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. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 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 a meaningful 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. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and TRM. 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 has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only one case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity compared with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.

Attachment I - CPT® Code List & Instructions

When a service may be considered medically necessary, not medically necessary, investigational or a benefit exclusion

Great or Small Saphenous Veins

Treatment of the great or small 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:

- There is demonstrated saphenous reflux and CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2 or greater; **AND**

- There is documentation of one 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** the symptoms significantly interfere with activities of daily living, **AND** conservative management including compression therapy for at least 3 months has not improved the symptoms.

Sclerotherapy techniques, other than microfoam sclerotherapy, stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of great or small saphenous veins is **investigational**.

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

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, **OR** the great or small saphenous veins have been previously eliminated (at least 3 months); **AND**

- There is demonstrated accessory saphenous reflux; **AND**

- There is documentation of one 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** the symptoms significantly interfere with activities of daily living, **AND** conservative management including compression therapy for at least 3 months has not improved the symptoms.

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.

Sclerotherapy techniques, other than microfoam sclerotherapy, stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of accessory saphenous veins are **investigational**.

Treatment of accessory saphenous veins by surgery, endovenous radiofrequency or laser ablation, microfoam sclerotherapy or cyanoacrylate adhesive that do not meet the criteria described above is considered cosmetic and **therefore a benefit exclusion.**

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**.

Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins is **investigational**.

Endovenous radiofrequency or laser ablation of tributary veins is **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**.

Sclerotherapy, stab avulsion, hook phlebectomy, or transilluminated powered phlebectomy of perforator veins is **investigational**.

Telangiectasias, and Reticular Veins, and other CEAP Category 1 veins

Treatment of telangiectasia such as reticular veins, spider veins, angiomata, hemangiomata and other CEAP Category 1 veins is considered cosmetic and **therefore a benefit exclusion.**

Other Techniques

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

- Mechanochemical ablation (MOCA) of any vein
- Endovenous cryoablation of any vein
- Cyanoacrylate adhesive of any vein not listed above

Policy Guidelines

The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system. The following is the Clinical portion of the CEAP.

Clinical Classification

C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C2r	Recurrent varicose veins
C3	Edema
C4	Changes in skin and subcutaneous tissue secondary to CVD
C4a	Pigmentation and eczema
C4b	Lipodermatosclerosis and atrophie blanche
C4c	Corona phlebectatica
C5	Healed venous ulcer
C6	Active venous ulcer
C6r	Recurrent active venous ulcer
S	Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
A	Asymptomatic

The Etiologic, Anatomic, And Pathophysiologic portions of the classifications are online (http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf).

It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. When ultrasound guidance is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.

Reference Resources

1. Blue Cross and Blue Shield Association Medical Policy MPRM 7.01.124 – Treatment of Varicose Veins/Venous Insufficiency. Last Reviewed June 2020. Accessed December 2020.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non- compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered compete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

09/2010	New policy. CAC approved 07/2010.
03/2014	ICD 10 remediation. Revised /updated standard language (document precedence and audit information sections) added. Code tables reformatted. Hyperlinks created for attachments. ICD diagnosis list hyperlink also created for URL for website.
03/2015	Local expert input and changes to be c/w BCBSA policy- eliminates prior requirement for treating saphenous vein if no reflux is identified for accessory, tributary and perforators.
10/2016	Adopted BCBSA MPRM 7.01.124, Updated coding table ICD 10 Section.
10/2017	Policy updated with literature review; references added, CPT® Codes 37473, 37474 & 37243 added to coding table Policy statements remain unchanged.
11/2017	Added codes effective 01/01/2018 36465 &36466 to require prior authorization.
07/2018	Policy reviewed, aligned with MPRM 7.01.124 added language. The use of cyanoacrylate adhesive for permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation is considered not medically necessary.
11/2018	Policy clarified as to the definition of CEAP Category 1 veins. Removed ICD-10-CM table.
07/2019	Updated to align with MPRM 7.01.124. Use of cyanoacrylate adhesive is now medically necessary under certain conditions. Codes 36482& 36483 added to require prior authorization.
01/2020	Policy reviewed with clarification to policy statement Cyanoacrylate adhesive of any vein ADDED: “not listed above”.
01/2021	Policy Reviewed. Formatting changes: Investigational techniques moved to specific names vein sections. Added code 0524T to align with Corporate Investigational Medical policy.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP
Senior Medical Director

Attachment I

CPT® Code List & Instructions

Code	Number	Description	Policy Instructions
The following codes will be considered as medically necessary or investigational when applicable criteria have been met.			
CPT®	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)	Prior approval required
CPT®	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	Prior approval required
CPT®	36468	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk	Prior approval required
CPT®	36470	Injection of sclerosing solution; single vein	Prior approval required
CPT®	36471	Injection of sclerosing solution; multiple veins, same leg	Prior approval required
CPT®	36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	Prior approval required
CPT®	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)	Prior approval required

Code	Number	Description	Policy Instructions
CPT®	36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated	Prior approval required
CPT®	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)	Prior approval required
CPT®	36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated	Prior approval required
CPT®	36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)	Prior approval required
CPT®	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	Prior approval required
CPT®	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)	Prior approval required
CPT®	37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	Prior approval required
CPT®	37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)	Prior approval required

Code	Number	Description	Policy Instructions
CPT®	37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions	Prior approval required
CPT®	37718	Ligation, division, and stripping, short saphenous vein	Prior approval required
CPT®	37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below	Prior approval required
CPT®	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	Prior approval required
CPT®	37760	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open,1 leg	Prior approval required
CPT®	37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	Prior approval required
CPT®	37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions	Prior approval required
CPT®	37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions	Prior approval required
CPT®	37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)	Prior approval required
CPT®	37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg	Prior approval required
CPT®	37799	Unlisted procedure, vascular surgery	Prior approval required
CPT®	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	Investigational
HCPCS	S2202	Echosclerotherapy	Prior approval required