



Guidelines for Medical Necessity Determination for Treatment of Varicose Veins

This edition of the Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for the treatment of varicose veins of the lower extremities. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at [130 CMR 433.00](#): *Physician Services* and [130 CMR 450.000](#): *Administrative and Billing Regulations* and [Subchapter 6](#) of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Organization (SCO), or Program of All-Inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for the treatment of varicose veins of the lower extremities, and reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

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SECTION I. GENERAL INFORMATION

SAPHENOUS VEINS

The venous system of the lower extremities consists of superficial veins, deep veins, and perforator veins (which connect the deep and superficial veins). The main superficial veins of the lower extremities are the great saphenous veins (GSV), the small saphenous vein (SSV), and accessory saphenous veins (ASV). There are unidirectional valves, mostly present in the superficial veins, which prevent the backward flow of blood. Sometimes these valves become incompetent, which can lead to reflux or backward flow. This backward flow in the venous system can lead to the development of varicose veins, pain, or other discomfort (ache, pain, tightness, skin irritation, heaviness, muscle cramps), itching, edema, thrombophlebitis, ulcers, bleeding, or changes in the skin of the lower extremities. Varicose veins of the lower extremities are defined as dilated subcutaneous veins measuring ≥ 3 mm in diameter in an upright position. This spectrum of disease resulting from venous reflux is referred to as chronic venous disease (CVD). Dilated intradermal veins and venules between 1 and 3 mm in diameter (often referred to as spider veins), reticular veins, or telangiectasia can also result from venous reflux.

The CEAP classification, which stands for clinical manifestations (C), etiology (E), anatomic distribution of disease (A), and underlying pathologic findings (P), is used to describe and classify the extent of the disease that results from venous reflux (see Appendix A for details of CEAP classification).

If CVD is suspected as the cause of symptoms in the lower extremities after a comprehensive history and physical is performed, a trial of conservative measures for three months, including elevation, analgesics, graded compression stockings, and skin or wound care if needed may be successful in treating symptoms, especially healing venous ulcers. If symptoms persist, and reflux of ≥ 500 milliseconds (ms) in the saphenous veins is documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician), interventional treatment is recommended for CVD with CEAP classification of C₂ or higher. C₂ corresponding to a clinical classification of varicose veins (≥ 3 mm). When venous ulcers are present, interventional treatment along with continuation of compression therapy is recommended to decrease recurrence.

Interventional treatments include ligation and stripping (open venous surgery), endovenous laser ablation of the saphenous vein (ELAS), endovenous radiofrequency ablation (RFA), cyanoacrylate glue, and foam sclerotherapy (endovenous chemical ablation). ELAS and RFA are also referred to as endovenous thermal ablation (EVTA), endovenous catheter ablations (EVCA), or endovenous laser treatment (EVLV). When ulcers are present, compression is recommended as adjuvant treatment to interventional treatments to prevent ulcer recurrence.

When open surgery is performed on the great saphenous vein, it should be high ligation and invagination stripping of the saphenous vein to the level of the knee. When open surgery of the small saphenous vein is performed, it should be high ligation at the knee crease, with selective invagination stripping of the incompetent portion.

EVTA procedures are generally performed on an outpatient basis with local anesthetic and require no sedation. The procedure is done under ultrasonographic guidance which is inclusive of the procedure. A catheter is placed percutaneously into the saphenous vein, which delivers thermal energy (laser or radiofrequency), which in turn causes irreversible fibrosis and occlusion of the vein. EVTA procedures are associated with reduced pain, morbidity, and recovery time over open surgery.

Foam sclerotherapy of the saphenous veins involves injection of a liquid sclerosant along with gas into the veins, using ultrasound guidance which is inclusive of the procedure. The walls of the vein are destroyed in this process, causing sclerosis of the veins. Foam sclerotherapy is generally performed on an outpatient basis with local anesthetic and require no sedation.

Cyanoacrylate glue is a non-thermal, non-tumescent treatment for varicose veins. It is an adhesive that rapidly polymerizes when injected into the vein, causing fibrosis and occlusion. This therapy is performed on an outpatient basis with topical anesthetic. It does not require sedation.

The ambulatory conservative hemodynamic correction of venous insufficiency (CHIVA) method is a minimally invasive technique to treat CVD. Clinical data from large, quality, prospective clinical trials fully evaluating this technique in comparison to standardized techniques is still lacking.

Ambulatory selective varicose vein ablation under local anesthesia (ASVAL) treatment for saphenous reflux has not been evaluated in large, quality, prospective clinical trials fully evaluating this technique in comparison to standardized techniques.

Liquid sclerotherapy does poorly in the treatment of saphenous vein incompetence. Clinical data evaluating long-term safety and efficacy of treatment of any vein with cyanoacrylate adhesive, cryosurgery, and mechanochemical ablation are lacking.

PERFORATOR VEINS

There is an established association between incompetent perforating veins and venous ulcers. Treatment of incompetent perforating veins can be done using subfascial endoscopic perforator vein surgery (SEPS) under general or epidural anesthesia, EVTA as previously described, or ultrasound-guided foam sclerotherapy. EVTA and sclerotherapy techniques used in the treatment of incompetent perforators can be referred to as percutaneous ablation of perforators (PAPS). Sclerotherapy of the perforator vein can be complicated by inadvertent embolization of the artery, resulting in necrosis. This is preventable by using proper technique.

Patients with superficial and perforator vein incompetence (PVI) with a normal deep venous system can experience improvement in symptoms and perforator incompetence with treatment of the superficial system, including the saphenous and tributary veins. If symptoms persist, treatment of incompetent perforator vein is recommended when there is reflux of ≥ 500 milliseconds (ms) documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician) in the perforator vein with a diameter of ≥ 3.5 mm at the level of previous or active venous ulceration (CEAP class C_5 - C_6). There is a higher rate of treatment failure or ulcer recurrence in patients with deep venous occlusive disease (post-thrombotic syndrome).

TRIBUTARY VEINS

Almost all cases of symptomatic varicosities are associated with reflux in the saphenous system. These symptomatic varicose tributaries of CEAP class C_2 or higher can be treated at the same time or following treatment of the saphenous system.

Symptomatic tributary veins can be treated using ambulatory phlebectomy techniques (also referred to as stab or hook or mini phlebectomy), which involve avulsion of varicose veins through small stab wounds.

Transilluminated powered phlebectomy (TIPP) is an alternative technique using a powered unit with an oscillating resector hand piece, which allows a decreased number of incisions and faster removal of a large amount of varicose veins.

Symptomatic tributary veins can also be treated using sclerotherapy.

TELANGIECTASIAS

Dilated intradermal or subdermal veins and venules less than 3 mm in diameter often referred to as spider veins, reticular veins, or telangiectasia can also result from venous reflux. However, these veins do not cause symptoms, and their treatment with liquid or foam sclerotherapy is regarded as cosmetic.

MassHealth considers approval for coverage of treatment of varicose veins of the lower extremities on an individual, case-by-case basis, in accordance with 130 CMR 433.000 and 130 CMR 450.204.

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SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for the treatment of varicose veins on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure, including postoperative recovery. These criteria include, but are not limited to, the following.

1. Treatment of the saphenous veins (great, small, or accessory) by open surgery (ligation and stripping), endovenous thermal ablation (radiofrequency or thermal), foam sclerotherapy, or cyanoacrylate glue may be medically necessary for the treatment of symptomatic varicose veins when all of the following criteria (a through d) are met.
 - a. A comprehensive history and physical is performed and fails to reveal another diagnosis other than CVD as the cause of the symptoms.
 - b. There is a failure of symptoms to respond to conservative treatment for at least three months. Conservative treatment must include graded compression stockings. Analgesics, elevation, and skin and wound care can also be used to treat symptoms if indicated.
 - c. The presence of saphenous reflux ≥ 500 milliseconds in the vein to be treated must be documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician)
 - d. Varicose veins must be present with CEAP classification of either of the following (i or ii):
 - i. C₂ accompanied by symptoms such as ache, pain, tightness, skin irritation, heaviness, muscle cramps, thrombophlebitis, or recurrent bleeding.
 - ii. C₃ or higher (including venous ulceration, edema, and dermatitis).
2. Treatment of perforator veins using subfascial endoscopic perforator vein surgery (SEPS), EVTA, ultrasound-guided foam sclerotherapy, or cyanoacrylate glue may be medically necessary for the treatment of recurrent or persistent leg ulcers when all the following criteria (a through e) are met.
 - a. A comprehensive history and physical is performed and fails to reveal another diagnosis other than CVD as the cause of the symptoms.
 - b. Reflux in the saphenous veins ≥ 500 milliseconds, documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician), if present, has been successfully treated followed by compression stockings as adjuvant treatment for at least three months.
 - c. If there is no reflux or ≤ 500 milliseconds reflux in the saphenous vein, documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician), there must have been failure of symptoms to respond to conservative treatment for at least three months. Conservative treatment must include graded compression stockings. Analgesics, elevation, and skin and wound care can also be used to treat symptoms if indicated.
 - d. There must be the presence of reflux of ≥ 500 milliseconds (ms) documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician) in the perforator vein with a diameter of ≥ 3.5 mm at the level of the leg ulcers (CEAP class C₅-C₆).

- e. Deep venous occlusive disease is not present on venous duplex ultrasound of the leg.
3. Treatment of symptomatic varicose tributaries using ambulatory phlebectomy techniques (stab, hook, or mini phlebectomy), transilluminated powered phlebectomy, or sclerotherapy may be medically necessary when all the following criteria (a through d) are met.
- a. A comprehensive history and physical is performed and fails to reveal another diagnosis other than CVD as the cause of the symptoms.
 - b. Reflux in the saphenous veins ≥ 500 milliseconds documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician), if present, has been successfully treated or is being concurrently treated.
 - c. If there is no reflux or ≤ 500 milliseconds reflux in the saphenous vein documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician), there must have been failure of symptoms to respond to conservative treatment for at least three months. Conservative treatment must include graded compression stockings. Analgesics, elevation, and skin and wound care can also be used to treat symptoms if indicated.
 - d. Varicose tributaries are ≥ 3 mm and ≤ 6 mm, accompanied by symptoms including pain, heaviness, aching, soreness, burning, thrombophlebitis, or recurrent bleeding.

NOTE: Sclerotherapy of symptomatic tributaries of one leg, regardless of how many, is considered as one unit. Up to three units per leg are allowed per authorization period following treatment of axial reflux of the leg. Any further request for sclerotherapy of symptomatic varicose tributaries requires resubmission of a PA request and is subject to the guidelines of this policy.

4. If multiple procedures are requested, all criteria for each individual procedure must be met.

NOTE: Selection of the specific method used to treat CVD will depend on the member's clinical history, including any contraindications. The provider is expected to review the risks and benefits of the procedure with the member.

B. NONCOVERAGE

MassHealth does not consider treatment of varicose veins to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

- 1. The procedure is performed for cosmetic purposes or solely to improve appearance.
- 2. The treatment of dilated intradermal veins and venules less than 3 mm in diameter (CEAP class C_1), often referred to as spider veins, reticular veins, or telangiectasia, is generally considered cosmetic and not medically necessary.
- 3. There is sclerotherapy of symptomatic varicose tributaries (CEAP class C_2) before correction of reflux in the saphenous system.
- 4. There is treatment of symptomatic varicose tributaries (CEAP class C_2) with EVTA,
- 5. There is treatment of incompetent perforator veins at the same time as or before correction of reflux in the saphenous system

6. There is treatment of incompetent perforator veins caused by deep venous occlusive disease or post thrombotic syndrome.
7. There is treatment of incompetent perforator veins with any forms of phlebectomy.
8. There is treatment of incompetent perforator veins with liquid sclerotherapy.
9. There is treatment of incompetent saphenous veins using conservative hemodynamic correction of venous insufficiency (CHIVA) technique.
10. There is treatment of incompetent saphenous veins using ambulatory selective varicose vein ablation under local anesthesia (ASVAL) technique.
11. There is treatment of incompetent saphenous veins using any forms of phlebectomy.
12. There is treatment of any veins with cryoablation, cryostripping, or mechanochemical ablation.
13. There are conditions in which any superficial vein treatment is contraindicated, including prolonged immobilization, acute deep venous occlusive disease, severe generalized infection, local infection of the leg where treatment is to be performed, hypercoagulable disorder, active thrombophlebitis, and known allergy to sclerosants if being used.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

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Requests for PA for the treatment of varicose veins of the lower extremities must be accompanied by clinical documentation that supports the medical necessity for this procedure.

- A. Documentation of medical necessity must include all the following.
 1. A complete history, including current acute and chronic diagnoses, allergies, and a complete current list of medications.
 2. Onset of diagnosis and symptoms of chronic venous disease.
 3. A comprehensive description of all conservative treatment measures tried and duration of such treatments.
 4. A comprehensive list of all surgeries and procedures previously performed on the leg(s) to treat chronic venous disease.
 5. A complete physical, including a detailed examination of the leg(s) and CEAP classification of chronic venous disease present in the leg(s).
 6. Results of a venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician) documenting flow in the venous system of the leg(s), specifically, the presence of reflux \geq 500 milliseconds (ms) of the system in question.
 7. Other pertinent information that MassHealth may request.

- B. Clinical information must be submitted by the MassHealth-enrolled qualified health professional performing the procedure. Providers are strongly encouraged to submit requests electronically. Providers must submit the request for PA and all supporting documentation by using the [Provider Online Service Center \(POSC\)](#) or by completing a MassHealth Prior Authorization Request form (using the [PA-1](#) paper form found at www.mass.gov/masshealth) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

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These Guidelines are based on review of the medical literature and current practice in the treatment of varicose veins. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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Approved by: 
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APPENDIX A

CEAP Classification.

1. Clinical classification

C0 No visible or palpable signs of venous disease

C1 Telangiectases, spider veins, or reticular veins (< 3mm)

C2 Varicose veins (≥ 3 mm)

C3 Edema

C4a Pigmentation and/or eczema

C4b Lipodermatosclerosis and atrophie blanche

C5 Healed venous ulcer

C6 Active venous ulcer

S: Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction.

A: Asymptomatic.

2. Etiologic classification

Ec: Congenital

Ep: Primary

Es: Secondary (postthrombotic)

3. Anatomic classification

As: Superficial veins

Ap: Perforator veins

Ad: Deep veins

4. Pathophysiologic classification

Pr: Reflux

Po: Obstruction

Pr,o: Reflux and obstruction

Pn: No venous pathophysiology identifiable