Guidelines for Medical Necessity Determination for Treatment of Varicose Veins of the Lower Extremities

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 433.000 (Physician Services) and 450.000 (Administrative and Billing Regulations) and Subchapter 6 of the Physician Manual for information about coverage, limitations, service conditions, and prior authorization requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), integrated care organization (ICO), senior care organization (SCO), or program of all-inclusive care for the elderly (PACE), should refer to the ACPP's, MCO's, ICO's, SCO's or PACE's medical policies for covered services.

MassHealth requires prior authorization for the treatment of varicose veins of the lower extremities, and reviews requests for prior authorization 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.

SECTION I. GENERAL INFORMATION

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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 theses 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 which 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 3 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 corresponds 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) 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 (EVLT). 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 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.

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 for 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 data 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 described above 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 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 C5-C6.). There is a higher rate of treatment failure or ulcer recurrence in patients with deep venous occlusive disease (post-thrombotic syndrome).

TRIBUTORY VEINS

Almost all cases of symptomatic varicosities are associated with reflux in the saphenous system. These symptomatic varicose tributaries of CEAP class C2 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 miniphlebectomy, involves 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 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 450.204.

SECTION II. CLINICAL GUIDELINES

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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 post-operative 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) or foam sclerotherapy 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. Failure of symptoms to respond to conservative treatment for at least 3 months. Conservative treatment must include graded compression stockings. Analgesics, elevation, 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 documented by venous duplex ultrasound (performed by a qualified physician or technologist supervised by a qualified physician)

    d. The presence of varicose veins 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 or ultrasound guided foam sclerotherapy 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 3 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), failure of symptoms to respond to conservative treatment for at least 3 months. Conservative treatment must include graded compression stockings. Analgesics, elevation, skin and wound care can also be used to treat symptoms if indicated.

    d. 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 miniphlebectomy), 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), failure of symptoms to respond to conservative treatment for at least 3 months. Conservative treatment must include graded compression stockings. Analgesics, elevation, skin and wound care can also be used to treat symptoms if indicated.

    d. Varicose tributaries are ≥ 3mm 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 3 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 prior authorization 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.

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. When the procedure is performed for cosmetic purposes or solely to improve appearance;

2. Treatment of dilated intradermal veins and venules less than 3 mm in diameter (CEAP class C1) often referred to as spider veins, reticular veins or telangiectasia is considered cosmetic and not medically necessary.

3. Sclerotherapy of symptomatic varicose tributaries (CEAP class C2) prior to correction of reflux in the saphenous system.

4. Treatment of symptomatic varicose tributaries (CEAP class C2) with EVTA

5. Treatment of incompetent perforator veins at the same time or prior to correction of reflux in the saphenous system

6. Treatment of incompetent perforator veins caused by deep venous occlusive disease or post thrombotic syndrome.

7. Treatment of incompetent perforator veins with any forms of phlebectomy.

8. Treatment of incompetent perforator veins with liquid sclerotherapy.

9. Treatment of incompetent saphenous veins using conservative hemodynamic correction of venous insufficiency (CHIVA) technique.

10. Treatment of incompetent saphenous veins using ambulatory selective varicose vein ablation under local anesthesia (ASVAL) technique.

11. Treatment of incompetent saphenous veins using sclerotherapy methods other than foam sclerotherapy.

12. Treatment of incompetent saphenous veins using any forms of phlebectomy.

13. Treatment of any veins with cryoablation, cryostripping, mechanochemical ablation or cyanoacrylate glue

14. 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 prior authorization 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 of 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 ≥ 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 prior authorization and all supporting documentation 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 regarding POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

Select References

1. American College of Phlebology. Practice Guidelines: Superficial Venous Disease. Treatment of Superficial Venous Disease of the Lower Leg. rev121013. Accessed March 14, 2016. Available at: http://www.phlebology.org/wp-content/uploads/2014/10/SuperficialVenousDiseaseGuidelines.pdf

2. Carradice D, Mekako AI, Mazari FA, et al. Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. Br J Surg. 2011 Apr;98(4):501-10

3. Gloviczki P, Comerota AJ, Dalsing MC, et al. The Care of Patients with Varicose Veins and Associated Chronic Venous Diseases: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011;53:2S-48S.

4. Wittens, C. et al. Management of Chronic Venous Disease
European Journal of Vascular and Endovascular Surgery. 2015: 49 (6): 678 – 737

5. Khilnani NM, Grassi CJ. Kundu S, et al.. Multi-Society Consensus Quality Improvement Guidelnes for the Treatment of Lower-Extremity Superficial Venous Insufficiency with Endovenous Thermal Ablation from the Society of Interventional Radiology, Cardiovascular Interventional Radiological Society of Europe, American College of Phlebology, and Canadian Interventional Radiology Association. J Vasc Interv Radiol. 2010;21:14-331.

6. Rabe E, Breu FX, Cavezzi A, et. al. European guidelines for sclerotherapy in chronic venous disorders. Phlebology. 2014; 29 (6):338-54 doi: 10.1177/0268355513483280. Epub 2013 May 3.

7. Kundu S, Grassi CJ, Khilnani NM, et al. Multi-disciplinary Quality Improvement Guidelines for the Treatment of Lower Extremity Superficial Venous Insufficiency with Ambulatory Phlebectomy from the Society of Interventional Radiology, Cardiovascular Interventional Radiological Society of Europe, American College of Phlebology and Canadian Interventional Radiology Association. J Vasc Interv Radiol. 2010;21:1-13.

8. O'Meara S, Cullum N, Nelson EA, et al. Compression for venous leg ulcers. Cochrane Database Syst Rev. 2012;11:CD000265. PMID 23152202

9. Nesbitt C, Bedenis R, Bhattacharya V, et al. Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices. Cochrane Database Syst Rev. 2014;7:CD005624. PMID 25075589

10. Darvall KA, Bate GR, Adam DJ, Bradbury AW. Recovery after ultrasound-guided foam sclerotherapy compared with conventional surgery for varicose veins. British Journal of Surgery. 2009; 96(11): 1262-1267.

11. Morrison N, Gibson K, Vasquez M, Weiss R, Cher D, Madsen M, Jones A. VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2017; 5(3):321-330

12. Proebstle TM, Alm J, Dimitri S, Rasmussen L, Whiteley M, Lawson J, Cher D, Davies A. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2015; 3(1): 2-7.

13. Kim KY, Kim JW. **Early experience of transilluminated cryosurgery for varicose vein with saphenofemoral reflux: review of 84 patients (131 limbs)**. Ann Surg Treat Res. 2017 Aug;93(2):98-102. https://doi.org/10.4174/astr.2017.93.2.98

14. Bellmunt-Montoya S, Escribano JM, Dilme J, Martinez-Zapata MJ. CHIVA method for the treatment of chronic venous insufficiency (Review). Cochrane Database of Systematic Reviews. 2015. Issue 6. DOI: 10.1002/14651858.CD009648.pub3

15. Atasoy MM, Oğuzkurt L. The endovenous ASVAL method: principles and preliminary results. *Diagnostic and Interventional Radiology.* 2016;22(1):59-64. doi:10.5152/dir.2015.15161.

16. Kuyumcu G, Salazar GM, Prabhakar AM, Ganguli S. Minimally invasive treatments for perforator vein insufficiency. *Cardiovascular Diagnosis and Therapy.* 2016;6(6):593-598. doi:10.21037/cdt.2016.11.12.

17. Shi H, Liu X, Lu M, Lu X, Jiang M, Yin M. The Effect of Endovenous Laser Ablation of Incompetent Perforating Veins and the Great Saphenous Vein in Patients with Primary Venous Disease. European Journal of Vascular and Endovascular Surgery. 2015; 49(5):574-580

18. Lawrence PF, Alktaifi A, Rigberg D, DeRubertis B, Gelabert H, Jimenez JC. Endovenous ablation of incompetent perforating veins is effective treatment for recalcitrant venous ulcers. Journal of Vascular Surgery. 2010; 54 (3): 737-742

19. Lin F, Zhang S, Sun Y, Ren S, Liu P. The Management of Varicose Veins. *International Surgery.* 2015;100(1):185-189. doi:10.9738/INTSURG-D-14-00084.1.

20. Winokur RS, Khilnani NM. Superficial Veins: Treatment Options and Techniques for Saphenous Veins, Perforators, and Tributary Veins. Techniques in Vascular and Interventional Radiology. 2014; 17(2): 82-89

21. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. British Journal of Surgery. 2011; 98 (8): 1079-1087

22. Tang T, Kam J, Gaunt M. ClariVein® – Early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins. *Phlebology.* 2017;32(1):6-12. doi:10.1177/0268355516630154.

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.

Revised Policy Effective: March 1, 2019 Approved by: 

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Supersedes Sclerotherapy for the Treatment of Varicose Veins of the Lower Extremities policy dated: March 15, 2016

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, as well as 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