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

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth uses to determine medical necessity for sclerotherapy 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 and 130 CMR 450.000 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 managed care organization (MCO) or a MassHealth-contracted integrated care organization (ICO) should refer to the MCO’s or ICO’s medical policies for covered services.

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

SECTION I. GENERAL INFORMATION

Varicose veins are dilated, palpable subcutaneous veins 3 mm or larger in diameter; reticular veins are dilated non-palpable subdermal veins 1–3 mm in diameter; and telangiectasias are dilated intradermal venules less than 1 mm in diameter.

The term chronic venous disorders (CVD) includes the full spectrum of morphologic and functional abnormalities of the venous system, ranging from telangiectasia and reticular veins to varicose veins and venous ulceration. A classification system was developed by an international committee organized by the American Venous Forum (AVF) in 1994. It was adopted worldwide to facilitate meaningful communication about CVD and to serve as a basis for a more scientific analysis of the management alternatives. The CEAP classification of CVD is based on the clinical manifestations (C), etiology (E), anatomic distribution of disease (A), and underlying pathologic findings (P).

Backflow or “reflux” in the great saphenous vein (GSV) is the most common underlying cause of varicose veins. Reflux within one of the truncal veins leads to pooling in its tributaries (branches), causing visible varicose veins to develop. Therefore, reflux in the proximal truncal veins and valvular incompetence at the saphenofemoral and/or saphenopopliteal junctions must be treated in order to successfully treat varicose tributary veins. The goal of treatment of varicose veins is to reduce abnormal pressure in the deep veins that pushes out into the superficial ones and relieve related symptoms. There are several procedures that can be performed alone or in combination to treat truncal reflux. Surgical ligation and stripping is the historic standard against which other procedures have been evaluated; however, endovenous ablation through laser and radiofrequency, a minimally-invasive alternative to surgery, is currently recommended over surgical ligation and stripping in most cases.
Varicose tributary veins frequently improve, or, less commonly, disappear following treatment of the GSV with endovenous ablation. However, some patients will require adjunctive procedures to eliminate residual varicose tributaries. Ambulatory phlebectomy is considered the gold standard in the United States for the treatment of residual varicose tributary veins.

Some residual varicose tributary veins may be treated with sclerotherapy. Sclerotherapy involves injecting a foam or liquid sclerosing solution (sclerosant) directly into a vein with the goal of causing occlusion, subsequent fibrosis, and eventual obliteration of the vein. Sclerotherapy has been shown to be effective in treating small to medium-sized varicose veins ≥ 3 mm and ≤6 mm in diameter when all proximal sources of truncal reflux have been eliminated. Treatment of telangiectasias and reticular veins is considered cosmetic. MassHealth considers approval for coverage of sclerotherapy on an individual, case-by-case basis, in accordance with 130 CMR 433.000, 130 CMR 450.204, and other applicable MassHealth regulations.

SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

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

1. Sclerotherapy may be considered medically necessary for the treatment of symptomatic residual or recurrent varicose tributary veins of the superficial venous system in the following circumstances.
   a. The member has symptoms caused by the varicosities including, but not limited to
      i. pain, burning, aching, itching, discomfort, or other symptoms leading to impairment of activities of daily living; or
      ii. bleeding or recurrent bleeding episodes from a rupture of a varicose vein; or
      iii. lower extremity skin ulcers secondary to venous stasis that don't heal; or
      iv. recurrent thrombophlebitis; and
   b. the member has failed at least three months of conservative treatment, including daily exercise, weight reduction if necessary, periodic leg elevation, and graduated compression stockings; and
   c. the vein(s) to be treated is ≥3 mm. and ≤ 6 mm. in diameter, measured in the upright position; and
   d. there is no evidence of proximal sources of truncal reflux, as demonstrated by duplex ultrasonography. Any proximal truncal reflux should have been previously eliminated with endovenous ablation (laser or radiofrequency).

2. Treatment frequency is as follows:
   a. the number of injections needed to perform sclerotherapy and responses to sclerotherapy differ based on the anatomical site being treated. Only one sclerotherapy session should be reported per leg regardless of how many veins are treated during the session.
b. coverage for sclerotherapy is presumptively limited to three sessions per leg. Additional sessions beyond three may be authorized on a case-by-case basis upon receipt of a new PA request and interim clinical notes to document medical necessity.

B. NONCOVERAGE

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

1. Treatments that are considered cosmetic and not medically necessary, such as
   a. the treatment of asymptomatic varicose veins;
   b. the treatment of varicose veins less than 3 mm. in diameter, including, but not limited to, reticular veins; or
   c. the treatment of telangiectasias.

2. Conditions that are better treated with other modalities, such as
   a. treatment of larger veins > 6 mm. in diameter and tortuous veins, because they do not respond well to sclerotherapy because of technical limitations; and
   b. the treatment of truncal saphenous veins, because surgical ligation and stripping or endovenous ablation are the effective treatments for these veins.

3. The treatment of varicose tributary veins in the presence of proximal truncal reflux unless the treatment is occurring concurrently with truncal endovenous ablation (laser or radiofrequency).

4. Ultrasound-guidance during the injection of a sclerosing solution (sclerosant) for the treatment of varicose tributary veins is not medically necessary.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for sclerotherapy 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 REQUIRES ALL OF THE FOLLOWING:

1. Medical records from the treating health care practitioner that include a thorough history and physical examination with description of the varicose vein(s) and presence of any other pertinent findings. If the proximal source(s) of truncal reflux was previously eliminated, documentation must include the operative note(s) from the primary procedure(s), i.e., surgical ligation and stripping or endovenous ablation (laser or radiofrequency), and ambulatory phlebectomy, if applicable.

2. Narrative description of the clinical manifestations, etiology, anatomic distribution of disease, and underlying pathologic findings for clinical classification of level of CVD.
3. Duplex ultrasonography providing anatomical and hemodynamic assessment of the deep, superficial, and perforating venous systems. The report must provide information on the patterns of veins, vein patency, vein diameters, and valve functions that support the medical necessity for treatment of varicose veins. If the proximal source(s) of truncal reflux was (were) previously eliminated, post-procedural duplex ultrasonography must be submitted documenting occlusion of the truncal vein(s).

B. Clinical information must be submitted by a licensed physician, licensed nurse practitioner, or licensed physician assistant. Providers are strongly encouraged to submit requests electronically. Providers must submit all information about the diagnosis 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 pertinent 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 1-800-841-2900.

SELECT REFERENCES


These Guidelines are based on review of the medical literature and current practice in sclerotherapy for the treatment of varicose veins of the lower extremities. 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, contact your health care provider for guidance or explanation.

Policy Effective Date: 3/15/16
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