

# Varicose Veins of the Lower Extremities Clinical Coverage Criteria

## Overview

Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence). The venous insufficiency results in dilated, tortuous, superficial vessels that protrude from the skin of the lower extremities. Spider veins (telangiectases) are dilated capillary veins that are most often treated for cosmetic purposes.

Accepted treatments for eliminating saphenous reflux include endoluminal radiofrequency ablation (RFA), endoluminal laser ablation (EVLA), polidocanol microfoam, cyanoacrylate embolization ablation, and mechanochemical ablation.

# **Policy**

This Policy applies to the following Fallon Health products:

- □ Commercial

- NaviCare
- **⊠ PACE**

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for treatment of varicose veins of the lower extremities. National Government Services, Inc. is the Part A/Part B Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services, Inc. has an LCD for Varicose Veins of the Lower Extremity, Treatment of (L33575), and an LCA: Billing and Coding for Treatment of Varicose Veins of the Lower Extremity (A52870) (MCD search 02/08/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health follows MassHealth Guidelines for Medical Necessity Determination for Treatment of Varicose Veins of the Lower Extremities for MassHealth members. Please use the following link to access the MassHealth Guidelines: <u>Guidelines for Medical Necessity Determination for Treatment of Varicose Veins of the Lower Extremities</u>

Prior authorization is required. Photos need to be submitted. All veins to be treated must have documented reflux on ultrasound, including those after a prior procedure.

Interventional treatments must be performed using equipment and sclerosants approved by the FDA in accordance with FDA-approved Labeling (Instructions for Use).

#### **Fallon Health Clinical Coverage Criteria**

For varicose vein and venous insufficiency treatment of lesser or greater saphenous veins and their tributaries, the member must have had:

- A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, AND
- 2. The patient is symptomatic and has one or more of the following:
  - Pain or burning in the extremity severe enough to impair mobility
  - Recurrent episodes of superficial phlebitis
  - Non-healing skin ulceration
  - Bleeding from a varicosity
  - Stasis dermatitis
  - Refractory dependent edema

For venous ligation, vein stripping and/or sclerotherapy, polidocanol microfoam sclerotherapy, cyanoacrylate embolization ablation, or mechanochemical ablation, the above criteria must be met.

For endoluminal therapy (radiofrequency or laser ablation) these additional criteria must be met:

- Absence of aneurysm in the target segment
- Maximum vein diameter of 12 mm for ERFA or 20 mm for laser ablation
- Absence of thrombosis or vein tortuosity, which would impair catheter advancement
- The absence of significant peripheral arterial diseases

#### For tributary 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.

Stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary as described in this policy are met.

If sclerotherapy is used with endovenous radiofrequency ablation, it may be covered if the criteria for reasonable and necessary as described in this policy are met.

Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation, and sclerotherapy.

One pre-operative Doppler ultrasound study or duplex scan will be covered.

#### Medicare

Fallon Health follows coverage indications in National Government Services, Inc. LCD for Varicose Veins of the Lower Extremity, Treatment of (L33575) and LCA: Billing and Coding for Treatment of Varicose Veins of the Lower Extremity (A52870) for Medicare members including Medicare Advantage, NaviCare and PACE plan members.

#### Policy References:

LCD link: Varicose Veins of the Lower Extremity, Treatment of (L33575)

LCA link: Billing and Coding for Treatment of Varicose Veins of the Lower Extremity (A52870)

Treatments for eliminating saphenous (great saphenous vein (GSV), anterior accessory GSV (AAGSV), small saphenous vein (SSV)) reflux (saphenofemoral or saphenopopliteal) are radiofrequency ablation (RFA), laser ablation (EVLA), polidocanol microfoam (PEM), cyanoacrylate embolization (CAE) ablation, and mechanochemical ablation (MOCA). Coverage is only provided for devices with FDA approval or clearance consistent with saphenous ablation and used according to its approved instructions for use.

RFA and EVLA are classified as thermal tumescent (TT) techniques; PEM, CAE and MOCA are non-thermal non-tumescent (NTNT) techniques. Each endovenous ablation approach has advantages and disadvantages; which one is best depends on the unique clinical/anatomical scenario. While saphenous vein ligation and stripping remains an important option in selected cases, it has been largely supplanted by endovenous ablation therapy as primary treatment of saphenous (axial/truncal) vein incompetence.

- 1. Treatments to eliminate the saphenous vein reflux will be considered medically necessary if the plan member remains symptomatic after a six-week trial of conservative therapy and has reflux in a saphenous vein. The components of the conservative therapy include, but are not limited to:
  - weight reduction,
  - a daily exercise plan,
  - periodic leg elevation, and
  - the use of graduated compression stockings.

For coverage of endovenous ablation therapy, the following additional criteria must be met:

- A maximum vein diameter of 12 mm for CAE, PEM and MOCA; and
- Absence of thrombosis or vein tortuosity, which would impair catheter advancement (except for PEM).

The conservative therapy must be documented in the medical record. Inability to tolerate compressive bandages or stockings and the reason for such intolerance must be documented in the medical record.

The patient is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record:

- stasis ulcer of the lower leg,
- significant pain and significant edema that interferes with activities of daily living,
- bleeding associated with the diseased vessels of the lower extremities,
- · recurrent episodes of superficial phlebitis,
- stasis dermatitis, or
- refractory dependent edema.
- 2. Treatments for symptomatic varicose tributaries are either compressive sclerotherapy or microphlebectomy. The treatments of the tributary veins will be considered medically necessary if

saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy.

#### **Exclusions**

- The following treatments are not covered:
  - Surgery, endovenous ablation, or sclerotherapy are typically not performed for varicose veins that develop or worsen during pregnancy because most will spontaneously resolve or improve after delivery.
  - o Reinjection following recanalization or failure of vein closure without recurrent signs or symptoms.
  - Sclerotherapy of the saphenous vein at its junction with the deep system.
  - Noncompressive sclerotherapy
  - o Coil embolization
  - Sclerotherapy for large, extensive or truncal varicose veins/varicosities.
  - Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy for
    patients with severe distal arterial occlusive disease; obliteration of deep venous system; an
    allergy to the sclerosant: or a hypercoaguable state.
  - Any interventional treatment that uses equipment or sclerosants not approved for such purposes by the FDA.
- Cosmetic surgery is not covered. The following treatments are considered cosmetic and will be denied as such:
  - Interventional treatment of asymptomatic varicose veins/varicosities
  - Treatment of telangiectases (CPT code 36568)
  - Sclerotherapy for cosmetic purposes

# Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Fallon Health recognizes that multiple injections are needed to perform sclerotherapy and that responses differ due to the anatomical site being treated. Fallon would not expect to see more than three sclerotherapy sessions for each leg.

Only one sclerotherapy service per treatment session should be reported for either leg, regardless of how many veins are treated per session.

CPT code 37799 should be used to report Trivex procedure.

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
36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than
	telangiectasia), same leg
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 (list separately in addition to code for primary procedure)
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; subsequent vein(s) 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)
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 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
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, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37799	Unlisted procedure, vascular surgery

## References

- National Government Services, Inc. Local Coverage Determination (LCD) for Varicose Veins of the Lower Extremity, Treatment of (L33575). Revision Effective Date: November 21, 2019. Available at: <a href="https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx">https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx</a>. Accessed 02/08/2022.
- 2. National Government Services, Inc. Local Coverage Article. Billing and Coding for Treatment of Varicose Veins of the Lower Extremity (A52870). Revision Effective Date: November 21, 2019.

Available at: <a href="https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx">https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx</a>. Accessed 02/08/2022.

 MassHealth Guidelines for Medical Necessity Determination for Treatment of Varicose Veins of the Lower Extremities. Effective March 1, 2019. Available at: https://www.mass.gov/files/documents/2019/02/28/mng-varicose-veins.pdf. Accessed 02/08/2022.

# **Policy history**

Origination date:

05/01/2014

Approval(s):

Technology Assessment Committee 12/18/2013 (Adopted Interqual Criteria), 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review); 05/27/2020

(adopted Fallon Health criteria).

02/08/2022 (Added clarifying language related to Medicare Advantage,

NaviCare, PACE and MassHealth under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.