Clinical Policy: Sclerotherapy and Chemical Endovenous Abalation for Varicose Veins

Reference Number: CP.MP.146
Date of Last Revision: 04/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sclerotherapy is a minimally invasive procedure to diminish abnormally dilated and symptomatic veins.[1] In this procedure liquid, foam, or glue irritants are injected into unwanted varicose veins causing their eventual reduction.[1-2] This policy describes the medical necessity requirements for sclerotherapy and endovenous ablation with chemical adhesives.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that sclerotherapy using liquid or foam irritants (including, but not limited to, Varithena) are **medically necessary** when meeting the following:[2-5]

A. Varicose veins, one of the following:
   1. Perforating vein located beneath a healed or open venous ulcer and both of the following:
      a. Junctional reflux ≥ 500 milliseconds;
      b. Diameter ≥ 3.5 mm;
   2. Ultrasound-documented varicosities of the greater saphenous vein, smaller saphenous vein, perforating veins, tributary veins, or accessory veins and both of the following:
      a. Junctional reflux ≥ 500 milliseconds and/or vein diameter ≥ 3 mm;
      b. Complications attributed to the varicosities, including any of the following:
         i. Intractable ulceration;
         ii. Hemorrhage or recurrent bleeding episodes from a ruptured varicosity;
         iii. Recurrent superficial thrombophlebitis;
         iv. Severe and persistent pain and swelling, including both of the following:
            a) Duration ≥ 6 months;
            b) Failure of ≥ 3 months of conservative treatment, including compression therapy, unless contraindicated (i.e., suspected or proven peripheral arterial disease, severe peripheral neuropathy, etc.);

B. None of the following contraindications:
   1. Previous administration of sclerotherapy agent < 6 weeks prior;
   2. Allergy to sclerotherapy agent;
   3. Pregnant or within 3 months after delivery;
   4. Acute febrile illness;
   5. Local or general infection;
   6. Severe distal arterial occlusive disease (ankle-brachial index 0.4 or less);
   7. Critical limb ischemia, arterial ulcer(s), gangrene;
   8. Obliteration of deep venous system;
   9. Recent deep venous thrombosis;
   10. Acute deep venous thrombophlebitis or acute superficial thrombophlebitis;
   11. Inability to ambulate;

12. Tortuosity of the great saphenous vein severe enough to impede catheter placement;
13. Klippel-Trenaunay Syndrome or other congenital venous abnormalities;

C. If cyanoacrylate adhesive (e.g. VenaSeal™) is requested, it is for treatment of the small saphenous vein only.

II. It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence in the published peer-reviewed literature to support the use of sclerotherapy for any of the following indications:

A. Asymptomatic varicose veins: superficial reticular veins and/or telangiectasias;
B. For the treatment of all other conditions than those specified above.

Background

Varicose veins are enlarged, twisted blood vessels often found in the lower extremities and can cause significant pain and discomfort and can negatively impact quality of life.[1,6-8] Varicose veins are considered a sign of chronic venous insufficiency, a condition characterized by dysfunction of the valves in veins, which can cause increased blood pressure, blood pooling, and venous reflux in affected areas.[6] Additionally, varicose veins can cause superficial thrombophlebitis, bleeding, and ulceration. The pathophysiology that leads to varicosities include inadequate muscle pump function, incompetent venous valves (reflux), venous thrombosis, and nonthrombotic venous obstruction.[9]

Sclerotherapy

According to clinical practice guidelines by the Society for Vascular Surgery and the American Venous Form, sclerotherapy is a recommended treatment option for varicose veins.[2] Sclerotherapy is a minimally invasive and cost-effective procedure used to treat varicose veins.[3,10-11] To perform this procedure, chemical irritants are injected into the unwanted vein to close varicosities.[1-2,9-10] Destruction of venous endothelial cells and the formation of a fibrotic obstruction facilitate the venous closure due to injection of sclerosing agents.[2,12] Liquid and foam sclerotherapy are the two predominant modalities for the introduction of sclerosing agents.[2,8] Categories of sclerosing agents include osmotic, alcohol, and detergent agents.[2]

Systematic reviews of randomized controlled trials of sclerotherapy have found that choice of sclerosing agents, dose, formulation (foam versus liquid), among other factors lack a significant effect on the efficacy of sclerotherapy for varicose veins.[7,10] Trials using standardized sclerosant doses and clearly defined outcomes are needed in order to obtain higher quality evidence.[7]

There is no consensus in the literature regarding the optimal number of sclerotherapy treatments required to reduce the symptoms associated with varicose veins. Treatment of symptomatic recurrent varicose veins should be performed after careful evaluation of the patient with duplex scanning to assess the etiology, source, type, and extent of recurrent varicose veins.[2] Unnecessary retreatment of an effectively sclerosed vein should not be performed since retreatment of any single area should be delayed for 6–8 weeks to allow the treated veins to completely heal.[6]

Endovenous ablation with cyanoacrylate

Although cyanoacrylate adhesive has been introduced as a chemical adhesive for use in endovenous ablation, future follow-up studies are needed to support the efficacy and safety in treatment of varicose veins. The notable literature currently consists of a retrospective and a prospective study without randomization.[13] Further long-term studies are needed to support the use of cyanoacrylate prior to integration into medical necessity guidelines.[13]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Codes that support medical necessity

CPT® Codes	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.
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
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)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New policy	05/17	06/17
References reviewed and updated. CPT codes updated.	04/18	04/18
Updated description to include mention of glue irritants. Added contraindication for previous administration of sclerotherapy and	03/19	04/19

Reviews, Revisions, and Approvals	Revision Date	Approval Date
syndrome/congenital abnormalities. In "I." added stipulation that liquid or foam agents to be used in sclerotherapy. Added statement that cyanoacrylate adhesive is investigational with supporting background information. In I.A.2.d. removed failure of ≥3 weeks prescription dose analgesic medications for pain and added failure of ≥ 3 months of conservative treatment including compression therapy unless contraindicated.		
Added VenaSeal as an example of cyanoacrylate in the investigational statement in section III. Added codes for cyanoacrylate to a new table of codes that do not support medical necessity. Added perforating veins under a current or healed ulcer as an indication; Edited previous criteria for saphenous veins to apply to saphenous veins or perforating veins. Specialist review.	09/19	10/19
Changed requirement for junctional reflux of greater saphenous veins to 3 mm, from 2.5 mm. Background updated with no impact on criteria. References reviewed and updated. Revised policy statement adding Varithena as an example of a foam irritant.	03/20	04/20
In I.A.2., added tributary and accessory vein treatment as indications when meeting the established criteria.	07/20	08/20
"Experimental/investigational" verbiage replaced in policy statement with descriptive language. References reviewed and updated. Replaced all instances of "member" with "member/enrollee."	04/21	04/21
Renamed policy from "Sclerotherapy for Varicose Veins" to "Sclerotherapy and chemical endovenous ablation for Varicose Veins." Clarified in III to cyanoacrylate is used in endovenous ablation and not sclerotherapy. Updated background accordingly. Changed "review date" in policy header to "date of last revision," and "date" in the revision log header to "revision date."	08/21	
Annual review. Added I.C, that if cyanoacrylate adhesive (VenaSeal) is requested, it is for the small saphenous vein only. Removed section III stating that cyanoacrylate adhesive is not medically necessary. Removed table of codes that do not support medical necessity and added codes 36482 and 36483 to table of codes that support medical necessity. References reviewed and updated. Description and background updated with no impact on criteria. Specialist reviewed.	04/22	04/22

References

1. Scovell S. Injection sclerotherapy techniques for the treatment of telangiectasias, reticular veins, and small varicose veins. UpToDate. www.uptodate.com. Published January 14, 2022. Accessed March 09, 2022.
2. Kabnick LS, Scovell S. Overview of lower extremity chronic venous disease. UpToDate. www.uptodate.com. Published September 22, 2020. Accessed March 09, 2022.
3. Behravesh S, Yakes W, Gupta N, et al. Venous malformations: clinical diagnosis and treatment. Cardiovasc Diagn Ther. 2016;6(6):557-569. doi:10.21037/cdt.2016.11.10

4. 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(5 Suppl):2S-48S. doi:10.1016/j.jvs.2011.01.079
5. Almeida JI, Wakefield T, Kabnick LS, Onyeachom UN, Lal BK. Use of the Clinical, Etiologic, Anatomic, and Pathophysiologic classification and Venous Clinical Severity Score to establish a treatment plan for chronic venous disorders. *J Vasc Surg Venous Lymphat Disord*. 2015;3(4):456-460. doi:10.1016/j.jvsv.2015.05.007
6. Weiss MA, Hsu JT, Neuhaus I, Sadick NS, Duffy DM. Consensus for sclerotherapy. *Dermatol Surg*. 2014;40(12):1309-1318. doi:10.1097/DSS.0000000000000225
7. Kaygin MA, Halici U. Evaluation of liquid or foam sclerotherapy in small varicose veins (ceap c1) with venous clinical severity score. Rev Assoc Med Bras (1992). 2018;64(12):1117-1121. doi:10.1590/1806-9282.64.12.1117
8. Koramaz İ, El Kılıç H, Gökalp F, et al. Ablation of the great saphenous vein with nontumescent n-butyl cyanoacrylate versus endovenous laser therapy. J Vasc Surg Venous Lymphat Disord. 2017;5(2):210-215. doi:10.1016/j.jvsv.2016.09.007
9. Lim CS, Davies AH. Graduated compression stockings. CMAJ. 2014;186(10):E391-E398. doi:10.1503/cmaj.131281
10. de Ávila Oliveira R, Riera R, Vasconcelos V, Baptista-Silva JC. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev. 2021;12(12):CD001732. Published 2021 Dec 10. doi:10.1002/14651858.CD001732.pub3
11. Worthington-Kirsch RL. Injection sclerotherapy. *Semin Intervent Radiol*. 2005;22(3):209-217. doi:10.1055/s-2005-921954
12. Health Technology Assessment. Cyanoacrylate embolization (VenaSeal closure system) for the treatment of varicose veins. Hayes. www.hayesinc.com. Published October 31, 2019 (annual review December 09, 2021). Accessed March 08, 2022.
13. Armstrong DG, Meyr AJ. Compression therapy for the treatment of chronic venous insufficiency. UpToDate. www.uptodate.com. Updated July 06, 2021. Accessed March 08, 2022.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.