Clinical Policy: Sclerotherapy and chemical endovenous ablation for Varicose Veins

Reference Number: CP.MP.146
Date of Last Revision: 08/21

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. In this procedure, liquid, foam, or glue irritants are injected into unwanted varicose veins, causing their eventual reduction. This policy describes the medical necessity requirements for sclerotherapy, and for 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:

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.

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.

III. It is the policy of health plans affiliated with Centene Corporation that current research does not support the use of cyanoacrylate adhesive (e.g. VenaSeal™) for endovenous ablation over other currently available alternatives. Uncertainty remains regarding the comparative effectiveness of the VenaSeal System with other endovenous techniques due to lack of well-designed comparative trials.

Background

Varicose veins can cause significant pain and discomfort, superficial thrombophlebitis, bleeding, and ulceration. As such, chronic venous insufficiency, including symptomatic varicosities, can have a substantial negative impact on quality of life.[1] The pathophysiology that leads to these varicosities include inadequate muscle pump function, incompetent venous valves (reflux), and venous obstruction.[2]

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.[4] Sclerotherapy is a minimally invasive and cost effective procedure used to treat varicose veins. To perform this procedure, chemical irritants are injected into the unwanted vein to close varicosities. Destruction of venous endothelial cells and the formation of a fibrotic obstruction facilitate the venous closure due to injection of sclerosing agents. Liquid and foam sclerotherapy are the two predominant modalities for the introduction of sclerosing agents; examples of such sclerosing agents include osmotic, alcohol and detergent agents.[3,4] A systemic review by Tisi *et al* evaluated 17 randomized controlled trials, and concluded 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.[6]

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.[4] Retreatment of any single area should be delayed for 6–8 weeks to allow the treated veins to heal fully; in this manner, unnecessary retreatment of an effectively sclerosed vein is not performed.[12]

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.[7,9] Further long-term studies are needed to support the use of cyanoacrylate prior to integration into medical necessity guidelines.

Coding Implications

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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

Codes that do not support medical necessity

CPT® Codes	Description
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Updated description to include mention of glue irritants. Added contraindication for previous administration of sclerotherapy and 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.	03/19	04/19
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	

References

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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.

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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.