Clinical Policy: Sclerotherapy and Chemical Endovenous Ablation for Varicose Veins and Other Symptomatic Venous Disorders

Reference Number: CP.MP.146 Coding Implications
Date of Last Revision: 03/25 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 or foam irritants or glue 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®) is **medically necessary** when meeting all the following:

A. Documentation of symptomatic venous disorder of CEAP (Clinical Class, Etiology, Anatomy, Pathology) class two (C2s) or greater (see table 1 for CEAP classification);

B. One of the following:

1. Perforating vein located beneath an open venous ulcer, and both of the following:
   a. Reflux > 500 milliseconds;
   b. Diameter > 3.5 mm;
2. Perforating vein located beneath a healed venous ulcer, and all of the following:
   a. Reflux > 500 milliseconds;
   b. Diameter > 3.5 mm;
   c. Truncal reflux has already been treated;
3. Both of the following:
   a. One of the following:
      i. Axial reflux > 500 milliseconds and vein diameter ≥ 3 mm in the great saphenous vein or accessory veins;
      ii. Reflux > 500 milliseconds and vein diameter ≥ 3 mm in the small saphenous vein;
   b. Complications attributed to venous reflux, including any of the following:
      i. Ulceration;
      ii. Hemorrhage or recurrent bleeding episodes from a ruptured varicosity or telangectasia;
      iii. Superficial thrombophlebitis;
      iv. Severe and persistent pain and/or swelling that interferes with the quality of daily life and persists despite six weeks of conservative treatment, including any of the following, unless contraindicated (i.e., suspected or proven peripheral arterial disease, severe peripheral neuropathy, etc.):
         a) Compression therapy;
         b) Ambulation;
         c) Limb elevation;
         d) Avoiding prolonged sitting and standing;

4. Documentation of Revised Venous Clinical Severity Score (r-VCSS) ≥ 6;

C. None of the following contraindications:
1. Previous administration of sclerotherapy agent in the same vein less than six weeks prior;
2. Allergy to sclerotherapy agent;
3. Pregnancy or within three 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), or gangrene;
8. Obliteration of deep venous system;
9. Acute deep venous thrombophlebitis or acute superficial thrombophlebitis;
10. Prolonged immobility;
11. Tortuosity of the great saphenous vein severe enough to impede catheter placement;
12. Klippel-Trenaunay Syndrome or other congenital venous abnormalities;
13. Potential requirement of the great or small saphenous vein for an arterial or coronary bypass;

D. If cyanoacrylate adhesive (e.g. VenaSeal™) is requested, treatment is for one of the following:
1. The small saphenous vein;
2. The great saphenous vein.

Note: Photographic documentation and/or ultrasound images may be requested to support written documentation.

Table 1. CEAP classification system[3,4]

C (Clinical Manifestations), **E** (Etiology), **A** (Anatomic Distribution), **P** (Pathophysiology)	
Class	**Description**
C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C2r	Recurrent varicose veins
C3	Edema
C4	Changes in skin and subcutaneous tissue secondary to chronic venous disease
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophie blanche
C4c	Corona phlebectatica
C5	Healed venous ulcer
C6	Active venous ulcer
C6r	Recurrent active venous ulcer
s	Symptomatic (may be assigned to classes above)
a	Asymptomatic (may be assigned to classes above)

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 such as 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. Although commonly asymptomatic, they can cause significant pain and discomfort and can negatively impact quality of life.[1,5,6,7] Varicose veins are considered a sign of chronic venous insufficiency, a condition characterized by dysfunction of the valves in veins with venous reflux, which can cause increased local venous blood pressure and blood pooling in affected areas.[5] Additionally, varicose veins can uncommonly be associated with 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.[8]

Sclerotherapy

According to clinical practice guidelines by the Society for Vascular Surgery and the American Venous Forum, sclerotherapy is an acceptable treatment option for varicose veins.[2] Sclerotherapy is a minimally invasive and cost-effective procedure used to treat varicose veins.[9-11] To perform this procedure, chemical irritants are injected into the unwanted vein to close varicosities.[1,2,8,10] 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.[2,7] 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.[6,10] Trials using standardized sclerosant doses and clearly defined outcomes are needed to obtain higher quality evidence.[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.[2] Unnecessary retreatment of an effectively sclerosed vein should not be performed since retreatment of any single area should be delayed for six to eight weeks to allow the treated veins to completely heal.[5]

Clinical practice guidelines updated in 2022 by the Society for Vascular Surgery, the American Venous Forum, and the American Vein and Lymphatic Society recommend that evaluation of venous reflux be performed with duplex ultrasound scanning and all of the following[13]:

1. Performed with the patient standing whenever possible (if patient cannot stand then a sitting of reverse Trendelenburg position can be used);

2. Use of either a Valsalva maneuver or distal augmentation when assessing the common femoral vein and saphenofemoral junction;
3. Use of distal augmentation with either manual compression or cuff deflation when evaluating more distal segments;
4. Performed in an accredited lab by a credentialed ultrasonographer;
5. Ultrasound scan interpreted by a physician trained in venous duplex ultrasound evaluation.

Endovenous ablation with cyanoacrylate

Cyanoacrylate adhesive closure (CAC) uses cyanoacrylate glue (ie VenaSeal) to seal the vein from the saphenofemoral junction without the use of tumescent anesthesia.[14,15] This technique has been shown to be safe and effective and prevents the potential complication of nerve injury.[12,14,15] According to a Hayes review of nine studies, there is an overall low-quality body of evidence regarding the use of VenaSeal due to overall study limitations, lack of follow up on the effectiveness past one year, small amount of studies comparing cyanoacrylate with other alternatives, and "limited numbers of studies reporting the same patient-centered outcomes."[12]

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 2024, 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

CPT® Codes	Description
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
"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
Annual review. Policy title updated to include other symptomatic venous disorders. Minor rewording in policy description with no impact on criteria. Added Criteria I.A. for documentation of symptomatic CEAP Class 2s or greater. Added Criteria I.B. regarding ultrasound documentation requirements. Updated Criteria C. to reflect current guidelines. Removed recent deep vein thrombosis from Criteria I.D.9. Changed "Inability to ambulate" to "prolonged immobility" in I.D.10. Added I.D.13. regarding potential requirement of the great or small saphenous vein for an arterial or coronary bypass. Updated E.2. to include the great saphenous vein in a member/enrollee with a documented lidocaine allergy. Added note at the end of section I. regarding potential requests for photographic documentation and/or ultrasound images to support written documentation. Added table 1., CEAP classification system. Background updated to include 2022 clinical practice guidelines by the Society for Vascular Surgery, the American Venous Form, and the American Vein and Lymphatic Society regarding best practice recommendations for performing and interpreting	04/23	04/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
duplex ultrasound scanning for venous reflux. References reviewed and updated. Reviewed by internal specialist.		
Removed criterion I.B. regarding positioning during ultrasound.	09/23	09/23
Annual review. Updated reflux from ≥ 500 milliseconds to > 500 milliseconds in Criteria I.B.1.a. and in Criteria I.B.2.a. Updated perforating vein diameter from ≥ 3.5 mm to > 3.5 mm in Criteria I.B.1.b. and Criteria I.B.2.b. Updated axial reflux from ≥ 500 milliseconds to > 500 milliseconds in Criteria I.B.3.a.i. Updated reflux from ≥ 500 milliseconds to > 500 milliseconds in Criteria I.B.3.a.ii. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	04/24	04/24
Annual review. Added clarifying language to Criteria II.A. References reviewed and updated.	02/25	02/25
Removed "only" from criteria in I.D.1. Removed requirement of a documented lidocaine allergy from criteria I.D.2.	03/25	03/25

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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.

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.

 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.