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

Reference Number: WNC.CP.130 Coding Implications
Last Review Date: Revision Log

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

Note: 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.

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 WellCare of North Carolina® that sclerotherapy using liquid or foam irritants (including, but not limited to, Varithena®) are medically necessary when meeting 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. Ultrasound-documented varicosities related to reflux performed in a standing, sitting or reverse Trendelenburg position;
C. 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 telangiectasia;
         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;

D.

E. 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. 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. ;
10. Acute deep venous thrombophlebitis or acute superficial thrombophlebitis;
13. prolonged immobility; Tortuosity of the great saphenous vein severe enough to impede catheter placement; Klippel-Trenaunay Syndrome or other congenital venous abnormalities.
14. Potential requirement of the great or small saphenous vein for an arterial or coronary bypass;
15.

F. If cyanoacrylate adhesive (e.g., VenaSeal™) is requested, it is for treatment of ONE of the following:
1. the small saphenous vein only.
2. The great saphenous vein in a member/enrollee who has a documented lidocaine allergy.

G.

H. 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 WellCare of North Carolina® 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
   1. 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.[1,5-7] 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 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 Form, 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]

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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.[5]
Clinical practice guidelines updated in 2022 by the Society for Vascular Surgery, the American Venous Form, and the American Vein and Lymphatic Society recommend that evaluation of venous reflux performed with duplex ultrasound scanning and all of the following[13]:

1. Performed with the member standing whenever possible (if member 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 ultra-sonographer;
5. Ultrasound scan interpreted by a physician trained in venous duplex ultrasound evaluation.

Endovenous ablation with cyanoacrylate
Cyanoacrylate adhesive closure (CAC) uses cyanoacrylate glue (i.e. 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 2022, 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.

CPT®* Codes	Description
SUPPORT MEDICAL NECESSITY	
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 (e.g., 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 (egg, 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 (e.g., 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 (e.g., 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)

HCPCS ®* Codes	Description
No applicable codes.	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
No applicable codes.	

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Renamed policy from "Sclerotherapy for Varicose Veins" to "Sclerotherapy and Chemical Endovenous Ablation for Varicose Veins." Clarified in Section III that cyanoacrylate is used in endovenous ablation and not sclerotherapy. Updated background accordingly. References updated.	02/22	05/22
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	02/23	02/23

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
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.		
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual review. Policy title updated to include other symptomatic venous disorders. Minor rewording in policy description with no impact on criteria. CRITERIA Additions: I.A. for documentation of symptomatic CEAP Class 2s or greater. I.B. regarding ultrasound documentation requirements. C. to reflect current guidelines. I.D.1 "in the same vein" I.D.13. regarding potential requirement of the great or small saphenous vein for an arterial or coronary bypass. F.2. to include the great saphenous vein in a member/enrollee with a documented lidocaine allergy. note at the end of section I. regarding potential requests for photographic documentation and/or ultrasound images to support written documentation. Table 1., CEAP classification system. CRITERIA Deletions: Deleted previous criteria and replaced with above. Removed recent deep vein thrombosis from Criteria I.D.9. CRITERIA Changes: I.D.10 "Inability to ambulate" to "prolonged immobility" Criteria II. "not medically necessary" to "there is insufficient evidence in the published peer-reviewed literature to support the use of sclerotherapy for any of the following indications." 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 duplex ultrasound scanning for venous reflux.		

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North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and*

Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
Professional (CMS-1500/837P transaction)
Institutional (UB-04/837I transaction)
Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer

to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

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.

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

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.