Missouri Care

WellCare (Nebraska)

Sclerotherapy for Varicose Veins:

Policy Number: CP.MP.146

Last Review Date: 4/20

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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]

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]

Although cyanoacrylate adhesive has been introduced as an injectable agent for use in sclerotherapy, 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.

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]

POSITION STATEMENT

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.

I. 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, or perforating 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. Sclerotherapy is **not medically necessary** 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.

III. Cyanoacrylate adhesive (e.g. VenaSeal™) is considered investigational for the treatment of varicose veins.

CODING

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)

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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REVIEWS, REVISIONS, and APPROVALS

	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 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