



Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource

MEDICAL POLICY STATEMENT	
North Carolina Marketplace	
Policy Name & Number	Date Effective
Saphenous Vein Ablation, Adhesive Injection NC-MP-MM-1396	05/01/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Saphenous Vein Ablation, Adhesive Injection

B. Background

Varicose veins (varicosities) are dilated, thickened, elongated, and twisted blood vessels that may appear threadlike or as large grape-like clusters under the skin, most often on the legs. Varicose veins are considered a sign of chronic venous insufficiency, a condition characterized by dysfunction of the valves in veins leading to increased blood pressure, blood pooling, and venous reflux in affected areas. Varicose veins may be asymptomatic, or the associated venous insufficiency may cause symptoms such as heaviness, aching, numbness, swelling, and ulceration of the affected limb. In addition, risk is increased for thrombophlebitis, deep vein thrombosis (DVT), and pulmonary embolism.

Approximately 25 million adults in the United States are affected by varicose veins. This condition can have a significant impact on patients' quality of life (QoL) and increase the health care burden, with an estimated \$1 billion incurred annually for treatment in the United States. Conservative therapy includes weight reduction, exercise and prescribed physical activity (walking, treadmill, cycling), periodic leg elevation and compressive therapy with use of surgical grade compression stockings. Non-surgical treatment for this condition includes radiofrequency ablation (RFA) and endovenous laser ablation (EVLA).

A third, more recent treatment method is Cyanoacrylate adhesive closure (CAC), a catheter-directed procedure that seals the saphenous vein without the use of tumescent anesthesia. It involves the endovenous delivery of cyanoacrylate adhesive to the vein, inducing a foreign body response resulting in fibrosis and closure. Closure rates for CAC are high without use of post procedure compression, which is unique to this nonthermal method of ablation.

C. Definitions

- **Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification** - The CEAP classification for chronic venous disorders serves as a basis to categorize the clinical presentation of the patient, the underlying etiology, what anatomic veins are affected, and the underlying pathology in those veins. The 7 clinical categories are:
 - C0 - No visible or palpable signs of venous disease
 - C1 - Telangiectasies or reticular veins
 - C2 - Varicose veins; distinguished from reticular veins by a diameter of 3mm or more
 - C3 - Edema
 - C4 - Changes in skin and subcutaneous tissue secondary to CVD
 - C4a - Pigmentation or eczema
 - C4b - Lipodermatosclerosis or atrophie blanche
 - C5 - Healed venous ulcer
 - C6 - Active venous ulcer

- **Cyanoacrylate adhesive closure (CAC)** - A nonthermal ablation technique uses a glue delivered into the saphenous vein using a catheter for access that induces a foreign body reaction leading to inflammation and fibrotic occlusion of the vessel.
- **Saphenous veins** - Either of two main superficial veins of the leg, one larger than the other. These are:
 - Great saphenous vein (GSV) - originating in the foot and passing up the medial side of the leg and through the saphenous opening to join the femoral vein, and the
 - Small saphenous vein (SSV) - originating similarly and passing up the back of the leg to join the popliteal vein at the knee.

D. Policy

- I. CareSource considers Saphenous Vein Ablation with cyanoacrylate adhesive medically necessary when **ALL** of the following are met:
 - A. Failure of ≥ 3 months of conservative treatment, which may include:
 1. weight reduction,
 2. exercise plan and prescribed physical activity (walking, treadmill, cycling)
 3. periodic leg elevation, or
 4. compression therapy.
 - B. If contraindicated (suspected or proven peripheral arterial disease, venous leg ulceration, superficial thrombophlebitis or severe peripheral neuropathy, etc.) conservative treatment may be waived.
 - C. Documentation in the medical record of CEAP class C2-C6 disease
 - D. Reflux (>500 msec), and/or vein diameter ≥ 3 mm, and **ANY** of the following:
 1. Ulceration secondary to venous stasis;
 2. Significant pain or significant edema associated with saphenous reflux that interferes with activities of daily living (ADLs);
 3. Hemorrhage or recurrent bleeding associated with ruptured superficial varicosity;
 4. Recurrent episodes of superficial phlebitis; and
 5. Refractory dependent edema.
- II. Non-covered/Contraindications
 - A. CEAP clinical classification C0-C1 is cosmetic and not medically necessary;
 - B. Previous administration of sclerotherapy agent < 6 weeks prior;
 - C. Allergy to cyanoacrylate adhesive;
 - D. Pregnancy;
 - E. Recent or acute deep venous thrombosis (DVT);
 - F. Severe distal arterial occlusive disease (ankle-brachial index 0.4 or less);
 - G. Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
 - H. Failure of a vein closure without recurrent signs or symptoms;
 - I. Any interventional treatment that uses equipment not approved for such purposes by the FDA; and
 - J. Inability to ambulate.

E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	02/15/2023	New Policy
Date Revised		
Date Effective	05/01/2023	
Date Archived		

H. References

1. CMS. LCD39121- Treatment of Varicose Veins of the Lower Extremities (April 3,2022). Retrieved February 15, 2023 from www.cms.gov.
2. Moneta G. Classification of lower extremity chronic venous disorders – UpToDate. Collins KA (Ed), UpToDate, Waltham, MA. Retrieved February 15, 2023 from www.uptodate.com.
3. Merriam-Webster Medical Dictionary. “Saphenous Vein.” Retrieved February 15, 2023 from www.merriam-webster.com.
4. Zegarra TI, Tadi P. CEAP Classification Of Venous Disorders. [Updated 2022 Mar 26]. Stat Pearls. Retrieved February 15, 2023 from www.ncbi.nlm.nih.gov.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.