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VenaSeal (Cyanoacrylate) Policy

Indication/Usage:

The VenaSeal™ (**Cyanoacrylate**) procedure delivers a small amount of a medical chemical adhesive to seal the diseased vein, rerouting blood to nearby healthy veins and providing symptom relief. Chemical adhesive is used for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV). The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux.

Medical Indications for Authorization Commercial Members

Endovascular embolization with cyanoacrylate is considered medically necessary for the treatment of symptomatic venous reflux disease of the Great or Small Saphenous Veins and Accessory Veins when the criteria listed below is met.

CEAP clinical classification greater than 2, and a venous duplex scan within 6 months of planned treatment documenting reflux (>500 msec) of the saphenous or accessory veins and vein size greater than 3 mm.

- A. Any 1 of the following high risk conditions
 - Hemorrhage from a ruptured superficial varicosity
 - Recurrent superficial thrombophlebitis
 - Leg ulceration due to saphenous vein insufficiency **or**
- B. Persistent pain, swelling, burning or itching associated with saphenous reflux or isolated accessory saphenous reflux is demonstrated and severely interferes with ADL's **and** have failed 3 consecutive months of conservative management including weight reduction, exercise, leg elevation and compression stockings.

Treatment plan must be documented including the CPT codes, and indicates if treatment is to the left leg, the right leg, or both leg

Medicare Members

CMS

No NCD found

Palmetto Corporation **LCD ID L39121 Treatment of Varicose Veins of the Lower Extremities**

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Chronic venous disorders of the lower extremity incorporate a spectrum of morphologic and functional abnormalities of the venous system. Symptoms and findings include pain, leg heaviness, aching, swelling, skin dryness, tightness, itching, irritation, and muscle cramps. Clinical signs of venous disease include dilated veins (e.g. telangiectasia, varicose veins), leg edema, skin changes (Lipodermatosclerosis; a fibrosing dermatitis of the subcutaneous tissue), and skin ulceration. The presence of symptoms and clinical signs of venous disease correlates with the presence of venous reflux (in the superficial or deep veins) and/or venous obstruction identified on duplex ultrasound.¹

The Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification 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. CEAP is a classification system. The following is the clinical portion of the CEAP:^{2,10}

CEAP classification for chronic venous disorders:

Clinical Classification	
C ₀	No visible or palpable signs of venous disease
C ₁	Telangiectasias, reticular veins
C ₂	Varicose veins
C _{2r}	Recurrent varicose veins
C ₃	Edema
C ₄	Changes in skin and subcutaneous tissue secondary to chronic venous disease
C _{4a}	Pigmentation or eczema
C _{4b}	Lipodermatosclerosis or atrophie blanche
C _{4c}	Corona phlebectatica
C ₅	Healed
C ₆	Active venous ulcer
C _{6r}	Recurrent active venous ulcer
S	With symptoms attributable to venous disease
A	Absence of symptoms attributable to venous disease

Venous duplex ultrasound examination confirms the diagnosis demonstrating the presence of venous reflux (>500 milliseconds for superficial or perforator veins; >1000 milliseconds for deep veins).³

A variety of treatment modalities are available to treat varicose veins/chronic venous insufficiency.

Treatment modalities include conservative management and invasive procedures.

Conservative Management (Non-Invasive Procedures)

Components of conservative therapy should be discussed and individualized to meet the needs of each patient and must be documented in the medical record. The discussion should include, but is not limited to:

- Weight reduction
- Exercise plan and prescribed physical activity (walking, treadmill, cycling)
- Periodic leg elevation
- Compressive therapy with use of surgical grade compression stockings (minimum 20-30 mmHg)

For patients who meet any 1 of the following criteria, conservative therapy may be waived.

- C4-C6 disease (skin changes assigned to venous disease, healed venous leg ulceration, and active venous leg ulceration)
- Hemorrhage
- Recurrent superficial thrombophlebitis

Chemical Adhesive (Cyanoacrylate Embolization):

This 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. It is used for the treatment of incompetent saphenous veins (GSV, SSV, AAGSV).^{8,14,15,22}

Covered Indications

Medicare will consider invasive procedures (only with the techniques outlined in this local coverage determination (LCD) and under the conditions described) as reasonable and necessary when documentation in the medical record includes a history, physical examination, CEAP clinical classification, and a venous duplex scan documenting reflux (>500 msec).

1. Saphenous veins (GSV, SSV, AAGSV) management, with UGFS, endovenous thermal ablation (radiofrequency or laser), chemical adhesive (cyanoacrylate embolization), MOCA, and surgery (surgical ligation and stripping) is considered reasonable and necessary with documentation in the medical record of CEAP class C2-C6 disease, reflux (>500 msec), and **ANY** of the following signs or symptoms:
 - a. Ulceration secondary to venous stasis;
 - b. Significant pain or significant edema associated with saphenous reflux that interferes with activities of daily living (ADLs);
 - c. Bleeding associated with ruptured superficial varicosity;
 - d. Recurrent episodes of superficial phlebitis;
 - e. Stasis dermatitis;

f. Refractory dependent edema

CPT Codes

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)

Limitations

SummaCare considers VenaSeal (Cyanoacrylate) experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare

Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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