

## BlueCross BlueShield of Tennessee Medical Policy Manual

### Varicose Vein Treatments for the Lower Extremities

#### DESCRIPTION

Varicose veins, enlarged, dilated, and tortuous vessels are a common clinical manifestation of chronic venous insufficiency. These veins can be found anywhere on the body but occur most often in the lower extremities.

The superficial venous system of the lower extremities includes the great and small saphenous veins and their tributaries. The deep system includes the popliteal and femoral veins. Perforator veins interconnect these parallel systems. One way valves are located throughout the superficial system, that aids the cephalad flow of venous blood. Typically varicose veins are related to incompetence of these valves which leads to increased hydrostatic pressure in the unsupported superficial venous system that can ultimately result in an accumulation of blood and expansion/bulging of the veins. Valves in the perforator veins can also become incompetent thus allowing a backflow of blood to the superficial system resulting in high venous pressure and the development of varicose veins.

Telangiectasias (i.e. spider veins, spider bursts, web veins, thread veins, dilated venules) are permanently dilated blood vessels that create fine, thread-like veins. Usually, they are limited to the dermis and are small ( $\leq 1$  mm in diameter). The treatment of telangiectasias is most commonly performed for cosmetic improvement.

The CEAP classification is a method commonly used to document the severity of chronic venous disease and is based on clinical presentation (C), etiology (E), anatomy (A), and pathophysiology (P).

CEAP Classification:

Class	Definition
C - Clinical Classification, supplemented by "A" for asymptomatic and "S" for symptomatic presentation	Class 0: No visible or palpable signs of venous disease Class 1: Telangiectasia, reticular veins, malleolar flare Class 2: Varicose veins Class 3: Varicose veins with edema alone (no skin changes) Class 4: Varicose veins with skin changes ascribed to venous stasis (e.g., pigmentation, venous eczema, lipodermatosclerosis) Class 5: Varicose veins with skin changes including healed ulceration Class 6: Varicose veins with skin changes including active ulceration
E - Etiology	Congenital, Primary, Secondary, No venous disease
A - Anatomy	Superficial, Perforator, Deep, No venous location
P - Pathophysiology	Reflux or obstruction (alone or combined); Basic or Advanced

The treatment of varicose veins depends on the severity of the problem. Asymptomatic varicose veins and those with moderate symptoms are treated with conservative measures such as exercise, elevation of leg(s), supportive stockings, the avoidance of tight clothing, and prolonged standing. Varicose veins with severe symptoms may be treated with more invasive techniques including surgery.

Surgical techniques, generally used to treat large varicose veins, include ligation (tying off a vein), stripping (removing a long segment of vein with a special instrument), ambulatory phlebectomy (removal of a vein through tiny incisions), endoluminal radiofrequency ablation (e.g., VNUS® Closure™ System) and endoluminal laser ablation [e.g., EVLT (endovenous laser therapy) procedure kit]. Radiofrequency energy or laser therapy is similarly designed to damage the intimal wall of the vessel, resulting in fibrosis and ultimately obliteration of a long segment of the vein.

Sclerotherapy is a non surgical procedure used to eradicate varicose veins and/or improve the appearance of the leg. This involves injection of a sclerosant/foam directly into the vein resulting in changes to the lining of the vein wall. The vein is then considered sclerosed or thrombosed no longer able to serve as conduit for venous blood flow.

#### POLICY

- Surgical interventions (e.g., ligation, stripping, ambulatory phlebectomy) for the treatment of varicose veins are considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Endoluminal radiofrequency ablation and/ or endoluminal laser ablation for the treatment of varicose veins is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Sclerotherapy of the great saphenous vein, with or without associated ligation of the saphenofemoral junction is considered **investigational**.
- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered **investigational**.

- Sclerotherapy or echosclerotherapy (also known as ultrasound - guided sclerotherapy) of documented and diseased perforator veins when performed either at the same time as, or for the treatment of residual or recurrent symptomatic disease following surgical ligation, stripping, ambulatory phlebectomy, endoluminal radiofrequency ablation, or endoluminal laser ablation of the great or small saphenous veins is considered **medically necessary** if the medical appropriateness criteria are met. (See **Medical Appropriateness below.**)
- Sclerotherapy or echosclerotherapy for all other varicose veins is considered **cosmetic**
- Treatment of asymptomatic veins and/or the treatment of telangiectasias or spider veins using techniques, including but not limited to the following, are considered **cosmetic**:
  - Surgical interventions
  - Sclerotherapy
  - Intense Pulsed Light (e.g. PhotoDerm, VasoLight, and VeinLase)
  - Transdermal laser therapy
  - Electrodesiccation

#### MEDICAL APPROPRIATENESS

- Varicose vein treatment is **medically appropriate** if **ANY ONE** of the following is met:
  - Surgical intervention, endoluminal radiofrequency, and endoluminal laser ablation, for the treatment of varicose veins if **ALL** of the following criteria are met:
    - Physician documented physical assessment that clearly demonstrates venous insufficiency as evidenced by **ANY ONE** of the following is met:
      - Leg ulcerations, recurrent cellulitis, continuous stasis dermatitis with associated dependent edema related to documented venous insufficiency (CEAP classification 4, 5, or 6)
      - History of a bleeding varix or recurrent bleeding of a varix (CEAP classification 4, 5, or 6)
      - Recurrent episodes of phlebitis or thrombophlebitis (CEAP classification 4, 5, or 6)
      - Edema with a greater than 2 cm difference in thigh, calf, or ankle circumference compared to the contralateral limb or the circumference obtained after 24 hour elevation.(CEAP 3)
      - Color images taken in an upright position (i.e., standing or reverse Trendelenburg) that document the presence of CEAP 2 or CEAP 3 disease in individuals with **ANY ONE** of the following:
        - Pain results in impaired mobility
        - Pain results in an inability to perform activities of daily living (ADL)
    - Venous duplex doppler and or spectral flow ultrasound study has been performed in the upright position (i.e., standing or reverse Trendelenburg) and **ALL** of the following are met:
      - Adequate venous capacity of the deep veins
      - Absence of acute deep venous thrombosis
      - Written documentation of high volume reflux with significant venous insufficiency in the saphenous veins as manifested by outward flow lasting more than 500 milliseconds
    - **ABSENCE** of **ALL** of the following:
      - Pregnancy
      - Symptomatic arterial disease
      - Acute deep venous thrombosis
      - Critical limb ischemia
      - Severe systemic disease
      - Local or general infection
      - Inability to ambulate
      - Advanced collagen/vascular disease
      - Acute superficial venous thrombophlebitis
      - Acute febrile illness
      - Uninterrupted anticoagulant therapy
  - Sclerotherapy or echosclerotherapy (also known as U/S sclerotherapy) if **ALL** of the following are met:
    - Procedure is performed on diseased or pathologic perforator veins
    - Written documentation of high volume reflux with significant venous insufficiency in the perforator vein as manifested by outward flow lasting more than 500 milliseconds from venous duplex doppler and or spectral flow ultrasound study
    - **ANY ONE** of the following is met:
      - Performed simultaneously with a **medically necessary** surgical intervention (e.g., ligation, stripping, ambulatory phlebectomy), endoluminal radiofrequency, or endoluminal laser ablation of the great or small saphenous
      - Performed following a **medically necessary** surgical intervention (e.g., ligation, stripping, ambulatory phlebectomy), endoluminal radiofrequency, or endoluminal laser ablation of the great or small saphenous when there is residual or recurrent symptomatic disease
    - **ABSENCE** of **ALL** of the following:
      - Pregnancy
      - Allergy to the sclerosant
      - Symptomatic arterial disease
      - Acute deep venous thrombosis
      - Critical limb ischemia
      - Severe systemic disease
      - Local or general infection
      - Inability to ambulate
      - Advanced collagen/vascular disease
      - Acute superficial venous thrombophlebitis

- Acute febrile illness
- Uninterrupted anticoagulant therapy

### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

### ADDITIONAL INFORMATION

Transillumination, as a technique to enhance phlebectomy and ultrasound guidance may be utilized by the provider. However, both are considered incidental to the procedures and use in the performance of surgical procedures for the treatment of varicose veins is inclusive in the code description for the surgical intervention.

- Complications of venous stasis include but are not limited to the following:
  - Induration
  - Dermatitis
  - Superficial ulceration
  - Large varicosities subject to trauma
  - Recurring phlebitis

No controlled studies were found in the published literature that validate the application or the long-term outcomes of sclerotherapy of the greater saphenous vein, with or without associated ligation of the saphenofemoral junction or provide comparisons to conventional techniques. In addition, no controlled studies were found in the published literature that validates the long-term application of endoluminal radiofrequency ablation or endoluminal laser ablation for the treatment of other conditions/diseases.

Currently, in the United States, endovenous thermal ablation and surgical ligation and stripping are performed most often for saphenous veins. Ambulatory phlebectomy is an alternative for tributary veins or localized varicosities, especially at larger vein diameters. Surface laser therapy can be used for cosmetic improvements in telangiectasias and reticular veins, but liquid sclerotherapy is considered first-line cosmetic therapy for these veins on the lower extremity.

There are two FDA approved solutions to perform sclerotherapy. (Sotradecol®, Polydocanol®) on veins less than 3mm in diameter. These solutions are much safer and have a better side effect profile than the old hypertonic saline solution. Foam application of these agents is considered off-label.

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