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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

The venous system of the lower extremities consists of the superficial system (greater, lesser and accessory saphenous veins), the deep system (popliteal and femoral veins) and the perforator veins that connect the superficial and deep systems. Tributaries are veins that empty into a larger vein. One-way valves direct the return of blood up the lower limb. Since venous pressure in the deep system is generally greater than the superficial system, valve incompetence may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins are a result of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations and hemorrhage.

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Description: (cont.)

Treatment modalities include the following:

Endovenous Laser Ablation:
A laser fiber is inserted in the saphenous vein is activated and slowly withdrawn resulting in fibrosis and occlusion of the vein.

Endovenous Mechanochemical Ablation:
Endovenous mechanochemical ablation utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulphate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in RF or EVLT ablation. ClariVein® is one example of mechanochemical ablation.

Endovenous Radiofrequency Ablation:
A catheter is inserted in the saphenous vein and high-frequency radio waves are emitted as the catheter is slowly withdrawn resulting in fibrosis and occlusion of the vein. Includes the VNUS® Closure™ System.

Endovenous Cryoablation:
A catheter is inserted and extreme cold is applied. Endovenous cryoablation has been investigated in the treatment of varicose veins.

Ligation and Stripping:
Ligation is the surgical tying of a vein. Stripping is the surgical removal of a vein.

Phlebectomy:
A hook-like instrument is inserted through several tiny incisions and a section of the vein is hooked and removed through the incision.

May also be known as stab avulsion, hook phlebectomy or ambulatory phlebectomy.

Photoderm VascuLight® Therapy:
Intense broad spectrum pulsed light selectively targets specific tissue. Used for vascular lesions, e.g., spider veins, birthmarks, age spots, freckles.

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Description: (cont.)

Sclerotherapy:
A liquid sclerosing solution is injected into a vein resulting in scarring and occlusion of the vein. Microfoam sclerotherapy is an aerated, detergent-like compound that spreads to sufficiently fill the vein, causing contraction and collapse.

Echosclerotherapy is the use of duplex ultrasound to guide the injection. A variation of echosclerotherapy is Comprehensive Objective Mapping, Precise Image-guided Injection, Antireflux Positioning and Sequential (COMPASS). The COMPASS protocol is a more detailed analysis of the deep and superficial venous systems. This includes preoperative doppler ultrasonography to identify the origin of reflux, intraoperative doppler ultrasonography to guide the injection of the sclerosing agent, positioning of the legs elevated to eliminate venous hypertension and reflux, and 2-3 sequential sessions of sclerotherapy until the varicosities resolve.

Transluminate sclerotherapy is the use of a hand held light placed externally against the lower extremity for illumination of the veins to guide the injection.

Transilluminated Powered Phlebectomy:
An illuminator is inserted through a groin incision, placed under the varicosities and as lights are dimmed the varicose veins become visible. A resector is inserted beneath the illuminated veins and the tip of the resector follows the veins slowly to chop and aspirate the fragments. Includes the Trivex™ System.

Subfascial Endoscopic Perforator Surgery (SEPS):
A minimally invasive procedure meant to interrupt incompetent perforator veins. Guided by duplex ultrasound, small incisions are made and the perforating veins are clipped or divided using endoscopic scissors. SEPS has been performed as an alternative to the open surgical procedure known as the Linton procedure.

Transdermal Laser Ablation:
Laser delivered through the skin to the vein. Transdermal laser ablation has been investigated in the treatment of varicose veins. Also known as transcutaneous laser ablation or non-endovenous laser ablation.

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Criteria:

Greater or Lesser Saphenous Veins:

- Treatment of the greater or lesser saphenous veins by surgery (ligation and stripping) or endovenous radiofrequency or laser ablation is considered ***medically necessary*** for symptomatic varicose veins/venous insufficiency with documentation of **ALL** of the following:

  1. Demonstrated saphenous reflux
  2. **One** or more of the following:

     - Ulceration secondary to venous stasis that fails to respond to compressive therapy
     - Recurrent superficial thrombophlebitis that fails to respond to compressive therapy
     - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
     - Persistent pain, swelling, itching burning or other symptoms are associated with saphenous reflux and **ALL** of the following:

       - Symptoms significantly interfere with activities of daily living
       - Conservative management including compressive therapy for at least 3 months has not improved symptoms

- If above criteria not met, treatment of greater or lesser saphenous veins by surgery, endovenous radiofrequency or laser ablation is considered ***cosmetic*** and ***not medically necessary***.

Accessory Saphenous Veins:

- Treatment of the accessory saphenous veins by surgery (ligation and stripping) or endovenous radiofrequency or laser ablation is considered ***medically necessary*** for symptomatic varicose veins/venous insufficiency with documentation of **ALL** of the following:

  1. Incompetence of the accessory saphenous vein is isolated, or the greater or lesser saphenous veins had been previously eliminated (at least 3 months)
  2. Demonstrated accessory saphenous reflux
  3. **ONE** or more of the following:

     - Ulceration secondary to venous stasis that fails to respond to compressive therapy
     - Recurrent superficial thrombophlebitis that fails to respond to compressive therapy
     - Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity
     - Persistent pain, swelling, itching burning or other symptoms are associated with saphenous reflux and **ALL** of the following:

       - Symptoms significantly interfere with activities of daily living
       - Conservative management including compressive therapy for at least 3 months has not improved the symptoms

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Criteria: (cont.)

- If above criteria not met, treatment of accessory saphenous veins by surgery, endovenous radiofrequency or laser ablation is considered ***cosmetic*** and ***not medically necessary***.

Symptomatic Varicose Tributaries:

- The following treatments are considered ***medically necessary*** as a component of the treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment (surgery, radiofrequency or laser) of the saphenous veins:

  1. Stab avulsion
  2. Hook phlebectomy
  3. Sclerotherapy or echosclerotherapy (up to four treatment sessions per leg)
  4. Transilluminated powered phlebectomy
  5. Photoderm vasculight (up to four treatment sessions per leg)

- Treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment of saphenous veins using any other techniques not listed above is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Perforator Veins:

- Surgical ligation (including subfascial endoscopic perforator surgery) or endovenous radiofrequency or laser ablation of incompetent perforator veins is considered ***medically necessary*** as a treatment of leg ulcers associated with chronic venous insufficiency with documentation of **ALL** of the following:

  1. Demonstrated perforator reflux
  2. Superficial saphenous veins (greater, lesser or accessory saphenous and symptomatic varicose tributaries) have been previously eliminated
  3. Ulcers have not resolved following combined superficial vein treatment and compression therapy for at least 3 months
  4. Venous insufficiency is not secondary to deep vein thromboembolism

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Criteria: (cont.)

- Ligation or ablation of incompetent perforator veins performed concurrently with superficial venous surgery is ***not medically necessary*** if above criteria are not met.

Other:

- Treatment of the following conditions is considered ***cosmetic*** and ***not medically necessary***:

  1. Angiomata
  2. Capillary venous ectasis (dilatation)/ venulectasia
  3. Hemangiomata
  4. Phlebectasia (vein dilatation)
  5. Reticular vein(s)
  6. Spider nevus (nevus araneous; congenital, spider-shaped birthmark)
  7. Stellate angioma (star-shaped tumor composed of blood vessels)
  8. Telangiectasias (spider veins; small dilated vessels creating small focal red lesions)

- The following techniques for all other indications not previously listed are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These techniques include, *but are not limited to:*

  - Sclerotherapy of perforator, greater or lesser saphenous or accessory saphenous veins
  - Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
  - Stab avulsion, hook phlebectomy or transilluminated powered phlebectomy of perforator, greater or lesser saphenous or accessory saphenous veins
  - Endovenous radiofrequency or laser ablation of tributary veins
  - Endovenous cryoablation of any vein
  - Transdermal laser ablation of varicose veins
  - Mechanochemical ablation of any vein

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Resources:

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VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

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16. International Venous Digest. Prospective Study of Sclerosing Foam in the Treatment of Truncal Varices of the Lower Limbs. *Phlebologie.* 2002.

17. International Venous Digest. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVeS Study). *J Vasc Surg.* 2003 Aug 2003;38(2):207-214.

18. InterQual® Care Planning Procedures Adult. Ligation and Stripping, Varicose Veins.

19. InterQual® Care Planning Procedures Adult. Sclerotherapy, Varicose Veins.

20. InterQual® Care Planning Procedures Adult. Endovenous Ablation, Varicose Veins.

21. Jafarian A, Emami-Razavi SH, Neshati M. Subfascial endoscopic perforator vein surgery: the first report from Iran. *Arch Iran Med.* 2006 Jan 2006;9(1):16-19.

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VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

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VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Resources: (cont.)

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41. Yamaki T, Nozaki M, Iwasaka S. Comparative study of duplex-guided foam sclerotherapy and duplex-guided liquid sclerotherapy for the treatment of superficial venous insufficiency. *Dermatol Surg.* 2004 May 2004;30(5):718-722; discussion 722.

FDA Summary Statements for VNUS® Closure™ System:

- FDA-approved indication: Endovascular coagulation of blood vessels in patients with superficial vein reflux.

FDA Summary Statements for VNUS® RFS and RFS Flex:

- FDA-approved indication: For use in vessel and tissue coagulation including treatment of incompetent (i.e., refluxing) perforator and tributary veins.

FDA Summary Statements for EVLT™ Diomed 810nm diode laser:

- FDA-approved indication: Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Resources: (cont.)

FDA Summary Statements for EVLT™ Kit and the D15 Plus and D30 Plus Diode Lasers:

- FDA-approved indication: The 810 nm Diomed Laser and EVLT Procedure Kit are intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The Diomed D15 plus and D30 plus and EVLT Kits are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity.

FDA Summary Statements for ELVeS® Ceralas D 10-60 810nm diode laser (VenaCure™):

- FDA-approved indication: Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

FDA Summary Statements for Angiodynamics Inc. 600 um Fiber and Venacure Procedure Kit:

- FDA-approved indication: Endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

FDA Summary Statements for powered surgical laser instruments. Device names include, *but are not limited to*:

Medilas™ D Fibertom Laser (Medilas D)
Medilas™ D SkinPulse Laser (SkinPulse)
Medilas™ D SkinPulse S (SkinPulse S)

- FDA-approved indication: Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.