

Medical Policy

Varicose Vein Treatment

Policy Number: 1025

Policy History			
Approve Date:	10/20/2014	Effective Date:	10/20/2014
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Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

- I. WEA Trust considers the following procedures as medically necessary for the treatment of varicose veins when the criteria outlined below are met.
- II. Radiofrequency saphenous vein ablation (RFA) may be indicated when **ALL** of the following are present.
 - A. Saphenofemoral valve incompetence is documented by duplex ultrasound or other imaging test and has reflux duration of 500 milliseconds (ms) or greater in the vein to be treated AND
 - B. Vein size is 3.0 mm or greater in diameter (not valve diameter at junction) AND
 - C. Saphenous venous insufficiency symptoms cause functional impairment, which include one or more of the following.
 - i. Leg edema interfering with activities of daily living
 - ii. Leg fatigue interfering with activities of daily living
 - iii. Leg pain interfering with activities of daily living and requiring chronic analgesic medication
 - iv. Persistent or recurrent superficial thrombophlebitis OR
 - v. Persistent or recurrent venous stasis ulcer OR
 - vi. More than one episode of minor hemorrhage from a ruptured superficial varicosity OR
 - vii. Single significant hemorrhage from a superficial varicosity AND
 - D. There is no clinically significant lower extremity arterial disease AND
 - E. There is no deep venous thrombosis on duplex ultrasound or other imaging test
 - F. There is no significant symptomatic improvement in response to three month or longer trial of fitted elastic support hose.

NOTE: A trial of conservative management is not required for person with persistent or recurrent varicosities who have undergone prior radiofrequency ablation as conservative management is unlikely to be successful in this situation.

- III. Endovascular laser saphenous vein ablation (EVLA) may be indicated when **ALL** of the following are present
- A. Saphenofemoral valve incompetence is documented by duplex ultrasound or other imaging test and has reflux duration of 500 milliseconds (ms) or greater in the vein to be treated AND
 - B. Vein size is 3.0 mm or greater in diameter (not valve diameter at junction) AND
 - C. Saphenous venous insufficiency symptoms cause functional impairment, which include one or more of the following.
 - i. Leg edema interfering with activities of daily living
 - ii. Leg fatigue interfering with activities of daily living
 - iii. Leg pain interfering with activities of daily living and requiring chronic analgesic medication
 - iv. Persistent or recurrent superficial thrombophlebitis OR
 - v. Persistent or recurrent venous stasis ulcer OR
 - vi. More than one episode of minor hemorrhage from a ruptured superficial varicosity OR
 - vii. Single significant hemorrhage from a superficial varicosity AND
 - D. There is no clinically significant lower extremity arterial disease AND
 - E. There is no deep venous thrombosis on duplex ultrasound or other imaging test AND
 - F. There is no significant symptomatic improvement in response to three month or longer trial of fitted elastic support hose AND
 - G. The member is not pregnant or nursing

NOTE: A trial of conservative management is not required for person with persistent or recurrent varicosities who have undergone prior endovenous ablation as conservative management is unlikely to be successful in this situation.

Endovenous ablation procedures are considered medically necessary adjunctive treatment of symptomatic accessory saphenous veins for persons who meet medical necessity criteria for endovenous ablation above and who are being treated or have previously been treated by one of the procedures listed above for incompetence (i.e., reflux) at the saphenofemoral junction or saphenopopliteal junction and anatomically related persistent junctional reflux is demonstrated after the great or small saphenous veins have been removed or ablated.

- IV. Saphenous vein stripping (ligation) may be indicated when all of the following are present.
- A. Saphenofemoral valve incompetence is documented by duplex ultrasound and reflux duration of 500 milliseconds or greater in the vein to be treated and/or other imaging test AND
 - B. Vein size is 3.0 mm or greater in diameter (not valve diameter at junction) AND
 - C. Saphenous venous insufficiency symptoms cause functional impairment, which includes one or more of the following.
 - i. Leg edema interfering with activities of daily living
 - ii. Leg fatigue interfering with activities of daily living
 - iii. Leg pain interfering with activities of daily living and requiring chronic analgesic medication
 - iv. Persistent or recurrent superficial thrombophlebitis OR
 - v. Persistent or recurrent venous stasis ulcer OR
 - vi. More than one episode of minor hemorrhage from a ruptured superficial varicosity OR
 - vii. Single significant hemorrhage from a superficial varicosity AND
 - D. No clinically significant lower extremity arterial disease AND
 - E. No deep venous thrombosis on duplex ultrasound or other imaging test AND
 - F. No significant symptomatic improvement in response to three months or longer trial of fitted elastic support hose AND
 - G. Radiofrequency or laser ablation is contraindicated or not available.

NOTE: A trial of conservative management is not required for person with persistent or recurrent varicosities who have undergone prior vein stripping/ligation as conservative management is unlikely to be successful in this situation.

- V. Leg vein sclerotherapy [liquid or foam (endovenous chemical ablation)] may be indicated for one or more of the following.
- A. More than one episode of minor hemorrhage from ruptured superficial varicosity OR
 - B. Single significant hemorrhage from a superficial hemorrhage from a superficial varicosity OR
 - C. Recurrent or residual symptomatic superficial varicosities (greater than 3.0 mm or less than 6.0 mm) are present after vein stripping or ablation (there must be a three to six -month observation period since the ablation or stripping procedure) OR
 - D. Skin ulcer with surrounding large superficial varices develop, but are not associated with saphenofemoral valve incompetence OR
 - E. Symptomatic superficial varices persist for which surgery is not advisable.

NOTE: If above criteria are met a maximum of 20 injections PER leg, per session with a maximum of two sessions over six months may be authorized (total of four sessions if both lower extremities are affected). Additional sets of injections may be authorized, one at a time, for a maximum of two additional sessions/PER leg over six months may be medically necessary for persistent or recurrent symptoms when the above criteria are met.

- VI. Ambulatory Phlebectomy may be indicated if ALL of the following are met.
- A. Visible and/or palpable veins (2.5 mm or greater in diameter) are causing symptoms interfering with activities of daily living AND
 - B. Have been (or are currently being) treated with one of the procedures previously listed

NOTE: A trial of conservative treatment is not required for persons with persistent or recurrent varicosities or ulcers who have undergone prior endovenous procedures or stripping in the same leg because conservative treatment is unlikely to be successful in this situation AND

- C. Doppler or duplex ultrasound studies completed prior to treatment demonstrate significant reflux at the saphenofemoral or saphenopopliteal junctions or involve the greater or lesser saphenous veins.

NOTE: If an ultrasound was initially performed, then a repeat ultrasound is not necessary prior to phlebectomy.

NOTE: If above criteria are met, up to two multiple stab phlebectomy sessions (maximum of 20 incisions per leg) over six months may be authorized (total of four sessions if both extremities are affected). Additional sessions may be authorized, one at a time, for maximum of two additional multiple stab phlebectomy sessions per extremity may be medically necessary for persistent or recurrent symptoms.

- VII. Perforator vein treatment is medically necessary if ALL of the following criteria are met:
- A. Vein to be treated is 3.0 mm or greater in diameter, AND
 - B. Reflux duration of 500 milliseconds or greater in the vein to be treated by recent imaging test after removal/ablation of the greater saphenous vein or small saphenous vein.

Limitations of Coverage

- I. Member policies should be reviewed for exclusions and preauthorization requirements.
- II. If services or procedures listed above are used for a condition/diagnosis other than is listed in the Indications of Coverage, related claims will deny as not medically appropriate.
- III. If services or procedures listed above are used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, related claims will deny as not medically necessary.

- IV. Routine post-operative ultrasound is considered not medically necessary.
- V. The use of ultrasound guidance during a treatment is an integral component of the procedure and is not reimbursed separately.
- VI. Treatment of any vein less than 3.0 mm in size (e.g. telangiectasias, spider veins, reticular veins) is considered cosmetic and a policy exclusion.
- VII. The following treatments are considered experimental or investigative as there is insufficient peer-reviewed literature in documenting the effectiveness of these treatments, comparing methodologies, and long-term outcomes.
 - A. Photothermal sclerosis
 - B. Transilluminated phlebectomy (TriVex)
 - C. Transdermal laser therapy
 - D. ClariVein® Occlusion Catheter: The Nonthermal Vein Ablation System also known as Endomechanical or mechanochemical ablation (MOCA)
 - E. Asclera polidocanol injections
 - F. Varithena injections
 - G. Micronized purified flavonoid fraction treatment
 - H. VeinGogh Ohmic Thermolysis System
 - I. Use of medical adhesive (e.g., VariClose Vein Sealing System, VenaSeal Closure System).
 - J. Synthetic matrix metalloproteinases inhibitors
 - K. Subfascial endoscopic perforator surgery (SEPS) for the treatment of venous insufficiency as a result of post-thrombotic syndrome
- VIII. In addition the following services are considered experimental and investigational in predicting predisposition to varicose veins, adequacy of treatment or possibility of recurrence due to insufficient evidence of their effectiveness:
 - A. Measurements of plasma growth factors (e.g., angiopoietin-1 (ANG1), angiopoietin-2 (ANG 2), epidermal growth factor (EGF), platelet-derived growth factor (PDGF) and vascular endothelial growth factor (VEGF).
 - B. Polymorphism genotyping of matrix metalloproteinases genes (e.g., MMP1, MMP2, MMP3 and MMP7).

Background

Varicose veins are enlarged, twisted veins that can be seen under the surface of the skin. Veins contain one way valves to help keep blood flowing toward the heart. Varicose veins in the legs occur when the valves are weakened or damaged and as a result, blood may back up and pool (venous insufficiency). The greater saphenous vein is the large superficial vein in the leg running from the groin to the ankle and the most common site of varicose veins. In the groin, the greater saphenous vein joins the femoral vein at the saphenofemoral junction. The femoral vein goes to the heart. The lesser saphenous vein is slightly smaller and starts at the knee and runs to the ankle.

Varicose veins are a common condition affecting about half of adults over 50 years. Women are more commonly affected than men. Factors which may contribute to the development of varicose veins include family history; gender; older age; hormonal changes during puberty, pregnancy, or menopause; hormone replacement; birth control pills, overweight/obesity; and standing/sitting for long periods of time.

In most cases, varicose veins do not cause pain or discomfort and are only a cosmetic concern. More serious varicose veins might cause symptoms including pain, throbbing, restlessness, heaviness, and cramping. These symptoms usually can be relieved by elevating the legs and/or wearing support stockings. Varicose veins may be an indication of circulatory problems and may lead to skin ulcers, bleeding, superficial thrombophlebitis, or deep

vein thrombosis. Spider veins are smaller than varicose veins and typically do not cause pain or require medical treatment.

Conservative treatments for varicose veins include weight loss, walking, good skin hygiene, elevation, and wearing compression stockings. There are three types of stockings: support pantyhose, over the counter gradient compression hose, and prescription strength compression hose which must be fitted by a professional. If conservative treatments fail to relieve symptoms, more invasive procedures may be indicated.

Invasive treatments for symptomatic varicose veins include radiofrequency ablation, laser ablation, sclerotherapy, phlebectomy, and vein stripping. These procedures and indications are described below. Depending on the severity of the varicose veins, more than one procedure may be medically necessary.

Endovenous radiofrequency ablation (VNUS® RF or Closure® procedure) of the saphenous vein is a minimally invasive procedure in which electrical energy is delivered through a radiofrequency catheter that has been passed through the skin to the desired location in the saphenous vein. It causes thermal destruction of the venous tissue. Ultrasonography is used to confirm and map all areas of venous reflux and to trace the path of the greater saphenous trunk from the saphenofemoral junction down the leg to the upper calf.

Endovenous laser ablation of the saphenous vein (EVLA) is a minimally invasive procedure in which endovenous laser causes thermal destruction of the venous tissues. Laser energy is delivered through a bare laser fiber that has been passed through the skin by micropuncture technique to the desired location in the saphenous vein. Ultrasonography is used to confirm and map all areas of reflux and to trace the path of the greater saphenous trunk from the saphenofemoral junction down the leg to the upper calf.

Sclerotherapy is the most common treatment for varicose veins (and spider veins). The procedure involves injecting a sclerosing agent (a liquid saline solution or foam) under ultrasound guidance. The chemical agent causes damage and scarring in the vein which causes the vein to close.

Saphenous vein stripping is a surgical procedure to treat large, severe varicose veins. The saphenous vein is tied off and pulled out by a specialized instrument that has been inserted into the vein. The attached perforator veins are avulsed during the procedure which causes bruising, pain, and soreness after surgery. Negative side effects of this procedure are saphenous nerve damage, swelling, and scarring. Nerve damage can be reduced if there is limited stripping below the knee.

Phlebectomy is a minimally invasive procedure that removes surface varicose veins. There are two types of phlebectomy: ambulatory and transilluminated powered phlebectomy (TIPP). In an ambulatory phlebectomy, the veins are removed with hooks through several small punctures or incisions in the legs. No stitches are required and the scars are minimal because the incisions are so small. This procedure is often done following an EVLA.

Transilluminated powered phlebectomy (TIPP) is similar to ambulatory phlebectomy but slightly more invasive. In a TIPP, two small incisions are made near the varicose vein. A tumescent canula illuminator (TCI) that contains a fiber optic light that makes the veins easily visible is inserted in one incision. Current literature does not support TIPP as superior over conventional ambulatory phlebectomy and is not indicated for policy coverage at this time

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