VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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

**Description:**

The venous system of the lower extremities consists of the superficial system (great small 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.

The standard classification of venous disease is the CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic) classification system.

The Etiologic, Anatomic, and Pathophysiologic portions of the classifications are online (http://www.veinforum.org/uploadDocs/1/Revised-CEAP-Classification---May-2004.pdf)

The following is the clinical portion of CEAP:

<table>
<thead>
<tr>
<th>Clinical Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>C1</td>
<td>Telangiectasies or reticular veins</td>
</tr>
<tr>
<td>C2</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>C3</td>
<td>Edema</td>
</tr>
<tr>
<td>C4a</td>
<td>Pigmentation and eczema</td>
</tr>
<tr>
<td>C4b</td>
<td>Lipodermatosclerosis and atrophie blanche</td>
</tr>
<tr>
<td>C5</td>
<td>Healed venous ulcer</td>
</tr>
<tr>
<td>C6</td>
<td>Active venous ulcer</td>
</tr>
<tr>
<td>S</td>
<td>Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>A</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>

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

**Description:** (cont.)

**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.

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

Description: (cont.)

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 sequential sessions of sclerotherapy.

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:

**Great-or Small Saphenous Veins:**

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

  1. Demonstrated saphenous reflux and CEAP (Clinical, Etiology, Anatomy, Pathophysiology) class C2 or greater.
  2. **ONE** or more of the following:

     - Ulceration secondary to venous stasis
     - Recurrent superficial thrombophlebitis
     - 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 great or small saphenous veins by surgery, endovenous radiofrequency laser ablation, or microfoam sclerotherapy is considered *cosmetic* and *not medically necessary*. 
VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS (cont.)

Criteria: (cont.)

Accessory Saphenous Veins:

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

  1. Demonstrated accessory saphenous reflux
  2. Incompetence of the accessory saphenous vein is isolated, or the great or small saphenous veins had been previously eliminated (at least 3 months)
  3. ONE or more of the following:
     - Ulceration secondary to venous stasis
     - Recurrent superficial thrombophlebitis
     - 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

- If above criteria not met, treatment of accessory saphenous veins by surgery, endovenous radiofrequency laser ablation, or microfoam sclerotherapy is considered cosmetic and not medically necessary.
VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS
(cont.)

Criteria: (cont.)

Symptomatic Varicose Tributaries:

Requests for sclerotherapy or echosclerotherapy extending beyond 12 months from the initial invasive treatment procedure will be subject to a new medical necessity review and requires submission of documentation to support medical necessity of the requested new treatments. Sclerotherapy or echosclerotherapy beyond 12 months of the initial invasive treatment procedure will be reviewed by the medical director(s) and/or clinical advisor(s).

- 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. Hook phlebectomy
  2. Photoderm vasculight (up to four treatment sessions per leg)
  3. Stab avulsion
  4. Transilluminated powered phlebectomy
  5. Sclerotherapy or echosclerotherapy (up to four treatment procedures per leg), when performed within 12 months of the initial varicose vein procedure

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

Criteria: (cont.)

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 (great, small 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

- 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. Angioma
2. Capillary venous ectasis (dilatation)/ venulectasia
3. Hemangioma
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)
VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS
(cont.)

Criteria: (cont.)

➢ 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 techniques, other than microfoam sclerotherapy, of great or saphenous or accessory saphenous veins
▪ Sclerotherapy of perforator
▪ Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins
▪ Stab avulsion, hook phlebectomy or transilluminated powered phlebectomy of perforator, great or small 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
▪ Cyanocrylate adhesive of any vein

Resources:

Literature reviewed 01/04/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

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

Resources: (cont.)


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

Resources: (cont.)


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

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


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

Resources: (cont.)


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

**Resources:** (cont.)


44. Weiss RA. American College of Phlebology. Radiofrequency Endovenous Occlusion (Closure® Technique), accessed 02/14/2005.


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

Resources: (cont.)

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.

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

Resources: (cont.)

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

Non-Discrimination Statement:

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Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dil ké’é atah nilिङिी Blue Cross Blue Shield of Arizona haad a yit’éego bìna’ídílíkidgö éi doocdago Háida biži ałniyeeedgígí t’áadool le’é yina’ídílíkidgö bee haa’haa’áanii hölőp dil t’áá hazaadk’éehjí háká a’doowolgo bee haa’há aá baaq̀í̈ ilínígóó. Ata’ halne’iligí kojí bích’hí hodiilinih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو أدى شخص تساعدك، أستثارة أسئلة بخصوص Blue Cross Blue Shield of Arizona لمن يحتاج إلى المساعدة والعلومات. يمكن للمنطقة الضرورية بلغتك من دون اية تكلفة للتحدث مع مترجم عنصل ب 877-475-4799.
VARICOSE VEINS, VENOUS INSUFFICIENCY AND LEG ULCER TREATMENTS
(cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyang wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화해주세요.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Domscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けるため、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合には、877-475-4799までお電話ください。

Farsi:
آگر شما یا کسی که شما را یا کمک می‌دهد، سوالی در مورد اطلاعاتی که باید به طور رایگان دریافت نماید، از 877-475-4799 لیکن حاضر نباشید.

Assyrian:
Blue Cross Blue Shield of Arizona یاری ندارید، پرسیدنن یا گفتگو کنید، می‌توانید محترم 877-475-4799.

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Thai: หากคุณ หรือผู้ที่คุณช่วยมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่ค่าใช้จ่าย ที่ 877-475-4799.