TITLE: VARICOSE VEIN AND VENOUS INSUFFICIENCY TREATMENTS

EFFECTIVE DATE: January 21, 2019

This policy was developed with input from specialists in general surgery, vascular surgery and interventional radiology, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determines the medical necessity of varicose vein and venous insufficiency treatments. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

Definitions:
A. Duplex ultrasonography/Doppler ultrasound are two imaging modalities done sequentially to outline anatomical structure of blood vessels (duplex) and to detect flow, direction of flow and flow velocity of the blood through vessels. Doppler ultrasounds are frequently used to map anatomy while duplex ultrasounds are used to check for evidence of thrombus.
B. Endovenous radiofrequency (RF) ablation and endovenous laser ablation are treatments intended as less invasive alternatives to traditional vein ligation and stripping for symptomatic varicosities of the great (greater) or small (lesser) saphenous vein. These procedures are often performed using percutaneous tumescent anesthesia. A catheter is inserted through a small incision (usually near the knee) into the affected vein and advanced up to the saphenofemoral junction. Proper placement is confirmed by Duplex ultrasound imaging. The RF electrodes or the laser are slowly withdrawn, occluding the vein as the energy is applied. These procedures are also referred to as endoluminal or endovascular ablation.
C. Giacomini vein is a thigh extension of the short saphenous vein, arising just above the saphenopopliteal junction and extending into the thigh.
D. Hyperpigmentation is an excess of pigment in a tissue or body part; one cause is venous insufficiency.
E. Phlebectomy is the surgical removal of segments of varicose veins. The procedures for removal may be known as ambulatory phlebectomy, stab phlebectomy, stab avulsion, microextraction, hook phlebectomy, or transilluminated powered phlebectomy (TIPP).
F. Reticular veins are defined as permanently dilated bluish intradermal veins usually from 1 to less than 3 mm in diameter; they may be tortuous.
G. Sclerotherapy is the injection of a chemical solution (sclerosant) into a vein that damages the endothelial lining of the treated vein, causing vessel occlusion and the development of fibrous tissue, with resultant obliteration of the targeted vein.
H. **Stasis dermatitis** is cutaneous inflammation resulting in erythema, scaling, and edema of the lower extremities due to impaired venous circulation.

I. **Surgical procedures** include ligation/stripping, endovenous radiofrequency ablation, and endovenous laser ablation.

J. **Telangiectasias** are dilated superficial blood vessels in the skin. This is often synonymous with the term “thread veins” or “spider veins.”

K. **Ultrasound-guided foam sclerotherapy** (USG): also known as echosclerotherapy, is a real-time ultrasound-guided injection procedure for treatment of varicose veins.

L. **Varicose veins** are tortuous, dilated veins often associated with incompetent valves. Symptoms of varicose veins that are due to venous hypertension may be relieved by elevation and graduated compression hosiery. Symptoms unrelieved by elevation and compression hosiery, especially overnight in bed, must be investigated for other causes.

M. **Vein ligation** is a surgical procedure consisting of the tying off of varicose veins.

N. **Vein stripping** is a surgical procedure to remove a vein or portion of a vein.

O. **Venous insufficiency** occurs when incompetent valves allow blood leakage or reflux, leading to elevated ambulatory venous pressure and capillary damage with extravasation of red blood cells and serum. This may lead to signs and symptoms such as edema, hyperpigmentation, stasis dermatitis, spider veins, varicosities, and ulceration.

**BENEFIT CONSIDERATIONS**

1. Prior authorization **is required** for varicose vein and venous insufficiency treatments. Please see the prior authorization list for product specific prior authorization requirements.

2. Coverage of sclerotherapy is limited to one visit per leg over a six month period. Additional visits require medical director review and documentation supportive of medical necessity.

3. The following services are **investigative and therefore not covered**:  
   • Sclerotherapy for great and/or small saphenous veins, including but not limited to Varithena® for treatment of great and/or small saphenous veins  
   • Mechanochemical ablation (MOCA), i.e., ClairVein®, for the treatment of varicose veins  
   • Medical adhesive, e.g., VenaSeal™ Closure System, for treatment of varicose veins  
   • Pelvic vein embolization.

4. Treatment for superficial veins, also referred to as telangiectasia, thread, reticular or spider veins **is excluded** from coverage in most plans.

5. Coverage may vary according to the terms of the member’s plan document.

6. Cosmetic surgery/procedures are generally an exclusion in the member’s plan document. Treatment of asymptomatic varicosities is considered cosmetic.

7. If medical necessity criteria are not met as defined in this policy, any associated procedures will not be covered. This includes, but is not limited to, facility and anesthesia services, professional fees, and associated supplies.

8. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

9. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be submitted to the medical director or external review for individual consideration. Practitioners are advised of the appeal process in their Medica Administrative Manual.

**MEDICAL NECESSITY CRITERIA**

I. Treatment of the **great saphenous vein (GSV)** or **small saphenous vein (SSV)** with ligation/stripping, endovenous radiofrequency ablation, or endovenous laser ablation is medically necessary when documentation in the medical records indicates that all of the following criteria are met:

   A. Trial of three month use of compression stockings, unless the treating physician documents that the use of compression stockings is contraindicated.

   B. A patent deep venous system of bilateral extremities evidenced by results of a duplex ultrasonography, performed within the past six months.

   C. Diameter of veins to be treated is at least 3 mm in size.

   D. Reflux duration, measured in the standing position, for GSV or SSV is greater than or equal to 0.5 seconds.

   E. GSV or SSV(s) to be treated correlate anatomically with the location of clinically significant symptoms.
and include documentation of **one of the following** functional impairments:

1. Recurrent superficial thrombophlebitis
2. Venous stasis dermatitis (including refractory dependent edema, erythema, scaling, and brown discoloration of the ankle)
3. External hemorrhage of the varicose vein
4. Venous ulceration
5. Moderate to severe pain resulting in functional impairment that interferes with activities of daily living (e.g., inability to perform household chores, prolonged standing, or essential job functions).

F. Written documentation from the medical record including **all of the following** information is required:

1. Detailed clinical history
2. Documentation of **one of the following**:
   a. Results of three month trial of compression stockings
   b. Specific clinical contraindications to a trial of compression stockings
3. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
4. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, high-resolution color photographs, taken in the provider’s office under the provider’s direction, documenting skin changes that account for functional impairment.

II. Treatment of accessory saphenous veins (posterior, anterior, or Giacomini veins) or perforator veins with endovenous radiofrequency/laser ablation, ultrasound-guided foam sclerotherapy, or phlebectomy done at least 3 months post saphenous vein procedure (GSV, SSV) or as a stand-alone procedure is medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:

A. Trial of three month use of compression stockings, unless the treating physician documents that the use of compression stockings is contraindicated.

B. Venous duplex scan, performed within the past six months, demonstrating **no** saphenous reflux/incompetence.

C. Reflux duration, measured in the standing position, meets the following parameters:
   1. Reflux duration for accessory saphenous veins (posterior, anterior, or Giacomini veins) is greater than 0.5 seconds
   2. Reflux duration for the perforator veins is greater than 0.35 seconds.

D. Diameter of the veins to be treated is at least 3 mm in size.

E. Accessory saphenous or perforator veins to be treated correlate anatomically with the location of clinically significant symptoms and include documentation of **one of the following** functional impairments:

   1. Recurrent superficial thrombophlebitis
   2. Venous stasis dermatitis (including refractory dependent edema, erythema, scaling, and brown discoloration of the ankle)
   3. External hemorrhage of the varicose vein
   4. Venous ulceration
   5. Moderate to severe pain resulting in functional impairment that interferes with activities of daily living (e.g., inability to perform household chores, prolonged standing, or essential job functions).

F. Written documentation from the medical record including **all of the following** information is required:

1. Detailed clinical history
2. Documentation of **one of the following**:
   a. Results of three month trial of compression stockings
   b. Specific clinical contraindications to a trial of compression stockings
3. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
4. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, high-resolution color photographs, taken in the provider’s office under the provider’s direction, documenting skin changes that account for functional impairment.

III. Treatment of accessory saphenous veins (posterior, anterior, or Giacomini veins), perforator veins, or significant small varicose veins (sometimes called small tributary veins, truncal, lateral truncal, pudendal, or branch veins) with endovenous radiofrequency/laser ablation, ultrasound-guided foam sclerotherapy, or phlebectomy, **at the same time** as the treatment of GSV or SSV veins, is medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:
A. Trial of three month use of compression stockings, unless the treating physician documents that the use of compression stockings is contraindicated.

B. A patent deep venous system evidenced by results of a duplex ultrasonography, performed within the past six months.

C. Diameter of the veins to be treated is at least 3 mm in size.

D. Reflux duration, measured in the standing position, meets the following parameters:
   1. Reflux duration for accessory saphenous veins and significant small varicose veins must be greater than 0.5 seconds
   2. Reflux duration for the perforator veins must be greater than 0.35 seconds.

E. Accessory, perforator, or significant small varicose veins to be treated must correlate anatomically with the location of clinically significant symptoms and include documentation of one of the following functional impairments:
   1. Recurrent superficial thrombophlebitis
   2. Venous stasis dermatitis (including refractory dependent edema, erythema, scaling, and brown discoloration of the ankle)
   3. External hemorrhage of the varicose vein
   4. Venous ulceration
   5. Moderate to severe pain resulting in functional impairment that interferes with activities of daily living (e.g., inability to perform household chores, prolonged standing, or essential job functions).

F. Written documentation from the medical record including all of the following information is required:
   1. Detailed clinical history
   2. Documentation of one of the following:
      a. Results of three month trial of compression stockings
      b. Specific clinical contraindications to a trial of compression stockings
      3. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
      4. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, high-resolution color photographs, taken in the provider’s office, under the provider’s direction, documenting skin changes that account for functional impairment.

IV. Treatment of significant small varicose veins (sometimes called small tributary veins, truncal, lateral truncal, pudendal, or branch veins) with ultrasound-guided foam sclerotherapy or phlebectomy, in a patient who has undergone saphenous vein ligation, stripping, or endovenous radiofrequency/laser ablation of the GSV and/or SSV is medically necessary when documentation in the medical record indicates that all of the following criteria are met:

A. The saphenous vein surgery or procedure was completed at least three months prior.

B. Venous duplex scan, performed within the past six months, demonstrates no saphenous reflux/incompetence.

C. Diameter of the veins to be treated is at least 3 mm in size.

D. Reflux duration for the smaller veins is greater than 0.5 seconds.

E. Small varicose veins to be treated correlate anatomically with the location of clinically significant symptoms and include documentation of one of the following functional impairments:
   1. Recurrent superficial thrombophlebitis
   2. Venous stasis dermatitis (including refractory dependent edema, erythema, scaling, and brown discoloration of the ankle)
   3. External hemorrhage of the varicose vein
   4. Venous ulceration
   5. Moderate to severe pain resulting in functional impairment that interferes with activities of daily living (e.g., inability to perform household chores, prolonged standing, or essential job functions).

F. Written documentation from the medical record including all of the following information is required:
   1. Detailed clinical history
   2. Documentation of one of the following:
      a. Results of three month trial of compression stockings
      b. Specific clinical contraindications to a trial of compression stockings
      3. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
      4. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, high-resolution color
photographs, taken in the provider’s office, under the provider’s direction, documenting skin changes that account for functional impairment.

V. Treatment of significant small varicose veins (sometimes called small tributary veins, truncal, lateral truncal, pudendal, or branch veins) with ultrasound-guided foam sclerotherapy or phlebectomy, in a patient who has not undergone saphenous vein ligation, stripping, or endovenous radiofrequency/laser ablation of the GSV and/or SSV, is medically necessary when documentation in the medical records indicates that all of the following criteria are met:

A. Trial of three month use of compression stockings, unless the treating physician documents that the use of compression stockings is contraindicated.
B. Venous duplex scan, performed within the past six months, demonstrates no saphenous reflux/incompetence.
C. Diameter of the veins to be treated is at least 3 mm in size.
D. Reflux duration for the smaller veins is greater than 0.5 seconds.
E. Small varicose veins to be treated must correlate anatomically with the location of clinically significant symptoms and include documentation of one of the following functional impairments:
   1. Recurrent superficial thrombophlebitis
   2. Venous stasis dermatitis (including refractory dependent edema, erythema, scaling, and brown discoloration of the ankle)
   3. External hemorrhage of the varicose vein
   4. Venous ulceration
   5. Moderate to severe pain resulting in functional impairment that interferes with activities of daily living (e.g., inability to perform household chores, prolonged standing, or essential job functions).
F. Written documentation from the medical record including all of the following information is required:
   1. Detailed clinical history
   2. Documentation of one of the following:
      a. Results of three month trial of compression stockings
      b. Specific clinical contraindications to a trial of compression stockings
   3. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
   4. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, high-resolution color photographs, taken in the provider’s office, under the provider’s direction, documenting skin changes that account for functional impairment.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY

<table>
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<tr>
<th>Original Effective Date</th>
<th>April 1, 2001 (III-SUR.19); April 1, 2004 (III-SUR.26)</th>
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<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
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References:

Pre-11/2015 Medical Policy Committee (MPC):
30. Harris EJ. Radiofrequency ablation of the long saphenous vein without high ligation versus high ligation


54. Michaels JA, Campbell WB, Brazier JE, et al. Randomised clinical trial, observational study and assessment of


11/2015 MPC:


Pre-06/2016 Medical Technology Assessment Committee (MTAC) (Sclerotherapy for Saphenous Veins):


06/07/2016 MTAC (Sclerotherapy for Saphenous Veins):


126. Scovell S. Liquid, foam, and glue sclerotherapy techniques for the treatment of lower extremity veins. Last updated June 1, 2016. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2016.


128. Todd KL III, Wright DI, VANISH-2 Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. Phlebology.

1/2016 MPC:
No new references added.

12/2016 MTAC (Review: Endovenous Mechnochemical Ablation (MOCA) for the Treatment of Varicose Veins):

1/2017 MPC:
No new references

8/2018 MTAC (Review: Medical Adhesive for the Treatment of Varicose Veins):

8/2018 MTAC (Review: Sclerotherapy for Saphenous Veins):


**11/2018 MPC:**
No new references