⊘ Medica. UTILIZATION MANAGEMENT POLICY

TITLE: <u>VARICOSE VEIN AND VENOUS INSUFFICIENCY TREATMENTS OF THE LOWER EXTREMITIES</u>

EFFECTIVE DATE: January 15, 2024

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. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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, Medicaid, and other government 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 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 utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

Definitions:

- A. **Cyanoacrylate adhesive closure** of symptomatic varicose veins is a minimally invasive procedure that uses a specially formulated medical adhesive (glue) that is injected into the vein using the VenaSeal™ closure system. The cyanoacrylate adhesive permanently closes the diseased vein.
- B. **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.
- C. 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. If more than one vein on the same leg needs to be ablated, they may be treated during the same visit.
- D. **Giacomini** vein is a thigh extension of the short saphenous vein, arising just above the saphenopopliteal junction and extending into the thigh.
- E. **Hyperpigmentation** is an excess of pigment in a tissue or body part; one cause is venous insufficiency.
- F. **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).
- G. **Reticular veins** are defined as permanently dilated bluish intradermal veins usually from 1 to less than 3 mm in diameter; they may be tortuous.
- H. **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

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- tissue, with resultant obliteration of the targeted vein.
- I. **Stasis dermatitis** is cutaneous inflammation resulting in erythema, scaling, and edema of the lower extremities due to impaired venous circulation.
- J. **Surgical procedures** include ligation/stripping, endovenous radiofrequency ablation, and endovenous laser ablation.
- K. **Telangiectasias** are dilated superficial blood vessels in the skin. This is often synonymous with the term "thread veins" or "spider veins."
- L. **Ultrasound-guided foam sclerotherapy** (USG): also known as echosclerotherapy, is a real-time ultrasound-guided injection procedure for treatment of varicose veins.
- M. **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.
- N. **Vein ligation** is a surgical procedure consisting of the tying off of varicose veins.
- O. **Vein stripping** is a surgical procedure to remove a vein or portion of a vein.
- P. **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 two visits per leg within a six-month period. Additional visits require medical director review for medical necessity.
- 3. Coverage of radiofrequency/laser ablation therapy is limited to one visit per leg within a six-month period. Additional visits require medical director for medical necessity.
- 4. The following services are *investigative* and therefore not covered:
 - Sclerotherapy for previously untreated great and/or small saphenous veins, (including Varithena®)
 - Mechanochemical ablation (MOCA), i.e., ClariVein®, for the treatment of varicose veins
 - Medical adhesive (e.g., cyanoacrylate adhesive, VenaSeal™) treatment of all other veins not specifically mentioned in the Medical Necessity Criteria section
 - Pelvic vein embolization.
- 5. Treatment for superficial veins, also referred to as telangiectasia, thread, reticular or spider veins *is excluded* from coverage in most plans.
- 6. Coverage may vary according to the terms of the member's plan document.
- 7. Cosmetic surgery/procedures are generally an exclusion in the member's plan document. Treatment of asymptomatic varicosities is considered cosmetic.
- 8. 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.
- 9. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
- 10. If it appears that the Medical Necessity Criteria and Benefit Considerations 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)**, **small saphenous vein (SSV**), **accessory saphenous veins** (posterior, anterior, or Giacomini veins) **or perforator veins** with ligation/stripping/phlebectomy, endovenous radiofrequency ablation, endovenous laser ablation, or cyanoacrylate adhesive (e.g., VenaSealTM) is medically necessary when documentation in the medical records indicates that **all of the following** criteria are met:

Note: Sclerotherapy for previously untreated great and/or small saphenous veins is investigative. However, sclerotherapy for small segments of residual reflux in GSV/SSV (after previous ablation) is

medically necessary if all of the following criteria are met.

Note: Cyanoacrylate adhesive (e.g., VenaSealTM) is considered investigative and therefore not covered for perforator veins.

- A. A patent deep venous system in the affected extremity as evidenced by results of a duplex ultrasonography, performed within the past six months.
- B. Diameter of veins to be treated is at least 3 mm in size.
- C. Reflux duration meets the following parameters:
 - 1. Reflux duration for GSV, SSV or accessary saphenous veins is greater than or equal to 0.5 seconds
 - 2. Reflux duration for perforator veins must be greater than 0.35 seconds.
- D. GSV, SSV, accessory saphenous veins 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).
- E. Written documentation from the medical record including **all of the following** information is required:
 - 1. Detailed clinical history
 - 2. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment
 - 3. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, adequate photographs, taken in the provider's office under the provider's direction, documenting skin changes that account for functional impairment.

Note: For individuals whose only indication is pain, photographs are not required.

- II. Treatment of **significant small varicose veins** (sometimes called small tributary veins, pudendal, or branch veins), **accessory saphenous veins** (posterior, anterior, or Giacomini veins) **or perforator veins** with ultrasound-guided foam sclerotherapy (e.g., Varithena®) or phlebectomy is medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:
 - A. One of the following is met:
 - 1. Will be treated as a stand-alone procedure (with no previous GSV or SSV treatment)
 - 2. At the same time as the GSV or SSV
 - 3. At least 3 months after the last GSV or SSV treatment.
 - B. Venous duplex scan, performed after the latest vein procedure, or within the last year if no previous vein surgery occurred, demonstrates **no** GSV or SSV reflux/incompetence (with the exception of small segments of GSV/SSV showing residual reflux after previous ablation procedure), or the incompetent GSV and/or SSV will be treated at the same time as the requested procedure.
 - C. Diameter of the veins to be treated is at least 3 mm in size.
 - D. Reflux duration meets the following parameters:
 - 1. Reflux duration for the accessary saphenous veins is greater than or equal to 0.5 seconds
 - 2. Reflux duration for the perforator veins must be greater than 0.35 seconds
 - 3. Reflux not required for significant small varicose veins.
 - E. Small varicose, 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:
 - Detailed clinical history
 - 2. Duplex ultrasonography report results demonstrating reflux and duration of reflux for affected extremities with correlation to functional impairment.
 - 3. For patients with thrombophlebitis, dermatitis, ulceration or hemorrhage, adequate photographs, taken in the provider's office, under the provider's direction, documenting skin changes that account for functional impairment.

Note: For individuals whose only indication is pain, photographs are not required.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/search.aspx

MINNESOTA HEALTH CARE PROGRAMS (MHCP)

- For MHCP members, refer to https://www.dhs.state.mn.us/main/idcplg?ldcService=GET_DYNAMIC_CONVERSION&RevisionSelection Method=LatestReleased&dDocName=id 000094#
- No MHCP policy found as of 09/21/2021.

DOCUMENT HISTORY

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Updates	

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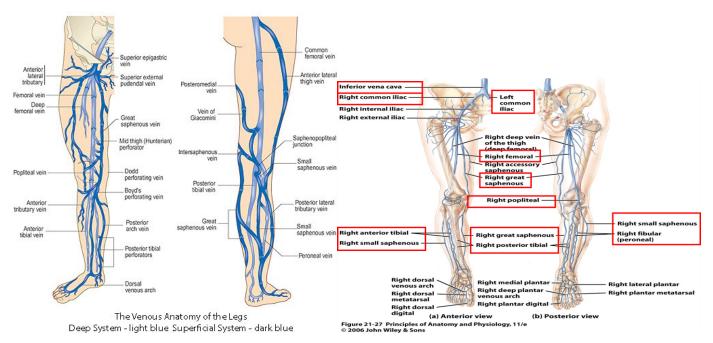
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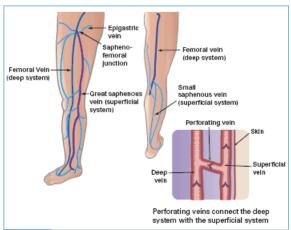
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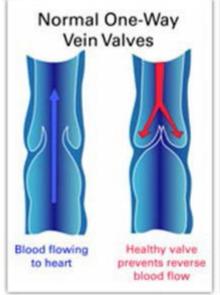
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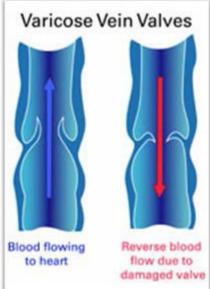
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Appendix 1









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