POLICY AND PROCEDURE MANUAL

Policy Title: Sclerotherapy and Endovascular Ablation	**Policy Number: F.19**
Primary Department: Medical Management	**NCQA Standard: N/A**
Affiliated Department(s): N/A	**URAC Standard: N/A**
Last Revision Date: 08/24/2018 **Revision Dates: 08/14/2015; 09/13/2016; 09/08/2017; 08/24/2018** **Effective Date: 10/20/2015**	**Next Review Date: 09/2019** **Review Dates: 09/25/2015; 09/23/2016; 09/28/2017; 09/26/2018**
Applicable Lines of Business: ☐MeridianCare ☒MeridianHealth ☐MeridianComplete ☒MeridianChoice	
Applicable States: ☐All ☒MI ☒IL ☐OH ☐_____ ☐_____	
Applicable Programs: ☒All ☐Other _____	
Policy is to be published: Internally Only ☐ Internally & Externally ☒	

Definitions:

Varicose Veins	Abnormally enlarged and tortuous vessels caused by venous hypertension and venous pooling in capacitance vessels which result from impaired venous return. This may result in venous thrombosis, dilatation of the veins and incompetent valves in the venous system. They are the visible surface manifestation of an underlying syndrome of venous insufficiency. Venous insufficiency due to venous hypertension is a progressive phenomenon resulting in clinical findings of prominence and engorgement of the superficial venous system, deep vein thrombosis, incompetence of the one way valves, edema, stasis dermatitis, brawny edema with pigmentation of the skin, and ulceration of the soft tissues. Mild forms of venous insufficiency are uncomfortable, annoying, or cosmetically disfiguring. It become clinically important when symptoms such as cramping, throbbing, burning, swelling, feeling of heaviness or fatigue, and alterations in skin pigmentation in the afflicted area become pronounced. Severe varicosities may be associated with dermatitis, ulceration, and thrombophlebitis.
Sclerotherapy	A minimally invasive procedure to diminish abnormally dilated and symptomatic veins. In this procedure, liquid or foam irritants are injected into unwanted veins, causing their eventual reduction.

Policy:

First-line treatment of varicose veins includes conservative methods to reduce the venous pooling in the extremity such as exercise, weight reduction, elevation of the legs, avoidance of prolonged immobility, or compression therapy. When these measures fail, medium to large incompetent veins may be treated with surgical stripping, ligation, sclerotherapy, endovenous laser therapy (EVLT), or endoluminal radiofrequency ablation (ERFA). EVLT involves ultrasonography to evaluate the veins, infiltration of the area to be treated with local anesthetic, and passage of an optical fiber into and along

the length of the Great Saphenous Vein (GSV) or Lesser Saphenous Vein (LSV). VNUS® RF (radiofrequency) Ablation system (also called the Closure® procedure) is a minimally invasive varicose vein treatment procedure that uses radiofrequency energy (electricity) to heat, collapse and seal off the targeted blood vessels.

Procedure:

Required Documentation:

Varicose vein treatment is a covered benefit when medically necessary as outlined below.

1. Treatment of varicose veins is covered when ALL of the following exists:
    a. A three-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed.
    b. The patient is symptomatic and has one or more of the following:
        i. Documented history of complications of venous stasis (dermatitis, ulceration, subcutaneous induration);
        ii. Recurrent episodes of superficial phlebitis in the affected area;
        iii. History of hemorrhage of large varicosities;
        iv. Significant leg aching, heaviness, or cramps and/or swelling during activity or after prolonged standing, severe enough to impair mobility;
        v. Non–healing skin ulceration;
        vi. Refractory dependent edema due to the varicosities in the absence of liver disease, CHF, or ESRD.
    c. An ultrasound or venogram documenting patency of the deep venous system.
    d. A minimum vein diameter of 3 mm.

Treatment Options:

1. Surgical Intervention
    a. Procedures such as: excision, ligation, stab phlebectomy.
2. Endovenous laser therapy (EVLT) and Endoluminal radiofrequency ablation (ERFA)
    a. Greater or lesser saphenous vein, if ultrasound shows evidence of venous reflux
    b. Maximum vein diameter of 20 mm for ERFA or 30 mm for EVLT.
    c. Thrombosis or significant vein tortuosity which would impair catheter advancement is a contraindication to ERFA or EVLT and a relative contraindication to stripping.
    d. Absence of significant peripheral arterial diseases.
    e. Perforator vein ERFA or endovenous occlusion (VNUS procedure) for perforator veins is a covered benefit
        i. Venous stasis dermatitis/ulceration
        ii. Chronic venous insufficiency
        iii. Doppler/ duplex ultrasound within 12 months prior to the requested procedure, confirms reflux of the incompetent and location on the medial aspect of the calf being treated.
3. Sclerotherapy (i.e., liquid, foam, ultra-sound guided, endovenous chemical ablation) is indicated for:
    a. Adjunctive therapy for accessory, perforator, reticular or varicose tributaries with prior occlusion of the saphenofemoral or saphenopopliteal junction by another method
    b. Approved agents: sodium tetradecyl sulfate (STS), polidocanol, sodium morrhuate
    c. Not covered:
        i. Perforator veins: when incompetence that is isolated to the perforator veins
        ii. Sclerotherapy with glycerin/glycerol
        iii. Asclera foam is FDA approved for spider veins and telangiectasias only, which are considered cosmetic and not a covered benefit
4. Subfascial endoscopic perforator surgery (SEPS) or an open Litton's procedure are indicatedwhen **ALL** of the following are met:
    a. Doppler and/or Duplex ultrasonography, performed no more than 12 months prior to the requested procedure, which confirms reflux of the incompetent perforator vein and location on the medial aspect of the calf being treated.
    b. Documentation of at least **ONE** of the following conditions:

i. Venous stasis dermatitis/ulceration
ii. Chronic venous insufficiency

Absolute Contraindications:
Meridian Health Plan (MHP) does not cover ANY of the following varicose vein treatments because each is considered **cosmetic** in nature and not medically necessary:

- Treatment of telangiectasis or varicose veins that are less than 3 mm in diameter by any method
- Intense pulsed-light source (photothermal sclerosis) treatment of a varicose vein

MHP does not cover ANY of the following varicose vein treatments, because each is considered **experimental or investigational** (this list may not be all-inclusive):

- Non-compressive sclerotherapy
- Transdermal laser therapy
- Transilluminated powered phlebectomy (TIPP, TriVex™)
- SEPS for the treatment of venous insufficiency as a result of post-thrombotic syndrome (deep venous system partially or totally occluded).
- Endomechanical ablative approach (e.g., ClariVein™ Catheter)
- Cryostripping (including cryoablation, cryofreezing) of any vein
- VeinGogh Ohmic Thermolysis System
- Cyanoacrylate adhesive / glue, n-butyl-cyanoacrylate (VenaSeal)

Line of Business Applicability:
This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual plans.

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html), or the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), or the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx) the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

State specific special instructions:

None: ☒
MI:
IL:
OH:

References:

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State Letters/Bulletins					
CMS National/Local Coverage Determination (NCD/LCD)	L34536				
Medicare Managed Care Manual:					
Medicaid CFR:					
State Administrative Codes:					
Contract Requirements:					
Related Policies:					