I. ACTION

<table>
<thead>
<tr>
<th>New Policy</th>
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</tr>
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<tbody>
<tr>
<td>X Revising Policy Number</td>
<td>CMS22.01</td>
</tr>
<tr>
<td>Superseding Policy Number</td>
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<tr>
<td>Archiving Policy Number</td>
<td></td>
</tr>
<tr>
<td>Retiring Policy Number</td>
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</tr>
</tbody>
</table>

II. POLICY DISCLAIMER

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

III. POLICY

For USFHP see: https://manuals.health.mil/

- TRICARE Policy Manual 6010.60-M, April 1, 2015, Cardiovascular System: Chapter 4, Section 9.1.
For Advantage MD see: https://www.cms.gov/medicare-coverage-database/

- Medicare Coverage Database: Local Coverage Determination (LCD): Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities (L34924)
- Medicare does not have a National Coverage Determination (NCD) for Treatment of Varicose Veins

IV. POLICY CRITERIA

A. When benefits are provided under the member’s contract, JHHC considers endovenous radiofrequency ablation (e.g. Venefit (formerly VNUS procedure) and endovenous laser ablation (EVLA) (e.g. VenaCure) of the greater saphenous, small saphenous and accessory saphenous veins medically necessary when ALL of the following are met:
   1. Submission of medical records which document all of the following:
      a. Duplex ultrasound of the involved extremity(s) mapping the course of the greater and lesser saphenous vein and prominent tributaries with evidence of reflux ≥ 500 milliseconds (0.5 seconds) in veins to be treated,
      b. Documentation of the size of the veins showing vein size of 4.5 mm or larger in veins to be treated,
      c. Pretreatment photographs or diagrams and documentation of the treatment plan,
      d. Documentation of at least a three-month trial of non-surgical management to include periodic elevation of legs during the day, avoidance of prolonged sitting, and use of graduated compression stockings, AND
   2. One or more of the following:
      a. Severe and persistent pain, aching, cramping, burning or swelling interfering with the activities of daily living, OR;
      b. Recurrent superficial thrombophlebitis, OR;
      c. Severe venous stasis with skin changes, OR;
      d. Intractable ulceration secondary to venous stasis, OR;
      e. More than one episode of minor hemorrhage from a ruptured superficial varicosity, OR;
      f. A single significant hemorrhage from a ruptured superficial varicosity

B. When benefits are provided under the member’s contract, JHHC considers sclerotherapy (liquid, foam, microfoam) using a sclerosant approved by the U.S. Food and Drug Administration for the intended use medically necessary in the treatment of symptomatic varicosities 3 mm to 6 mm in diameter when endothermal ablation is not an option, previous procedures to treat incompetent saphenous vein(s) has not resulted in relief of symptoms, and InterQual® criteria have been met.

C. When benefits are provided under the member’s contract, JHHC considers stab phlebectomy (also called micro phlebecony, or ambulatory phlebectomy) medically necessary when the previously listed treatments are not an option, previous procedures to treat incompetent saphenous vein(s) has not resulted in relief of symptoms and when criteria in section A 1 and 2 are met.

D. Unless specific benefits are provided under the member’s contract, JHHC considers the following treatment of varicosities investigational and experimental as they do not meet Technology Evaluation Criteria (TEC):
   1. Mechanochemical Ablation (MOCA) (e.g. ClariVein)
   2. Endovenous Cryoablation
   3. Cyanoacrylate Adhesive (e.g. VenaSeal)
   4. Ultrasound guided non-compounded foam sclerotherapy with compression maneuvers inclusive of imaging guidance (36465-36466)

E. Unless specific benefits are provided under the member’s contract, JHHC considers the following treatment of varicosities cosmetic in nature:
   1. Treatment of spider veins/telangiectasia in the absence of associated recurrent hemorrhage
   2. Transdermal laser treatments
3. Treatment of asymptomatic varicose veins

V. DEFINITIONS

*Accessory Saphenous Veins*: For the purposes of this policy include the Anterior Accessory of the Great Saphenous Vein (AAGSV), and the Posterior Accessory of the Great Saphenous Vein (PAGSV).

**CEAP Clinical Classification Score**: The CEAP (clinical, etiologic, anatomic, pathophysiologic) classification system for venous disease describes disease severity and is used to determine indications for referral or treatment. It is comprised of two parts, classification and severity scoring (Gloviczki, 2011).

**Table 1. Clinical Classification of CEAP**

<table>
<thead>
<tr>
<th>Score</th>
<th>Clinical Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>C₀</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>C₁</td>
<td>Telangiectasias 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>C₇</td>
<td>Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous disease</td>
</tr>
<tr>
<td>C₈</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>

**Duplex Ultrasound**: A non-invasive evaluation of blood flow through your arteries and veins. The duplex ultrasound combines two types of ultrasound technologies, traditional ultrasound that creates images of blood vessels and Doppler ultrasound that determines the speed and direction of blood flow.

**Endovenous Thermal Ablation**: Techniques of vein ablation where occlusion (ablation) of the treated vein is achieved by heat delivered into the vein through the percutaneously placed laser fiber or radiofrequency catheter. Endovenous thermal ablation causes a direct thermal injury to the vein wall, resulting in destruction of the endothelium, collagen denaturation of the media, and fibrotic and thrombotic occlusions of the vein (Glovicki).

**Endovenous Laser Ablation (EVLA)**: A type of endothermal vein ablation using a laser to heat up and collapse the vein. It involves the delivery of laser light through a glass fiber placed into the lumen of the vein. The optical fiber is then connected to a surgical laser, allowing high-intensity laser light to induce photocoagulation of blood and occlusion of the vein. It is performed with ultrasound guidance and local tumescent anesthetic (Hayes, 2017).
Endovenous Radiofrequency Ablation: A type of endothermal vein ablation that uses a catheter electrode to deliver a high-frequency alternating radiofrequency current that leads to venous spasm, collagen shrinkage and physical contraction. Using ultrasound guidance, the vein is cannulated, and local tumescent anesthetic is injected around the target venous segment. The catheter is then introduced through a sheath and the radiofrequency current is then delivered (Kayssi, 2015).

Sclerotherapy: Involves the injection of a chemical irritant (sclerosant) into a vein or varicosity, causing inflammation and subsequent fibrosis of the vessel wall while transforming the vein into a fibrous cord that cannot be recanalized. Sclerosants commonly used include polidocanol and sodium tetradecyl sulfate (STS), which can be administered as a liquid or foam (Hayes, 2016).

Ultrasound Guided Foam Sclerotherapy (UGFS): Vein occlusion procedure that uses ultrasound to guide intravenous injection of a sclerosing foam (e.g. polidocanol) to induce inflammation in the endothelial and subendothelial layers of the vein wall causing fibrosis and closure of the vein lumen. Foam displaces blood allowing use of reduced volume of sclerant and permitting greater contact with the vein walls. Ultrasound is used to monitor and limit the dispersion of foam (Nesbitt, 2014).

VI. BACKGROUND
Varicose veins are a chronic condition estimated to affect over 20% of the U.S. population (Zhang, 2014) and the incidence is increasing due to an aging and obese population (Jones, 2017). Treatments for varicose veins of the legs range from conservative measures such as compression, leg elevation, light walking, and obesity management. In severe cases of discomfort or ulceration, surgical treatment with open ligation and stripping was the standard of care, however less invasive procedures have been shown to be equally effective as surgery including endovenous laser ablation and endovenous radiofrequency ablation, with or without phlebectomy and/or sclerotherapy and have largely replaced open surgical procedures. Less invasive endovascular procedures can be performed under local/tumescent anesthesia in an office-based setting with minimal scarring, reduced pain, and quicker recovery time.

In 2017 the Agency for Healthcare Research and Quality (AHRQ) published the technology assessment, Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD). This systematic review assessed the comparative effectiveness of endovascular procedures and concluded there was no long-term difference in effectiveness between radiofrequency ablation (RFA) and high ligation plus stripping, but RFA was associated with less periprocedural pain, faster improvement in symptom scores and quality of life, and fewer adverse events. A meta-analysis was performed on three randomized control studies comparing venous ligation and stripping with endovascular laser treatment (EVLA) which demonstrated a significant benefit of EVLA compared with surgery regarding the risk of bleeding (hematoma/ecchymosis) (Jones, 2017). Jones (2017) also reports that when comparing surgical ligation and stripping with the minimally invasive procedures RFA and EVLA, no significant differences between treatment modalities were observed for the following outcomes: quality of life, venous clinical severity score (VCSS), and rates of recurrence and re-intervention. These findings reportedly are similar to findings published in the National Institute for Health and Care Excellence (NICE) Guidelines.

The NICE Guideline, Varicose veins: diagnosis and management, last reviewed in 2016, has ranked interventional treatments for varicosities based on strength of evidence. For confirmed varicose veins and truncal reflux, endothermal ablation (RFA or EVLA) is the recommendation of choice. If endothermal ablation is deemed unsuitable, ultrasound guided foam sclerotherapy could be offered. Surgical intervention for the treatment of varicose veins is recommended only if the above three interventions are not possible. These guidelines also recommend considering concurrent treatment, if incompetent varicose tributaries are to be treated. Similarly, the American College of Phlebology (ACP) 2015 Practice Guideline, Treatment of Superficial Venous Disease of the Lower Leg strongly recommends endothermal ablation (RFA or EVLA) as the preferred treatment for incompetent veins with a documented reflux of > 500 msec. of the greater saphenous vein (GSV), small
saphenous vein (SSV), and accessory saphenous (AAGSV, PAGSV) veins. Open surgery is recommended when veins are not amenable to endovenous procedures, but otherwise not recommended because of increased pain, recovery time and morbidity.

The ACP (2015) also provides guidance for the treatment of symptomatic tributary varicose veins with documented reflux. Stab phlebectomy, liquid or foam chemical ablation is recommended for visible symptomatic tributary veins and ultrasound-guided sclerotherapy is recommended when symptomatic tributary veins are non-visible. A newer sclerotherapy procedure to treat saphenous and accessory saphenous veins uses a non-compounded injectable foam. This procedure includes ultrasound compression maneuvers to guide and monitor the dispersion of the foam. Hayes (2016) reviewed a proprietary non-compounded microfoam scleroant used in this procedure, Varithena (polidocanol injectable foam), and concluded there is a low-quality body of evidence that is insufficient to evaluate the safety and effectiveness of this product for treating incompetent great saphenous veins, accessory saphenous veins, and visible varicosities above and below the knee in adults, compared with other treatments for varicose veins.

Alternate interventions for the treatment of symptomatic, incompetent varicose veins also include mechanochemical ablation (MOCA) (e.g. ClariVein), Cyanoacrylate adhesive (e.g. VenaSeal) and endovenous cryoablation. Mechanochemical ablation technology is an endovascular procedure involving a flexible catheter with a 360º rotating wire that causes a minimal mechanical damage to the endothelium and induces vasospasm. The rotating tip dispenses a sclerosant which is intended to seal the vein. Hayes (2018) conducted a review of ClariVein and indicates there is a low body of evidence that treatment of varicose veins appears to be safe and effective in the short term, however, substantial uncertainty remains regarding appropriate patient population, treatment parameters and the long-term durability of the procedure. Cyanoacrylate glue is a method of occlusion of varicose veins that does not require the use of tumescent anesthesia. Using a local anesthetic an introducer sheath is inserted distally into the vein to be treated. A delivery catheter is advanced and while the proximal vein is compressed, the adhesive is dispensed from the tip of the catheter to seal the vein. According to NICE Guidelines on this technology, current evidence on the safety and efficacy is limited in both quantity and quality. It is not recommended as a standard of care treatment (NICE, 2015). Endovenous cryoablation, also called cryofreezing or cryostripping has been proposed as a treatment for varicose veins. This procedure is not recommended in published society guidelines and is considered investigational due to insufficient evidence of effectiveness.

Historically, compression hosiery has been a component of conservative management for varicose veins along with periodic leg elevation, weight control, and exercise. According to the NICE guidelines (2013), compression therapy has a role in the treatment of varicose veins during pregnancy and after interventions, but they are not recommended as a first-line intervention, unless, interventional treatment is unsuitable. The American College of Phlebology (ACP) Practice Guideline, Treatment of Superficial Venous Disease of the Lower Leg also recommends use of compression in the post procedure period and after, however, advises against compression therapy as a prerequisite for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate. For patients presenting with a clinical classification score of CEAP C2, the ACP guideline suggests medical compression hose alone may be an acceptable form of treatment. A short trial of compression hose may also be appropriate per this guideline "where an alternate etiology of symptoms is considered, e.g. musculoskeletal pain or neuropathy”. The clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum also address compression therapy and recommends for healing venous ulcers. Compression therapy is not recommended as an initial treatment for candidates appropriate for endovenous ablation. The guideline supports the use of 20-30 mmHg graduated compression therapy as a suggested treatment for symptomatic varicose veins. (Gloviczki, 2011).
VII. CODING DISCLAIMER
CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require preauthorization.

<table>
<thead>
<tr>
<th>Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria.</th>
<th>Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply the Medical Policy criteria.</th>
<th>US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria.</th>
<th>Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria.</th>
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<tbody>
<tr>
<td>Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits</td>
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VIII. CODING INFORMATION

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<tr>
<th>CPT CODES</th>
<th>DESCRIPTION</th>
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<tr>
<td>0524T</td>
<td>Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring</td>
</tr>
<tr>
<td>36465</td>
<td>Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)</td>
</tr>
<tr>
<td>36466</td>
<td>Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg</td>
</tr>
<tr>
<td>36468</td>
<td>Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk</td>
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<tr>
<td>36470</td>
<td>Injection of sclerosing solution; single vein</td>
</tr>
<tr>
<td>36471</td>
<td>Injection of sclerosing solution; multiple veins, same leg</td>
</tr>
<tr>
<td>36473</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated</td>
</tr>
<tr>
<td>36474</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)</td>
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<tr>
<td>36475</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated</td>
</tr>
</tbody>
</table>
36476  Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36478  Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

36479  Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36482  Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated

36483  Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

37765  Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions

37766  Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions

<table>
<thead>
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<th>HCPCS CODES</th>
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<td>S2202</td>
<td>Echosclerotherapy</td>
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IX. REFERENCE STATEMENT
Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

X. REFERENCES


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XI. APPROVALS