



# Cardio Policy:

## Lower Extremity Venous Sclerotherapy

<b>POLICY NUMBER</b> UM CARDIO_1254	<b>SUBJECT</b> Lower Extremity Venous Sclerotherapy		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 6</b>
<b>DATES COMMITTEE REVIEWED</b> 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/01/19, 03/08/19, 05/08/19, 12/11/19, 01/23/20, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22	<b>APPROVAL DATE</b> April 13, 2022	<b>EFFECTIVE DATE</b> April 29, 2022	<b>COMMITTEE APPROVAL DATES</b> 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/01/19, 03/08/19, 05/08/19, 12/11/19, 01/23/20, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22	
<b>PRIMARY BUSINESS OWNER:</b> UM		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM v8: UM 1-2; UM 2-1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid	

### I. PURPOSE

Indications for determining medical necessity for Lower Extremity Venous Sclerotherapy.

### II. DEFINITIONS

Varicose veins are a manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension which are superficially located, dilated (> 3mm), tortuous, veins of the lower extremities. These dilated superficial veins of the lower limbs are considered pathologic when they are 5 mm or greater in diameter or sometimes 3 mm or greater in diameter when measured in the upright position and have greater than 500milliseconds of reflux by duplex scan.

Spider veins are intradermal venules of <1 mm, also known as telangiectasia or thread veins.

Reticular veins are intradermal venules of 1-3 mm. Superficial veins are truncal (GSV/SSV) and accessory/tributary veins located nearest to the skin. Perforator veins are the veins linking the superficial and deep veins. Deep veins are located deep to the muscular fascia, such as the common femoral vein. These can cause clinically significant pain and result in a decrease in quality of life and even disability which may necessitate treatment.

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences—edema and skin changes—should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A

duplex ultrasound scan of the deep and superficial venous systems must support the examination findings.

**Classification for chronic venous disorders (CVD and CVI) is based on clinical severity (C), etiology (E), anatomy (A), and pathophysiology (P) to improve the accuracy of the diagnosis (CEAP)**

- C 0- No visible or palpable signs of venous disease
- C 1- Telangiectasias or reticular veins less than 3 mm
- C 2- Simple varicose veins (3 or larger)
- C 3- Ankle edema of venous origin (not foot edema)
- C 4a- Skin pigmentation or eczema
- C 4b- Lipodermatosclerosis or atrophic blanche
- C 5- Healed venous ulcer
- C 6- Open venous ulcer

**S- Symptomatic**, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction

#### **A- Asymptomatic**

Etiologic Classification:

- Ec- Congenital Ep- Primary
- Es- Secondary (post-thrombotic)
- En- No venous cause identified

#### **Anatomic classification:**

- As- Superficial veins
- Ap- Perforator veins
- Ad- Deep veins
- An- No venous location identified

#### **Pathophysiologic classification:**

- Pr- Reflux
- Po- Obstruction
- Pr,o- Reflux and obstruction
- Pn- No venous pathophysiology

#### **Venous Clinical Severity Score(VCSS)**

Pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning)

None = 0: None

Mild = 1: Occasional pain or discomfort that does not restrict daily activities

Moderate = 2: Daily pain or discomfort that interferes with, but does not prevent, regular daily activities

Severe = 3: Daily pain or discomfort that limits most regular daily activities

#### **Varicose Veins**

None= 0: None

Mild = 1: Few, scattered, varicosities that are confined to branch veins or clusters. Includes “corona phlebectatica” (ankle flare), defined as >5 blue telangiectasia at the inner or sometimes the outer edge of the foot

Moderate = 2: Multiple varicosities that are confined to the calf or the thigh

Severe = 3: Multiple varicosities that involve both the calf and the thigh

### **Venous Edema**

None= 0: None

Mild= 1: Edema that is limited to the foot and ankle

Moderate= 2: Edema that extends above the ankle but below the knee

Severe= 3: Edema that extends to the knee or above

### **Skin Pigmentation**

None = 0: None, or focal pigmentation that is confined to the skin over varicose veins

Mild = 1: Pigmentation that is limited to the perimalleolar area

Moderate = 2: Diffuse pigmentation that involves the lower third of the calf

Severe = 3: Diffuse pigmentation that involves more than the lower third of the calf

### **Induration**

None = 0: None

Mild = 1: Induration that is limited to the peri-malleolar area

Moderate = 2: Induration that involves the lower third of the calf

Severe = 3: Induration that involves more than the lower third of the calf

### **Active Ulcer Number**

None = 0: None

Mild = 1: One Ulcer

Moderate = 2: Two Ulcers

Severe = 3: =Three Ulcers

### **Active Ulcer**

None = 0: No active ulcers

Mild = 1: Ulceration present for <3 mo

Moderate = 2: Ulceration present for 3-12 mo

Severe = 3: Ulceration present for >12 mo

### **Active Ulcer Size**

None = 0: No active ulcer

Mild = 1: Ulcer <2 cm in diameter

Moderate = 2: Ulcer 2-6 cm in diameter

Severe = 3: Ulcer >6 cm in diameter

### **Use of Compression Therapy based on compliance**

None = 0: Not used

Mild = 1: Intermittent use

Moderate = 2: Wears stockings most days

Severe = 3: Full compliance: stockings

**Sclerotherapy** is a form of surgery that involves injecting special solutions into the veins to seal them. The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately resulting in the occlusion of the vessel.

### **Types of Sclerosing agents**

- A. Hyperosmolar agents cause nonspecific cellular destruction, burning, affects RBCs- dehydration. Examples include hypertonic saline usually mixed with Lidocaine.

- B. Detergent's cause cell surface disruption and extraction of proteins within seconds, lasting hours. Examples include Glycerin with Lidocaine and Epinephrine, Polidocanol (Asclera, Varithena, STS-Sodium tetradecyl sulfate).
- C. Chemical agents cause direct corrosive effect, disrupts the intercellular cement, poisons cell surface proteins, and affects chemical bonds immediately on vein wall exposure. Sklermo or Chromex is a chemical agent and is not FDA approved for this procedure.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

### III. POLICY

**Indications for approving a request for medical necessity are:**

**All below indications are applicable only if there is documentation of failure of compression therapy for 90 days except in presence of non-healing ulcers.**

- A. Liquid Sclerotherapy of C1 disease of telangiectasia and their feeding reticular veins may be appropriate in presence of spontaneous and/or traumatic venous bleeding. Feeding reticular veins do not need to have presence of reflux. **(AUC Score 7)<sup>1,2,3</sup>**
- B. Foam or Liquid Sclerotherapy can be performed for incompetent symptomatic (C2 and VCSS>6 or C3-6) tributary/reticular veins ( $\geq 3\text{mm}$ ) and/ or GSV ( $\geq 5\text{mm}$ ) and/or SSV( $\geq 3\text{mm}$ ) and with reflux duration  $\geq 500\text{ms}$ . **(AUC Score 8)<sup>1,2,3,4</sup>**
- C. Foam or Liquid Sclerotherapy can be performed in primary or recurrent GSV, SSV or Accessory/Tributary varicose veins, C2, VCSS < 6. **(AUC Score 7)<sup>1,2,3</sup>**
- D. Foam Sclerotherapy for incompetent perforator vein(s) demonstrating reflux > 500ms and diameter > 3.5mm is considered medically necessary when there is an active/old healed venous ulcer. **(AUC Score 7)<sup>1,2,3,4</sup>**
- E. Foam or Liquid Sclerotherapy can be performed for large venous plexus or malformation demonstrating reflux >500ms and diameter >3mm in size is appropriate **(AUC Score 7)<sup>1,2,3,4</sup>**

***A complete Venous Duplex after each venous intervention is preferred to demonstrate the result of intervention on the intervened vein(s) and presence of reflux on target vein(s) of the same extremity.***

#### **Limitations:**

The following are considered not medically reasonable and necessary:

- A. The treatment of CEAP clinical classification C0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.

- B. The treatment of CEAP clinical classification C1 (telangiectasias or reticular veins) will be considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage except in patients with spontaneous and/or traumatic venous hemorrhage.
- C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

#### IV. PROCEDURE

- A. To review a request for medical necessity, the following items must be submitted for review:
  - 1. Progress note that prompted the request
  - 2. Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins with CEAP classification and VCSS score
  - 3. Prior venous intervention report
- B. Primary codes appropriate for this service: 36470- Injection of sclerosant; single incompetent vein (other than telangiectasia), 36471- Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg. 36465- Injection of non-compounded foam sclerosant with u/s compression maneuvers, inclusive of all imaging and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein). 36466- Injection of non-compounded foam sclerosant with u/s compression maneuvers, inclusive of all imaging and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg.

#### V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

#### VI. ATTACHMENTS

- A. None

#### VII. REFERENCES

- 1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD)(L38720). Treatment of Chronic Venous Insufficiency of the Lower Extremities. Retrieved from <https://www.cms.gov> January 5th, 2021.
- 2. Gloviczki P, Dalsing MC, Henke P, Lal BK, O'Donnell TF, Shortell CK, et al. Report of the Society for Vascular Surgery and the American Venous Forum on the July 20, 2016 meeting of the Medicare Evidence Development and Coverage Advisory Committee panel on lower extremity chronic venous disease. J Vas Surg. 2017;5(3);1-21.
- 3. Gibson K, Kabnick L; Varithena® 013 Investigator Group. A multicenter, randomized, placebo-controlled study to evaluate the efficacy and safety of Varithena® (polidocanol endovenous microfoam 1%) for symptomatic, visible varicose veins with saphenofemoral junction incompetence. Phlebology. 2017;32(3):185-193.
- 4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.

5. NCQA UM 2022 Standards and Elements.