



August 7, 2020

Novitas Solutions
Union Trust Building Suite 600
501 Grant Street
Pittsburgh, PA 15219

Comments submitted via: ProposedLCDComments@Novitas-Solutions.com

Re: Proposed Local Coverage Determination (LCD): Treatment of Chronic Venous Insufficiency of the Lower Extremities (DL34924)

To Whom It May Concern:

The American Venous Forum (AVF) and the Society for Vascular Surgery (SVS) appreciate the opportunity to comment on the Novitas Proposed Local Coverage Determination (LCD): Treatment of Chronic Venous Insufficiency of the Lower Extremities (DL34924). There are approximately 25 million people in the United States suffering from chronic venous insufficiency (CVI). Venous ulcerations are costly to payers and can lead to significant pain and infection in the affected patients, putting a significant burden on the health care system.

In the Fall of 2019, the AVF and SVS submitted a joint comment letter to Novitas in response to SUPERSEDED LCD L34924 Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities. We outlined our concerns with the previous Novitas LCD as follows:

1. Edema and pain, secondary to venous incompetency, are medically necessary indications for treatment
2. Vein size requirements are without merit or scientific evidence for treatment
3. Limitations of treatment modalities for pathologic perforators

In reviewing the current proposed Novitas LCD DL34924, we were pleased to note Novitas implemented many of our suggested changes. However, the societies recommend additional changes to the Novitas LCD prior to finalizing the LCD. Our recommendations are outlined below.

1. Definition of anatomy and physiology

CURRENT

Clinically significant reflux can also be found in accessory great saphenous veins (i.e., anterior or posterior) which parallel the GSV in the saphenous compartment, the SSV, circumflex veins which course oblique to the GSV, or perforating veins. The perforator veins drain from the superficial veins toward the deep (intramuscular) veins.

SUGGESTED

Clinically significant reflux can also be found in accessory great saphenous veins (i.e., anterior or posterior) which parallel the GSV in the saphenous compartment, the SSV, ~~circumflex veins which course oblique to the GSV~~, or perforating veins. The perforator veins drain from the superficial veins toward the deep (intramuscular) veins. The perforator veins drain from the superficial veins toward the deep (intramuscular) veins.

Pathologic perforator veins are defined by outward flow duration >500 ms, vein diameter >3.5 mm and located underneath skin damage or ulceration.

2. Sclerotherapy using foamed scleroscent

There are two methods in common usage in the US currently. Physician Compounded Foam (PCF) in which the MD mixes a gas (ie air, CO₂, O₂) with liquid scleroscent and immediately injects the foam. The other is Polidocanol Endovenous Microfoam (PEM) which is a commercially produced foam containing polidoconol and CO₂. We believe that since both techniques are widely used and known to be efficacious they should be identified to avoid confusion. PEM has distinct CPT codes 36465, 36466. This is similar to the way you handle the thermal techniques of laser and radiofrequency ablations.

CURRENT

Foam Sclerosant: Ultrasound-Guided Foam Sclerotherapy (UGFS):

Foam sclerotherapy is a procedure that is performed under ultrasound guidance. The target, non-target, perforating, and adjacent deep veins are evaluated by ultrasound. UGFS is used for treatment of primary and recurrent varicose veins, including the distal GSV and SSV, perforating veins, and venous malformations.³ UGFS is also useful in post-surgical neovascularization and other complex malformations

SUGGESTED

Foam Sclerosant: Ultrasound-Guided Foam Sclerotherapy (UGFS):

Foam sclerotherapy is a procedure that is performed under ultrasound guidance. The target, non-target, perforating, and adjacent deep veins are evaluated by ultrasound. UGFS is used for treatment of primary and recurrent varicose veins, including the distal GSV and SSV, perforating veins, and venous malformations.³ UGFS is also useful in post-surgical neovascularization and other complex malformations. **Foam Sclerotherapy can be performed using Physician Compounded Foam (PCF) in which the MD mixes a gas (ie air, CO₂, and/or O₂) with liquid scleroscent and immediately injects the foam. Alternatively Polidocanol Endovenous Microfoam (PEM) is commercially supplied and may be used in UGFS.**

3. Reflux studies for veins

Reflux studies for veins are done with provocative maneuvers such as Valsalva, rapid cuff compression and release or manual compression that cause the blood to flow downward across the vein valve. This allows for measurement of a valve closure time. Not spontaneous reflux.

CURRENT

Treatments for varicose veins are considered medically reasonable and necessary when ALL of the following criteria have been met:

- An evaluation of the patient has been performed including a history and physical examination, the CEAP clinical classification and the revised Venous Clinical Severity Score (VCSS), AND
- A duplex scan of the deep and superficial venous systems supports the examination findings,3 AND
- A duplex scan confirms spontaneous abnormally reversed venous flow (reflux) in the saphenous, tibial, deep femoral or perforator veins is 500 milliseconds or greater or the spontaneous reflux in the femoral or popliteal vein is 1000 milliseconds or greater,3 AND
- The CEAP clinical classification is C2 to C6, AND
- The documentation supports signs and/or symptoms that interfere with activities of daily living and/or quality of life.

SUGGESTED

Treatments for varicose veins are considered medically reasonable and necessary when ALL of the following criteria have been met:

- An evaluation of the patient has been performed including a history and physical examination, the CEAP clinical classification and the revised Venous Clinical Severity Score (VCSS), AND
- A duplex scan of the deep and superficial venous systems supports the examination findings,3 AND
- A duplex scan confirms **spontaneous** abnormally reversed venous flow (reflux) **with provocative maneuvers** in the saphenous, tibial, deep femoral varicose or perforator veins is 500 milliseconds or greater or the spontaneous reflux in the femoral or popliteal vein is 1000 milliseconds or greater,3 AND
- The CEAP clinical classification is C2 to C6, AND
- The documentation supports signs and/or symptoms that interfere with activities of daily living and/or quality of life.

4. Perforating vein reflux

Regarding perforating vein reflux, we recommend that you specify the minimal reflux duration and that the perforating vein be in proximity to the ulcer.

CURRENT

Perforator vein management by foam sclerotherapy, thermal ablation, chemical adhesive, mechanochemical ablation, or surgery will be considered medically reasonable and necessary when the primary or residual source of reflux is a perforator vein with underlying severe skin changes and/or venous leg ulceration.

SUGGESTED

Perforator vein management by foam sclerotherapy, thermal ablation, chemical adhesive, mechanochemical ablation, or surgery will be considered medically reasonable and necessary when the primary or residual source of reflux (**>500ms**) **is a perforator vein (>3.5 mm)** **located in the area of** severe skin changes and/or venous leg ulceration.

5. Treating symptomatic varicose tributaries by phlebectomy

We appreciate that you recognize the medical necessity of treating symptomatic varicose tributaries by phlebectomy after treatment of the saphenous vein. We agree that when tributary varices are present in association with saphenous reflux, phlebectomy may reasonably be performed after saphenous treatment, However concomitant phlebectomy and GSV ablation is a well-recognized, efficient, and cost effective approach to the management of this problem. Additionally symptomatic tributary varices may occur in the absence of saphenous reflux and the medical necessity of phlebectomy remains and should be covered in the case when the saphenous is competent or has been treated in the remote past.

CURRENT

Phlebectomy will be considered medically reasonable and necessary for bulbous tributaries above and below the knees along the distribution of the saphenous veins **after** treatment of the saphenous veins.

SUGGESTED

Phlebectomy will be considered medically reasonable and necessary for bulbous tributaries ~~above and below the knees along the distribution of the saphenous veins~~ **with or without** treatment of the saphenous veins, depending if saphenous reflux is present.

If saphenous ablation is performed, phlebectomy can be performed concomitantly or at a later stage.

6. Liquid Sclerotherapy

Although liquid sclerotherapy is used for injection of small reticular veins and telanjectasias for cosmetic purposes and should therefore not be considered medically necessary, liquid sclerotherapy may also be used in larger veins 4 mm or more and should not be summarily excluded from coverage. For instance residual symptomatic tributary varicose veins post Saphenous treatment are often well suited to this therapy. Additionally bleeding from varicose veins in areas of lipodermatosclerosis is well suited to sclerotherapy and clearly medically appropriate.

CURRENT

Invasive Procedures for the management of chronic venous insufficiency: Sclerotherapy: Liquid Sclerosant

“Liquid sclerotherapy is used to treat telangiectasias and reticular veins and is not recommended for the treatment of other lower extremity veins.”

#2 Liquid sclerotherapy is considered a cosmetic procedure, and therefore, not reasonable and necessary for the purposes of Medicare coverage.

SUGGESTED

Invasive Procedures for the management of chronic venous insufficiency: Sclerotherapy: Liquid Sclerosant

“Liquid sclerotherapy **is may be** used to treat telangiectasias and reticular veins **or may be used to treat bleeding varicose tributaries or symptomatic tributary varicosities after**

saphenous treatment, and is not recommended for the treatment of other lower extremity veins.” However when used for treatment of symptomatic varicose tributaries or bleeding veins is medically indicated and should be covered.

7. **FDA Labeling**

The fairly standard language regarding FDA labeling is somewhat problematic in the circumstance of PCF. While it is a common practice for physicians to compound liquid sclerosant with a gas such as Air or CO2 and to immediately inject the foam.

CURRENT

It is the responsibility of the provider to comply with all applicable State and Federal laws related to the human use of agents. Agents must be used per the FDA approved label.

SUGGESTED

It is the responsibility of the provider to comply with all applicable State and Federal laws related to the human use of agents. ~~Agents must be used per the FDA approved label.~~ Product labeling is an issue between the FDA and industry. As such, it should not be a determinant in CMS coverage policy.

8. **Hemorrhage**

Hemorrhage is not accounted for in the CEAP classification system and may be present in patients with C0 and C1 disease. We asked that a specific exception to CEAP language be adopted as below.

CURRENT

The treatment of CEAP clinical classification C0 (no visible or palpable signs of venous disease) and C1 (telangiectasies or reticular veins) disease is considered cosmetic, and therefore, not reasonable and necessary for the purposes of Medicare coverage

SUGGESTED

The treatment of CEAP clinical classification C0 (no visible or palpable signs of venous disease) and C1 (telangiectasies or reticular veins) disease is considered cosmetic, and therefore, not reasonable and necessary for the purposes of Medicare coverage

Treatment for hemorrhage, which may occur in C0 and C1 disease, does represent a medically necessary situation and should be covered in this policy.

9. **Consultant Summary**

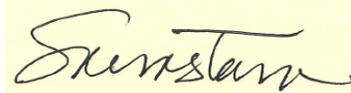
We noted in the “Consultation Summary” section of the proposed Novitas LCD DL34924 that Novitas had a consultation meeting with the “Vascular Surgery Society”. As official representatives from neither SVS nor AVF were in attendance at that meeting, we request that the payer clarify this wording in the final version of the LCD and consider the following possible wordingmeeting with “a vascular surgeon” was held on April 24, 2020.

Thank you in advance for your consideration of our comments. If you have any questions, please contact Trisha Crishock at trishacrishock@gmail.com.

Regards,



Mark Iafrati, MD
Chair, AVF Health Policy Committee



Sunita Srivastava, MD
Chair, SVS Coding Committee