# Local Coverage Determination (LCD):
Treatment of Varicose Veins of the Lower Extremities (L34010)

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## Contractor Information

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<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
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## LCD Information

### Document Information

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<td>L34010</td>
<td>For services performed on or after 10/01/2015</td>
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Treatment of Varicose Veins of the Lower Extremities

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
N/A

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**CMS National Coverage Policy**

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review a NCD. See §1869(f)(1)(A)(i) of the Social Security Act.
Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act, §1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Manual System, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.1 indicates services will be considered medically reasonable and necessary only if ordered and furnished by appropriately trained personnel.

This training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty or must reflect extensive continued medical education activities. If these skills have been acquired by way of continued medical education, the courses must be comprehensive, offered or sponsored or endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States, and designated by the American Medical Association (AMA) as Category 1 Credit.

**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence). The venous insufficiency results in dilated, tortuous, superficial vessels that protrude from the skin of the lower extremities. Spider veins (telangiectasias) are dilated capillary veins that are most often treated for cosmetic purposes. Treatment of telangiectasias is not covered by Medicare.

Historically, varicose veins have been treated by conservative measures such as exercise, periodic leg elevation, weight loss, compressive therapy and avoidance of prolonged immobility. When conservative measures are unsuccessful, and symptoms persist, the next step has been sclerotherapy or surgical ligation with or without stripping. Sclerotherapy involves the injection of a sclerosing solution into the varicose vein(s).

**Compressive sclerotherapy** is the injection of the sclerosant into an empty vein (elevated limb) followed by application of a compressive bandage or dressing. This is the most commonly performed sclerotherapy procedure for varicose veins of the lower extremity. Compressive sclerotherapy is indicated for local small to medium symptomatic varices, isolated incompetent perforators, or recurrence of symptomatic varices after adequate surgical removal of varices. It is not considered an appropriate option for large, extensive or truncal varicosities. Foam sclerotherapy is FDA indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. It is usually given with ultrasound guidance. **Non-Compressive sclerotherapy** is not covered by Medicare.

More recently, endoluminal radiofrequency ablation (ERFA) and endoluminal laser ablation have been developed as alternatives to sclerotherapy and surgical intervention. These procedures are designed to damage the intimal wall of the vein resulting in fibrosis and subsequent ablation of the lumen of a segment of the vessel. Both procedures utilize specially designed catheters inserted through a small incision in the distal thigh and advanced, often under ultrasound guidance, nearly to the saphenofemoral junction. The catheter is then slowly withdrawn while controlled radiofrequency or laser energy is applied. This is followed by external compression of the treated segment.

Doppler ultrasound or duplex studies are often used to map the anatomy of the venous system prior to the
procedure. There is adequate evidence that pre-procedural ultrasound is helpful, and Medicare will cover one ultrasound or duplex scan prior to the procedure to determine the extent and configuration of the varicosities.

Evidence and clinical experience supports the use of ultrasound guidance during the procedure (ERFA and laser ablation only) and shows that the outcomes may be improved and complication rates may be minimized when ultrasound guidance is used. The CPT codes for radiofrequency and laser include the intraoperative ultrasound service in the valuation and ultrasound may not be billed separately with these procedures.

In contrast to ERFA and laser procedures, intra-operative ultrasound guidance techniques have not been shown to increase the effectiveness or safety of sclerotherapy for varicose veins, therefore, intra-operative ultrasound guidance will not be separately covered for sclerotherapy.

**A. Indications for surgical treatment:** For example venous ligation, vein stripping and/or sclerotherapy.

1. A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, **AND**

2. The patient is symptomatic and has one, or more, of the following:
   a. Pain or burning in the extremity severe enough to impair mobility
   b. Recurrent episodes of superficial phlebitis
   c. Non-healing skin ulceration
   d. Bleeding from a varicosity
   e. Stasis dermatitis
   f. Refractory dependent edema

**B. Indications for ERFA or laser ablation**

In addition to the above (see A), the patient's anatomy and clinical condition are amenable to the proposed treatment including **ALL** of the following:

1. Absence of aneurysm in the target segment.
2. Maximum vein diameter of 12 mm for ERFA or 20 mm for laser ablation
3. Absence of thrombosis or vein tortuosity, which would impair catheter advancement.
4. The absence of significant peripheral arterial diseases.

**C. Limitations for ERFA and laser ablation:**

1. ERFA and laser ablation are covered only for the treatment of symptomatic varicosities of the lesser or greater saphenous veins and their tributaries which have failed 3 months of conservative therapy.
2. Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation, and sclerotherapy.
3. The treatment of asymptomatic varicose veins, or symptomatic varicose veins without a 3-month trial of conservative measures, by any technique will be considered cosmetic and therefore not covered.
4. The treatment of spider veins or superficial telangiectasis by any technique is considered cosmetic, and therefore not covered.
5. Coverage is only for devices specifically FDA-approved for these procedures.
6. One pre-operative Doppler ultrasound study or duplex scan will be covered.

Noridian notes that stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary as described in this LCD are met.

Noridian notes that if sclerotherapy is used with endovenous radiofrequency ablation, it may be covered if the criteria for reasonable and necessary as described in this LCD are met.
Noridian will not consider the treatment of asymptomatic veins with endoluminal ablation or sclerotherapy medically reasonable and necessary. If it is determined on review that the varicose veins were asymptomatic, the claim will be denied as a noncovered (cosmetic) procedure.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

Summary of Evidence

N/A

Analysis of Evidence  
(Rationale for Determination)

N/A

General Information

Associated Information

1. Each claim must be submitted with an ICD-10-CM code(s) that reflects the condition of the patient and indicates the reason(s) for which the service was performed.

2. The patient's medical record must contain a history and physical examination supporting the diagnosis of symptomatic varicose veins, and the failure of an adequate (at least 3 months) trial of conservative management.

3. The medical record must document the performance of appropriate tests, if medically necessary, to confirm the pathology of the vascular anatomy.

4. This documentation must be made available to Medicare upon request.

5. The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

6. When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

Sources of Information

Refer to Bibliography
1. Other carrier policies including those from Empire, HGSA and CIGNA.

2. Manufacturer’s Literature. VNUS Medical Technologies, Inc.


14. Noridian Contractor Advisory Committee Members.

15. Todd K., Wright, DI, VANISH-2 Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidoncanol endovenous microfoam 035% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. Phlebology. Sage

17. Lake Washington Vascular Surgeons, Bellevue, WA, USA; Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (The WAVES study); *Vascular*; 2017 Apr;25(2):149-156.


### Revision History Information

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<tr>
<td>12/01/2019</td>
<td>R13</td>
<td>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
<td>• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. )</td>
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<td>12/01/2019</td>
<td>R12</td>
<td>12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD</td>
<td>• Provider Education/Guidance • Revisions Due To Code Removal</td>
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<tr>
<td>01/01/2018</td>
<td>R11</td>
<td>12/7/17: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>01/01/2018</td>
<td>R10</td>
<td>requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Added 36473 and 36474 to the ICD-10 Codes that Support Medical Necessity section.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>10/01/2017</td>
<td>R9</td>
<td>12/6/17: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. 2018 CPT Coded added effective 01/01/2018: 36465, 36466, 36482, 36483</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
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DATE (08/22/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.

Add:

I87301 Chronic venous hypertension (idiopathic) without complications of right lower extremity

I87302 Chronic venous hypertension (idiopathic) without complications of left lower extremity
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<td>01/01/2017</td>
<td>R8</td>
<td>Clarification regarding coding under Group 1 Paragraph: 36299* is used for sclerotherapy with mechanical agitation (e.g. Clarivein® device) prior to January 1, 2017. On and after this date use the AMA assigned codes 36473 and 36474 to report this procedure. These codes are inclusive of the sclerosing agent. 37799* should be used to report &quot;Trivex Procedure&quot;</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>01/01/2017</td>
<td>R7</td>
<td>2017 CPT updates deleted 93965 effective 12/31/2016</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<td>01/01/2017</td>
<td>R6</td>
<td>2017 coding update to end-date 36299 effective 12/31/2016.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<tr>
<td>01/01/2017</td>
<td>R5</td>
<td>2017 CPT Code update to add 36473 and 36474</td>
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<td>03/13/2016 R4</td>
<td>This final LCD, effective 03/13/2016, combines JFA L36599 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD number.</td>
<td>Creation of Uniform LCDs Within a MAC Jurisdiction</td>
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<td>03/13/2016 R3</td>
<td>The LCD is revised editorially to be consistent for both Jurisdictions JE and JF AB MACs. The effective date remains the same.</td>
<td>Creation of Uniform LCDs Within a MAC Jurisdiction, Revisions Due To CPT/HCPCS Code Changes, Typographical Error</td>
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<tr>
<td>03/13/2016 R2</td>
<td>This I-10 version is the result of I-9 DL24375 finalizing in I-10</td>
<td>Creation of Uniform LCDs Within a MAC Jurisdiction</td>
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<td>10/01/2015 R1</td>
<td>This LCD is revised to remove the paragraph, “When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director’s review.” from the Associated Information field.</td>
<td>Other (Removed the paragraph, “When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director’s review.”)</td>
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### Associated Documents

#### Attachments
N/A

#### Related Local Coverage Documents

Article(s)
- A57707 - Billing and Coding: Treatment of Varicose Veins of the Lower Extremities
- A54715 - Response to Comments: Treatment of Varicose Veins of Lower Extremities
- A53079 - Sclerosing of Varicose Veins

#### Related National Coverage Documents

Created on 02/06/2020. Page 10 of 11
Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A
Updated on 11/08/2019 with effective dates 12/01/2019 - N/A
Updated on 12/07/2017 with effective dates 01/01/2018 - 11/30/2019
Updated on 12/06/2017 with effective dates 01/01/2018 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A