

Local Coverage Determination (LCD)

Treatment of Varicose Veins of the Lower Extremities

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information

Document Information

LCD ID

L39121

LCD Title

Treatment of Varicose Veins of the Lower Extremities

Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL39121](#) 

Original Effective Date

For services performed on or after 04/03/2022

Revision Effective Date

For services performed on or after 11/16/2023

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

02/17/2022

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Notice Period End Date

04/02/2022

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Issue**Issue Description**

This LCD outlines limited coverage for this service with specific details under *Coverage Indications, Limitations and/or Medical Necessity*.

Issue - Explanation of Change Between Proposed LCD and Final LCD

The final version has revised verbiage to clarify that Cyanocrylate is an ablation technique. Different types of foam; physician compounded foam (PCF) and non-compounded foam (NCF) is now included. Registered vascular technologist (RVT) to the Non-Invasive Venous Studies has been added. The limitation for the Klippel Trenaunay Syndrome was removed. The issue of the vein diameter was revised. Comments on conservative therapy was revised. The requirement of a statement of the objective of treatment in advance generalized systemic disease that limits quality -of -life was added. Finally, a requirement for incompetent perforator veins should be at least 3.5 mm in diameter for treatment was added.

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be 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, §1862(a)(7) states Medicare will not cover any services or procedures associated with routine physical checkups.

42 CFR §411.15(k)(1) Any services that are not reasonable and necessary for 1 of the following purposes: For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

CMS Internet-Only Manual, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provisions in LCDs

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4, §220.5 Ultrasound Diagnostic Procedures

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Chronic venous disorders of the lower extremity incorporate a spectrum of morphologic and functional abnormalities of the venous system. Symptoms and findings include pain, leg heaviness, aching, swelling, skin dryness, tightness, itching, irritation, and muscle cramps. Clinical signs of venous disease include dilated veins (e.g. telangiectasia, varicose veins), leg edema, skin changes (lipodermatosclerosis; a fibrosing dermatitis of the subcutaneous tissue), and skin ulceration. The presence of symptoms and clinical signs of venous disease correlates with the presence of venous reflux (in the superficial or deep veins) and/or venous obstruction identified on duplex ultrasound.¹

The Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification serves as a basis to categorize the clinical presentation of the patient, the underlying etiology, what anatomic veins are affected, and the

underlying pathology in those veins. CEAP is a classification system. The following is the clinical portion of the CEAP:^{2,10}

CEAP classification for chronic venous disorders:

Clinical Classification	
C ₀	No visible or palpable signs of venous disease
C ₁	Telangiectasias, reticular veins
C ₂	Varicose veins
C _{2r}	Recurrent varicose veins
C ₃	Edema
C ₄	Changes in skin and subcutaneous tissue secondary to chronic venous disease
C _{4a}	Pigmentation or eczema
C _{4b}	Lipodermatosclerosis or atrophie blanche
C _{4c}	Corona phlebectatica
C ₅	Healed
C ₆	Active venous ulcer
C _{6r}	Recurrent active venous ulcer
S	With symptoms attributable to venous disease
A	Absence of symptoms attributable to venous disease

Venous duplex ultrasound examination confirms the diagnosis demonstrating the presence of venous reflux (>500 milliseconds for superficial or perforator veins; >1000 milliseconds for deep veins).³

A variety of treatment modalities are available to treat varicose veins/chronic venous insufficiency. Treatment modalities include conservative management and invasive procedures.

Conservative Management (Non-Invasive Procedures)

Components of conservative therapy should be discussed and individualized to meet the needs of each patient and must be documented in the medical record. The discussion should include, but is not limited to:

- Weight reduction
- Exercise plan and prescribed physical activity (walking, treadmill, cycling)
- Periodic leg elevation
- Compressive therapy with use of surgical grade compression stockings (minimum 20-30 mmHg)

For patients who meet any 1 of the following criteria, conservative therapy may be waived.

- C4-C6 disease (skin changes assigned to venous disease, healed venous leg ulceration, and active venous leg ulceration)
- Hemorrhage
- Recurrent superficial thrombophlebitis

Invasive Procedures

A) Sclerotherapy:

Sclerotherapy is a minimally invasive percutaneous technique using chemical irritants, that is, liquid and foam sclerotherapy techniques, to close unwanted veins. Sclerotherapy for treatment of varicose veins or reflux is followed by compression therapy of the affected lower limb using either elastic or conventional bandaging.

- Liquid Sclerosant:

Liquid sclerotherapy can be used to treat telangiectasias, reticular veins, small varicose veins (3-6 mm), residual or recurrent veins following endovenous ablation or surgery, and perforator veins.⁴

Some examples of sclerotherapy agents are polidocanol, hypertonic saline, sodium tetradecyl sulfate, and glycerin.

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

Foam sclerotherapy is a procedure that is performed under ultrasound guidance and is a nonthermal therapy. The different types of foam are physician-compounded foam (PCF) and non-compounded foam (NCF). Foam preparations are used for treatment of symptomatic varicose veins ≥ 3 mm. The heavier foam is needed to displace the increased volume of blood in these larger veins, which increases the contact time of the sclerosant with the vein wall, enhancing the sclerosant effect. Ultrasound-guided foam sclerotherapy (UGFS) is used for the treatment of reflux of the superficial axial veins (great saphenous vein (GSV), small saphenous vein (SSV), accessory saphenous vein (ASV)), reflux of perforator veins, and venous malformations.⁵ It is recognized that foam sclerotherapy is not Food and Drug Administration (FDA)-approved. However, UGFS has been in use in the United States for more than 20 years and is a standard of care for many venous disorders with an excellent safety profile.²⁸

B) Thermal Ablation:

- **Radiofrequency Ablation (RFA), Endovenous Radiofrequency Ablation (ERFA):**

RFA is a minimally invasive percutaneous technique using radiofrequency energy and ultrasound guidance to puncture the vein and position a catheter to ablate incompetent veins. The device is used primarily to treat insufficiency of the axial veins (i.e., great, small, anterior accessory GSVs), but perforator veins can also be treated with a specialized radiofrequency stylet. The indications for RFA are the same as for other venous ablation techniques.⁶ Patients with persistent symptoms and signs of superficial venous disease and documented axial venous reflux (i.e., retrograde flow >500 ms for superficial or perforator veins) are candidates for treatment. The procedure may be performed in an outpatient setting.

- **Endovenous Laser Ablation (EVLA), Endovenous Laser Ablation Therapy (EVLT):**

EVLA is a percutaneous technique that uses laser energy to ablate incompetent superficial veins. The axial veins are the primary target for this therapy and include the GSV, SSV, and anterior accessory great saphenous veins (AAGSVs). A relative contraindication to thermal ablation (EVLA and RFA) is severe tortuosity of a vein segment in which passage of the device may not be possible. Minimally invasive therapies, including RFA and EVLA, provide similar or improved clinical outcomes compared with GSV ligation and stripping.^{7,24}

C) Chemical Adhesive (Cyanoacrylate Embolization):

This nonthermal ablation technique uses a glue delivered into the saphenous vein using a catheter for access that induces a foreign body reaction leading to inflammation and fibrotic occlusion of the vessel. It is used for the treatment of incompetent saphenous veins (GSV, SSV, AAGSV).^{8,14,15,22}

D) Mechanochemical Ablation (MOCA):

This nonthermal technique uses both mechanical damage to the vein endothelium with a rotating wire and simultaneous chemical injury with installation of a liquid sclerosant to lead to scarring and fibrosis. The most common site of treatment is the GSV. It is used for the treatment of incompetent saphenous veins (GSV, SSV, AAGSV).^{11,19}

E) Surgical: Ligation, Stripping, Phlebectomy:

Saphenous vein ligation and division is the detachment of the saphenous vein (GSV, SSV, AGSV) through an incision at the groin at its confluence with the saphenofemoral junction and common femoral vein. It is the traditional treatment and is called high ligation and saphenous vein stripping. The primary goal is removal of the refluxing veins at the saphenofemoral junction. Phlebectomy, also known as stab phlebectomy, ambulatory phlebectomy, or microphlebectomy, involves the removal of secondary smaller veins as the removal of the varicose veins are through a small 1-2 mm incision in the skin overlying the vein.²⁴

Covered Indications

Medicare will consider invasive procedures (only with the techniques outlined in this local coverage determination (LCD) and under the conditions described) as reasonable and necessary when documentation in the medical record includes a history, physical examination, CEAP clinical classification, and a venous duplex scan documenting reflux (>500 msec).

1. Liquid sclerotherapy will be considered reasonable and necessary to treat telangiectasias, reticular veins, small varicose veins (3-6 mm), residual or recurrent veins following endovenous ablation or surgery, and perforator veins. Treatment of telangiectasias and reticular veins (C1) (<3 mm) is considered reasonable and necessary with documentation of spontaneous and/or traumatic venous hemorrhage, **OR** for dilated intradermal veins in the elderly judged to be a substantial risk for hemorrhage with minimal trauma, **OR** near an active or healed ulcer if judged to contribute to local venous hypertension.
2. Saphenous veins (GSV, SSV, AAGSV) management, with UGFS, endovenous thermal ablation (radiofrequency or laser), chemical adhesive (cyanoacrylate embolization), MOCA, and surgery (surgical ligation and stripping) is considered reasonable and necessary with documentation in the medical record of CEAP class C2-C6 disease, reflux (>500 msec), and **ANY** of the following signs or symptoms:
 - a. Ulceration secondary to venous stasis;
 - b. Significant pain or significant edema associated with saphenous reflux that interferes with activities of daily living (ADLs);
 - c. Bleeding associated with ruptured superficial varicosity;
 - d. Recurrent episodes of superficial phlebitis;
 - e. Stasis dermatitis;
 - f. Refractory dependent edema
3. Incompetent perforator veins (IPVs) are the most common cause of recurrent varicose veins after treatment. Minimally invasive treatments have replaced traditional surgical treatments for IPVs. UGFS

and endovenous thermal ablation with either radiofrequency or laser energy sources will be considered reasonable and necessary⁹ with the following conditions:

- Demonstrated perforator reflux >500 msec; **AND**
- No saphenous reflux (greater, small, or accessory) and/or symptomatic varicose tributaries; **AND**
- An active venous ulcer; **AND**
- The IPV is at least 3.5 mm in diameter; **AND**
- The perforator is in the vicinity of the ulcer.

Non-Invasive Venous Studies

Pre-operative venous studies are considered reasonable and necessary prior to varicose vein treatment when initially performed by an accredited vascular technician. The study will fully define the anatomy, size, and tortuosity of the great and lesser saphenous vein, superficial venous segments, and perforators and will determine the extent of venous valvular incompetence. Medicare will cover a pre-procedure duplex scan used in conjunction with other non-invasive physiologic testing to determine the extent and configuration of the varicosities. It is expected that these studies will be performed by the physician planning to provide the therapy or by a registered vascular technologist (RVT). Medicare will cover intraoperative ultrasonic guidance in situations when it is medically necessary. Also, Medicare includes payment for the ultrasound in the payment for ERFA and laser ablation procedures. This A/B MAC will allow for post-procedure studies within a 6-month period.

Credentialing and Accreditation Standards

A vascular diagnostic study may be performed by a physician, a certified technologist, or in a certified vascular testing lab. The accuracy of non-invasive vascular diagnostic studies depends on the knowledge, skill, and experience of the technologist and interpreter. Services will be considered reasonable and necessary only if performed by appropriately trained providers.

All non-invasive vascular diagnostic studies must be performed meeting at least 1 of the following:

- Performed by a licensed qualified physician, **OR**
- Performed by a technician who is certified in vascular technology, **OR**
- Performed in facilities with laboratories accredited in vascular technology.

Limitations

Services that are not reasonable and necessary cannot be covered by Medicare in the following:

1. CEAP clinical classification C0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable and necessary and cannot be covered by Medicare;
2. CEAP clinical classification C1 (telangiectasias or reticular veins) is considered cosmetic and not reasonable and necessary with the exception of documentation of spontaneous and or traumatic venous hemorrhage;
3. Severe distal arterial occlusive disease;
4. Acute deep vein thrombosis (DVT) or superficial vein thrombosis;
5. Allergy to the sclerosant;
6. Pregnancy;
7. Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
8. Failure of a vein closure without recurrent signs or symptoms;
9. Any interventional treatment that uses equipment not approved for such purposes by the FDA

Summary of Evidence

Kuyumcu, et al. (2016) evaluated minimally invasive treatments for perforator vein insufficiency.⁹ Incompetent superficial veins are the most common cause of lower extremity superficial venous reflux and varicose veins; however, incompetent or insufficient perforator veins are the most common cause of recurrent varicose veins after treatment, often unrecognized. Perforator vein insufficiency can result in pain, skin changes, and skin ulcers and often merit intervention. They concluded that minimally invasive treatments have replaced traditional surgical treatments for incompetent perforator veins. Current

minimally invasive treatment options include ultrasound guided sclerotherapy (USGS) and endovascular thermal ablation (EVTA) with either laser or radiofrequency energy sources.

Kim, et al. (2017) conducted a 2-year analysis of the efficacy of mechanochemical ablation in patients with C2 or more advanced chronic venous disease.¹¹ This was an observational study during which data were prospectively collected from 6 vein centers using an electronic database. Patients with reflux in the GSV involving the sapheno-femoral junction and no previous venous interventions were included. They concluded that the sustained closure rates of >90% at 2 years with mechanochemical ablation is associated with significant clinical improvement, which is maintained at 24 months, making it a very good option for the treatment of GSV incompetence. Results showed early high occlusion rate with MOCA is associated with significant clinical improvement that is maintained at 24 months.

Lane, et al. (2017) presented a multi-center randomized controlled trial assessing the difference in pain during truncal ablation using MOCA and RFA with 6 months follow-up.¹² Patients undergoing local anesthetic endovenous ablation for primary varicose veins were randomized to either MOCA or RFA. The authors concluded that pain secondary to truncal ablation is less painful with MOCA than RFA with similar short-term technical, QOL, and safety outcomes. A limitation of this study is the lack of long-term follow-up.

Biemans, et al. (2013) compared endovenous laser ablation, foam sclerotherapy, and conventional surgery (high ligation and short stripping) for GSVs in a randomized controlled trial.¹³ The primary outcome was anatomic success defined as obliteration or absence of the treated vein on ultrasound examination after 1 year. The anatomic success rate was highest after EVLA (88.5%), followed by conventional surgery (CS) (88.2%), and UGFS (72.2%) ($P < 0.001$). 84.3% of all treated patients showed an improvement of the “C” of the CEAP classification. The 1-year result defined as anatomic success according to duplex ultrasound, is equally high for EVLA and CS and lower for UGFS.

Gibson, et al. (2017) reported the results of a prospective study of cyanoacrylate closure for the treatment of GSV, SSV, and/or ASVs with the VenaSeal[®] Closure System.⁸ Fifty subjects with symptomatic GSV, SSV,

and/or ASVs incompetence were each treated at a single session. Compression stockings were not used post-procedure. Duplex ultrasound showed that all treated veins (48 GSVs, 14 ASVs, and 8 SSVs) had complete closure at 7 days and 1 month. Phlebitis in the treatment area or side branches occurred in 10 subjects (20%) and completely resolved in all but 1 subject (2%) by 1 month. The authors concluded that cyanoacrylate closure is safe and effective for the treatment of 1 or more incompetent saphenous or accessory saphenous veins. Efficacy as measured by complete vein closure was high. Closure rates were high even without the use of compression stockings or side branch treatment. The limitations of this study include its single arm design and relatively small sample size at a single center.

Gibson, et al. (2018) reported on a prospective, randomized controlled, multicenter trial conducted under an investigational device exemption from the FDA at 10 trial centers in the United States.¹⁵ This trial demonstrates that duplex ultrasound assessed closure rates after GSV treatment with cyanoacrylate closure (CAC) were noninferior to RFA at 24 months. The 24-month complete closure rate was 95.3% in the CAC group and 94.0% in the RFA group, demonstrating continued noninferiority of CAC compared with RFA ($P = 0.0034$). Both treatments produced statistically and clinically significant improvement in venous clinical severity score (VCSS) and QOL measurements, and these improvements were maintained at 24 months. These results suggest that CAC of the GSV is safe and durable out to 2 years. The investigators will continue to observe the patient cohorts, and longer-term data will be collected at 3 and 5 years.

Smith PC (2009) reviewed the published literature on the methods and outcome of UGFS for the treatment of superficial venous incompetence.¹⁸ He concluded that there is sufficient evidence that UGFS is a safe and effective treatment for superficial truncal saphenous incompetence as well as for varices. This treatment is suitable for the management of primary uncomplicated varices, recurrent varicose veins, and patients with lipodermatosclerosis.

Kim, et al. (2019) conducted a single-center retrospective cohort study to compare MOCA and thermal ablation (RFA and EVLT) for venous ulcer healing in patients with clinical class 6 chronic venous insufficiency.¹⁹ 74% of patients treated with MOCA healed their ulcers compared with 35% of those

treated with thermal ablation ($P = 0.01$). A healed ulcer was defined as elimination of ulcer depth and superficial skin coverage. The mean time to heal was 4.4 months in the thermal ablation group compared with 2.3 months with MOCA ($P = 0.01$). The authors concluded that MOCA is safe and effective for treating venous ulcers and can be considered an alternative modality to thermal ablation techniques. The limitation of this study was a retrospective single-center review of a relatively small sample size rather than a prospective randomized controlled trial.

Analysis of Evidence (Rationale for Determination)

The analysis of evidence reviewed for the treatment of varicose veins of the lower extremities included a multicenter randomized controlled trial, prospective study, observational study, retrospective cohort study, single-center retrospective cohort study, published literature review, and practice guidelines of the Society for Vascular Surgery[®] and the American Venous Forum. The literature supports the key recommendations of the guidelines that in patients with chronic venous insufficiency, a complete history and detailed physical examination are complemented by duplex ultrasound scanning of the deep and superficial veins (GRADE 1A). Guidelines also recommend CEAP classification be used for patients with chronic venous disorders (GRADE 1A) and that the revised VCSS is used to assess treatment outcome (GRADE 1B).⁶ The “C” part of CEAP classification is more useful and practical in rating the severity of varicose veins. VCSS has been used to measure clinical improvement after treatment of varicose veins.

The literature reviewed and evaluated compared the different methods of treatment in patients with chronic venous insufficiency. Treatment of chronic venous insufficiency with liquid sclerotherapy, UGFS, thermal ablation (RFA or EVLA), chemical adhesive (cyanoacrylate embolization), MOCA, surgical ligation, stripping, and phlebectomy techniques is considered safe and effective with improved QOL and is considered medically reasonable and necessary when the coverage indications are met in this LCD.

General Information

Associated Information

Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations (NCDs), and all Medicare payment rules.

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD (***Coverage Indications, Limitations and/or Medical Necessity***). The documentation includes, but is not limited to, relevant medical history, physical examination, CEAP clinical classification, and a venous duplex scan. Duplex scan documentation must confirm the presence of reversed venous flow (reflux) with provocative maneuvers in the saphenous or perforator veins equal to 500 milliseconds or greater, and absence of deep venous obstruction.

The patient's medical record must document the following:

- History and physical exam supporting a diagnosis of symptomatic varicose veins;
- Exclusion of other causes of edema, ulceration, and pain in the limbs;
- Performance of appropriate tests to confirm the presence and location of incompetent perforating veins;
- Location and number of varicosities, level of incompetence of the vein, and the veins involved;
- Necessity of utilizing ultrasound guidance, if used

The medical record must also include pre-treatment photographs of the varicose veins for which claims for sclerotherapy are submitted to Medicare. These photographs must be made available to the contractor upon request for review.

Medicare recognizes that multiple injections are needed to perform sclerotherapy and that responses differ due to the anatomical site being treated.

- Only 1 sclerotherapy service per treatment session should be reported for either leg, regardless of how many veins are treated per session (Per CPT® 2020 Professional Edition code book). The medical record must include documentation to justify more than 3 sclerotherapy sessions for each leg per episode of care.
- Patients are not expected to require additional ablation of an individual vein by radiofrequency or laser.

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Local Coverage Determination (LCD):

Treatment of Chronic Venous Insufficiency of the Lower Extremities (L34924)

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
11/16/2023	R2	Under <i>CMS National Coverage Policy</i> the following regulation was removed and placed in the related Billing and Coding: Treatment of Varicose Veins of the Lower Extremities A58876 article: CMS Internet-Only Manual, Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, §3.4.1.3 Diagnosis Code Requirements. Under <i>Bibliography</i> reference #22 was deleted as this is a duplicate of reference #6, remaining references were renumbered accordingly, and changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the LCD. Acronyms were inserted and defined where appropriate throughout the LCD.	Provider Education/Guidance
04/03/2022	R1	Under <i>Associated Information</i> some revisions that were made from responses received during the comment period were inadvertently omitted. The revision reads as follows: Medicare recognizes that multiple injections are needed to perform sclerotherapy and that responses differ due to the anatomical site being treated. Only one sclerotherapy service per treatment session should be reported	Provider Education/Guidance

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		for either leg, regardless of how many veins are treated per session (Per CPT 2020 Professional edition code book). The medical record must include documentation to justify more than 3 sclerotherapy sessions for each leg per episode of care.	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A58876 - Billing and Coding: Treatment of Varicose Veins of the Lower Extremities [↗](#)

A59001 - Response to Comments: Treatment of Varicose Veins of the Lower Extremities [↗](#)

LCDs

DL39121 - Treatment of Varicose Veins of the Lower Extremities (MCD Archive Site) [↗](#)

Related National Coverage Documents

NCDs

220.5 - Ultrasound Diagnostic Procedures [↗](#)

Public Versions

Updated On	Effective Dates	Status	
11/06/2023	11/16/2023 - N/A	Currently in Effect	You are here

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Keywords

N/A