FUTURE Local Coverage Determination (LCD): Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins (L37796)

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Implementation of this LCD is being delayed. This LCD will not become effective on 05/07/2019. Please watch our website at Novitas-solutions.com for updates regarding this LCD. This update first displayed on the MCD on 05/02/2019.

From 01/31/2019 through 03/20/2019 this LCD displayed on the MCD with a Notice Period End Date of 3/20/19 and an Original Effective Date of 3/21/19. The new Notice Period End Date for this LCD is 05/06/19 and the new Original Effective Date is 05/07/2019. The new Original Effective Date and new Notice Period End Date first displayed on the MCD on 03/21/2019.

Please Note: Future Effective Date.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware

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Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
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LCD Information

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for sclerotherapy and endovenous non-thermal treatment of varicose veins. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for sclerotherapy and endovenous non-thermal treatment of varicose veins and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*
  - Chapter 6, Section 20 Outpatient Hospital Services
  - Chapter 15, Section 80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests
  - Chapter 16, Section 10 General Exclusions from Coverage, Section 20 Services Not Reasonable and Necessary, Section 120 Cosmetic Surgery
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4 Reasonable and

Necessary Provisions in LCDs
- CMS IOM Publication 100-09, *Medicare Contractor Beneficiary and Provider Communications Manual, C*hapter 5, Correct Coding Initiative

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1862 (a)(10). This section excludes Cosmetic Surgery.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1865 states effects of accreditation.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Lower extremity veins contain valves to direct blood flow, normally under low pressure, towards the heart.[1-2] Increased pressure can weaken or damage these valves, creating chronic venous insufficiency (CVI) and chronic venous disease (CVD), manifest as tortuous distended veins with retrograde flow.[2(p4),3] Chronic venous disease may evolve into ulcerative skin lesions in affected areas, rupture with life threatening hemorrhage and recurrent clot formation or phlebitis, as well as injury to adjacent tissue.[4-5] Numerous subjective complaints may be related to venous valvular insufficiency, venous hypertension and varicosities which must be correlated to a culprit vein to justify medical necessity for treatment.

Endovenous non-thermal therapy for chronic venous disease or symptomatic varicose vein disease is a covered service to beneficiaries of the Medicare program when criteria for medically necessary interventions are met. This policy specifically addresses methods of sclerotherapy, (e.g., "combined mechanical and chemical irritants", injection of foamed agents and chemical adhesive) for treatment of symptomatic varicose veins of the lower extremities.

Radiofrequency ablation (RFA) and endovenous radiofrequency laser ablation (EVLA) are classified as thermal tumescent (TT) techniques, while Non-Compounded Foam (NCF), Endovenous Chemical Adhesive (ECA) and combined Mechanical/Chemical Sclerosant (MCS, "MOCA") do not require tumescent anesthesia of the tissue adjacent to the treated vein and are referred to as non-thermal non-tumescent (NTNT) techniques. Criteria for medically necessary treatment vary for the two techniques. Please see L34924-Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities for information on other treatments for venous insufficiency and varicose veins of the lower extremities and the companion article for billing and coding instruction, A55229-Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities.

It is expected that initial treatment of varicose veins will be at least a 6-week trial of conservative treatment that commonly involves behavioral measures to relieve symptoms of venous hypertension and distension. These conservative measures may include but are not limited to[1(p2404-2405),2(p9),3(p1),4(e60),6-7]:

- Periodic leg elevation
- Use of graduated compression stockings
- Weight reduction
- Daily exercise
- When possible, avoiding factors that worsen symptoms

Documentation of diligent endeavor to pursue conservative measures shall be included in the patient's records.

Sclerotherapy or the introduction of various agents into the vein may cause an inflammatory response, leading to fibrosis, clot, or thrombosis to occur in portions of the vein's lumen which limits or interrupts blood flow.[8-11] In this policy, the procedure performed to occlude a vein or vein segment by chemical or mechanical irritants and thrombogenic agents or devices within the lumen is referred to as **Sclerotherapy,**[1(p2405),3(p3),10(p330)] **regardless of the approach taken.**[6(p11)] Injection of thrombogenic agents into veins near a junction with the deep venous system requires diligence and restrictive measures to avoid compromise of the deep system with clot propagation and embolization.

Procedures for varicose vein management continue to evolve with new technology and revision of older techniques.[11(p2)] Neither U.S. Federal Drug Administration (FDA) classification and marketing indication nor American Medical Association (AMA) Current Procedural Terminology® (CPT) category descriptors determine that a product meets Medicare reasonable and necessary requirements. All products with FDA clearance/approval used in accordance with the product designated application guidelines will be considered for the purpose of this LCD. It is the responsibility of the treating physician/practitioner to:

- determine and comply with FDA approval or clearance and specific use designation of any agent or device utilized for the procedure or treatment planned
- comply with all applicable State and Federal regulations, laws and licensure related to the use of the agents and devices utilized

Coverage is only allowed for devices or agents with FDA approval or clearance consistent with the designated application and use. For coding and billing information, please see A56268-Coding Article for Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins.

Covered Indications

1. Clinically symptomatic varicose vein not involving the saphenofemoral or saphenopopliteal junction or in situations where surgery or endovenous thermal ablation techniques have previously treated a refluxing junction with the deep venous system but failed to provide complete relief of all symptomatic varicosities.

2. Sclerotherapy is considered medically necessary for the treatment of symptomatic varicosities or symptomatic varicose tributaries of one of the saphenous veins when **all of** the following criteria are met:

    - The patient has a documented history of saphenous vein reflux due to valvular insufficiency, etiologic for the symptoms and findings.
    - The varicose vein, cluster or tributary is symptomatic, as described above, or poses a distinct risk to the

beneficiary's well-being and continued health, or the performance of the beneficiary's normal activities of daily living. The distinct nature of the risk **must be** clearly documented in the medical records.

- Previous ablation of the saphenous vein at the saphenofemoral junction or saphenopopliteal junction has been done or the junction secured such that there is absence of continued, recurrent or clinically significant reflux which would allow for embolism or propagation of clot to the deep vein.
- The vein size is greater than 3-millimeters (mm) and less than 12-mm in diameter* at least 25-mm below the junction with the femoral or popliteal vein and documented to have reverse flow (reflux) at that point.
- The varicosities result in any of the following:
    - Intractable ulceration secondary to venous stasis
    - More than one episode of minor hemorrhage or a single significant hemorrhage from the same or adjacent ruptured varicosity
    - Recurrent superficial thrombophlebitis in the same or adjacent vein
    - Localized surrounding edema, cellulitis or fat necrosis
    - Severe and persistent or recurrent pain, edema or cellulitis localized to the vein and interfering with activities of daily living and requiring analgesics, antibiotic or local therapy

*Present devices or agents available for sclerotherapy and non-thermal ablative techniques described in this LCD have not demonstrated reliable benefit for treatment of symptomatic veins outside this size range.[5(p216), 10(p322), 12-15]

Limitations

The following are considered not reasonable and necessary and therefore will be denied:

1. Vascular embolization or occlusion is not applicable for any varicose vein procedure and is therefore non-covered for such treatment.
2. Any method of sclerotherapy or ablation performed on a varicose vein that is not symptomatic by criteria of this LCD is not covered by Medicare.
3. Any form of sclerotherapy or non-thermal ablation used as treatment for symptomatic reflux or varicose changes of a truncal vein (greater or lesser saphenous vein) of the lower extremity.
4. Sclerotherapy or endovenous non-thermal ablation with catheter delivered liquid, foam or abrasion alone, or in combination, **are not considered medically necessary for primary treatment of saphenofemoral or saphenopopliteal junctional venous insufficiency** as data does not support efficacy and safety compared to the standards of surgical ligation or heat ablation (RFA, EVLA). Safety concerns for the beneficiary mandate this limitation. Beneficiary safety is paramount with any procedure and any sclerotherapy agent or device is considered inappropriate for the treatment of reflux at the saphenofemoral junction or saphenopopliteal junction for the concern of clot propagation or embolus into the deep and central venous systems (Deep Venous Thrombosis [DVT] and Pulmonary Embolus [PE]).
5. Imaging guidance and monitoring is included for some procedures. Imaging guidance utilized outside of the acceptable components of the procedure will be considered not medically reasonable and necessary and not reimbursed separately.
6. Ultrasound mapping or monitoring techniques are considered medically necessary only to initially determine the extent and configuration of symptomatic varicosities or valvular insufficiency. Post procedure assessment by imaging techniques is inappropriate to confirm efficacy or outcome of the procedure.
7. The following are considered cosmetic and therefore not covered by Medicare:

    - Treatment of veins less than 3mm in diameter
    - Treatment of telangiectasias or associated reticular veins

- Procedures for cautery or photothermal sclerosis (also referred to as an intense pulsed light source), transdermal laser treatment (e.g., Lumina, PhotoDerm VascuLight, VeinLase)

8. Endovenous ablation with any sclerotherapy technique is covered for a maximal vein diameter of no more than 12-mm over the entire course of the treated vein.
9. Injection of sclerosant into veins with the legs in a dependent position (veins distended) or treatment that is not followed by the application of a compressive dressing (Non-compressive sclerotherapy).
10. All treatment modalities covered for treatment of varicose veins, venous insufficiency, symptomatic varicosities are excluded for treatment of deep vein incompetence, acute superficial vein thrombosis, post thrombotic syndrome or other disease and sequella associated with deep vein thrombosis, incompetence or obstruction.
11. The methods delineated in this coverage determination for treating saphenous vein truncal incompetence and varicosities, consistent with truncal vein sclerotherapy, have not been shown to significantly differ from other forms of sclerotherapy in method or outcome, and subsequently are non-covered as ablative techniques for symptomatic disease of the greater saphenous or lesser saphenous trunks, or any branch adjacent to junctions with the deep veins.
    - Non-compounded foam sclerosant, including ultrasound guidance, of extremity truncal vein(s), has not been demonstrated substantially different in terms of efficacy or outcome from other methods of foam or liquid sclerotherapy and is non-covered for treatment of truncal vein insufficiency or varicose changes and conditions described in this local coverage determination.
    - Combined mechanical and chemical techniques inclusive of imaging guidance (e.g., MOCA utilizing infusion catheters with or without a distal diffusion extensor) have not been proven to substantially differ from other forms of sclerotherapy in method or outcome. It is incumbent on the provider to ensure agents and devices utilized have FDA clearance and marketing designation consistent with the intended use. At the time of publication of this local coverage determination, there is no FDA cleared device with marketing designation consistent with MOCA.
    - Endovenous ablation, thrombosis or embolization of incompetent vein of the extremity by transcatheter delivery of a chemical adhesive, inclusive of imaging and monitoring has not demonstrated clinical effectiveness and safety, sufficient to allow coverage for treatment of the entities deemed medically necessary in this coverage determination.
12. Due to advances in technology that may follow publication of this policy, all subsequent agents, devices, or methods proposed to address varicose veins of the lower extremity that are not specifically covered in this, or any other Novitas policy, or in any national policy, are non-covered. The redetermination process is available for consideration of any such advances.

Provider Qualifications

Services will be considered reasonable and necessary only if performed by appropriately trained personnel acting within their scope of practice under State law.

The following provider qualification requirements must be met for the service to be considered reasonable and necessary:

1. Chemical sclerotherapy for the treatment of symptomatic varicosities, as described in this LCD and meeting the definition of covered services, by all methods of chemical sclerotherapy may be performed by non-physician providers (NPPs [PA and APN]) under the direct supervision of a qualified physician**. Please see CMS IOM Publication 100-02 as referenced in the IOM Citations list above for information regarding direct supervision.
2. When ultrasound guidance is used for chemical sclerotherapy for the treatment of symptomatic varicosities, as described in this LCD and meeting the definition of covered services, the ultrasound guidance may be performed by NPPs and limited license physicians certified by a qualified vascular or ultrasound credentialing organization.

Examples of certification for non-physician providers include:

- Registered Vascular Technologist (RVT)-ARDMS
- Registered Physician in Vascular Interpretation (RPVI)-ARDMS
- Registered Phlebology sonographer (RPhS)-CCI
- Registered Vascular Specialist (RVS)-CCI

Examples of recognized credentialing organizations include:

- American Registry of Diagnostic Medical Sonographers (ARDMS) - Provides RDMS and RVT certification
- Cardiovascular Credentialing International (CCI) - RVS certification and RPhS certification
- Intersocietal Accreditation Commission (IAC) - Vein Center Division, Vascular Testing Division
- American College of Radiology (ACR)

** A qualified physician for this service/procedure is defined as:

A. Physician properly enrolled in Medicare, with full state licensure, and
B. Training and experience acquired through tenured practice or within the framework of an accredited residency and/or fellowship training program in the applicable specialty/subspecialty in the United States, reflecting equivalent education, training and expertise endorsed by an academic institution or specialty society in the United States.

For frequency limitations please refer to the Utilization Guidelines section below.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

Cyanoacrylate Closure (CAC) (also known as Cyanoacrylate Embolization [CAE])

The aim of the single-center clinical study by Chan et al[16] was to evaluate the efficacy and performance of endovenous cyanoacrylate (Sapheon VenaSeal Closure System) for the treatment of great saphenous vein (GSV) reflux. This prospective study was non-randomized for 57 legs in 29 patients, median age 63 years, at a tertiary vascular center. All endovenous procedures were performed in the center under local anesthesia. The mean follow-up period for this cohort of patients was nine months (range 1-13 months) and no patients defaulted follow-up visits. Fifty-seven (100%), fifty-three (75%), and seventeen (30%) legs passed the 3, 6, and 12 month follow-up points respectively. None of the recanalized GSVs resulted in clinical recurrence or deterioration of the clinical, etiological, anatomical, pathophysiological (CEAP) classification system score. The authors concluded the early results showed

simultaneous treatment of bilateral incompetent GSVs can be performed using one bottle of cyanoacrylate glue and may make the procedures more cost-effective than treating one leg at a time. Their analysis for recanalization showed that GSVs greater than or equal to 8-mm were more likely to have recanalization on follow-up.

The purpose of the prospective study (WAVES) by Gibson and Ferris[17] was to report the performance of cyanoacrylate closure (CAC) in a real-world setting in which multiple incompetent saphenous trunks were treated in the same setting and compression stockings were not used post-operatively. Fifty patients, median age 49.5 years, were included in the single-center, multi-investigator, single-arm prospective study. Patients were evaluated at seven days and at one month post-procedure. The authors recognize the limitations of the study include its single arm design and relatively small sample size at a single center. The conclusion is that CAC is safe and efficacious for the treatment of venous disease caused by refluxing truncal veins.

Morrison et al[18] conducted a phase 2 randomized controlled trial (RCT) comparing VenaSeal Sapheon Closure System with ClosureFast Radiofrequency Ablation (RFA), NCT01807585. The VenaSeal Closure System is a minimally invasive, non-tumescent, non-thermal procedure that uses a medical adhesive to close the diseased vein. The study enrolled 244 participants at 10 sites between March and December 2013. This VeClose study, consisted of 222 participants ranging from 21 to 70 years of age (overall mean age of 50 years). The primary endpoint of the study was complete closure of the target vein with the time frame of three months post procedure; adjunctive treatments were permitted after the three-month follow-up visit. Complete closure was defined by Doppler Ultrasound showing vein closure along the entire treated vein segment with no discrete segments of patency exceeding 5 centimeters (cm) in length. Secondary outcome measures included intraoperative pain during the procedure and ecchymosis at the first follow-up visit on day three. The authors conclude CAC was proven to be non-inferior to RFA for the treatment of incompetent GSVs at 3 months.

In a report by Morrison et al[10] 12-month outcomes of the VeClose trial were reported. One year follow-up was collected from 192 of the 222 enrolled participants (95 CAC and 97 RFA). When a three-month duplex ultrasound was not available (e.g., images missing, unreadable, visit not done), use of the predictive method was used for inputing missing data and images out of the three-month window (3%) were reviewed. Conclusions from the randomized, prospective, multi-center clinical trial stated the VenaSeal Closure System to be non-inferior to the RFA control with respect to three-month primary effectiveness endpoint, and similar to the RFA control with respect to safety. The conclusions from the one-year data evaluation was cyanoacrylate-based chemical ablation had similar efficacy to RFA in terms of occlusion, durability and relief from symptoms. Authors note limitations of this study include a modest dropout rate, with 12-month data unavailable for 12% of participants in the CAC group and 19.9% of the RFA group. Blinding was not part of this study. The participants will continue to follow-up to year three.

Endovenous Mechanochemical Ablation

The Venefit™ versus ClariVein® trial aimed to assess the intra-procedural patient experience of pain and return to function. This multi-center randomized control trial for non-tumescent, non-thermal mechanical occlusion chemically assisted endovenous ablation (MOCA) versus ClariVein, the thermal ablation requiring the use of tumescent anesthesia, was conducted in the United Kingdom. The early results were published by Bootun et al[19] and final results were published by Lane et al[11] A total of 119 patients were randomized to mechanochemical ablation (n=60) or radiofrequency ablation (n=59). The average age of the study participants was between 48.9 (SD 17) and 53.9 (SD 18) with treated vein diameter between 7.0-mm (SD 2.5) and 7.4-mm (SD 3.3). The one-month follow-up results reported by Bootun et al[19] indicated that intra-procedural pain was significantly lower in patients undergoing MOCA compared to RFA yet the difference may have been explained by the additional injections required for tumescent infiltration. The authors stated the overall occlusion rates in the small cohort study were similar to those seen in other studies.

Lane et al[11] concludes from the Venefit™ versus ClariVein® trial that mechanochemical truncal ablation offers patients reduced intra-procedural pain with equivalent technical success compared to RFA truncal ablation at six months. The authors recommend further research with larger studies and extended follow-up to assess long-term outcomes and recurrence rates.

In 2012, Elias and Raines[20] reported on the final results of the initial clinical trial for mechanochemical tumescentless endovenous ablation. The aim of the study was to assess the safety and efficacy of the ClariVein® system of the GSV. Thirty GSVs were treated in 29 patients. The average age of patients was 54.3 years with a range of 31-90 years. The authors concluded mechanochemical ablation using ClariVein appears to be safe and have good efficacy and follow-up of the initial 30 patients and subsequent patients is to be continued. The authors note veins which may not be candidates for mechanochemical ablation include those with previous thrombophlebitis which have recanalized and are incompetent. The study stated the ClariVein technique eliminates the need for tumescent anesthesia and the technique should be considered as another viable alternative for the management of saphenous incompetence.

The analysis by Kim et al[21] was to show early efficacy results of mechanochemical ablation for symptomatic GSV reflux at twenty-four months. The study originally enrolled 124 patients and follow-up was available for 79 of them at 12-months and for 65 patients at the 24-month follow-up. The mean age for the follow-up group was 70 years, plus or minus 14 years, with an average body mass index of 30.5, plus or minus 6. The mean diameter of GSV in the upper thigh was 7.6-mm and the mean treatment length was 39cm. Sodium tetradecyl sulfate was used in 84% of patients and polidocanol in 16% during MOCA. Adjunctive treatment of the varicosities was performed in 14% of the patients (phlebectomies 9% and sclerotherapy 5%). The authors conclude early high occlusion rate with mechanochemical ablation is associated with significant clinical improvement maintained out to 24 months. The authors also state the significant number of patients lost to follow-up may weaken the data reported at 24 months. The study reports limitations of not having a control group and previously reported data from other studies were used for comparison. This study also did not look at disease–specific quality of life (QoL) scores.

The aim of the van Eekeren et al[13] study evaluated the feasibility and safety of endovenous mechanochemical ablation (MOCA) for the treatment of GSV incompetence. The study reported 100% initial technical success of MOCA in 30 limbs of 25 patients (18 women; mean age 52 years). The conclusion was the study showed endovenous MOCA, using polidocanol, is feasible and safe in the treatment of GSV incompetence. The authors noted larger studies with a prolonged follow-up are indicated to prove the efficacy of this technique in terms of obliteration rates. van Eekeren et al[22] also reported six-week results of postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. The study included 68 patients and all completed the 6-week follow-up assessment. The authors state the study is not to observe anatomical success and larger comparative studies are needed to assess the long-term efficacy of MOCA. The report suggests patients treated with MOCA perceived fewer problems with daily physical activities. The authors do note both groups had a significant improvement in perceived health change as well as improvement of disease-specific quality of life.

van Eekeren et al[23] also reported one-year results of MOCA of GSV insufficiency (GSV diameter 3-12mm) reporting technical success rate of 99%; this prospective observational study was registered under number NCT01459263. Combining adjunctive therapies, such as sclerotherapies or phlebectomies, with primary treatment of GSV reflux was discussed. The authors considered one of the advantages of MOCA is that the sclerosant enters branch varicosities in the area of the treated GSV, which do not have to be treated with adjunctive therapy and that many branch varicosities diminish in size or resolve completely once GSV reflux has been eliminated. At one-year follow-up, only 22% of the patients were adjunctively treated with sclerotherapy or ultrasound guided foam sclerotherapy (UGFS). However, the authors indicated long-term follow-up is needed to observe the additional effect of MOCA on branch varicosities as they can increase in time. The authors concluded MOCA is a safe and effective technique in treating GSV insufficiency with good clinical and anatomic success at one-year follow-up. The main objective of this study was

to evaluate postoperative pain and early quality of life in patients treated with RFA or MOCA, not to observe anatomical success. The study stated the MOCA technique is related to low postprocedural pain scores, low complication rate, improved quality of life, and rapid resumption of normal activities and work. The authors note results of postoperative pain from different endovenous treatments are difficult to compare as outcomes of postoperative pain have been valued in various ways; the authors advocate a uniform use of outcome measures for postoperative pain.

The aim of the Vun et al[14] study was to assess the efficacy of the ClariVein system of mechanochemical ablation of superficial vein incompetence. Fifty-one GSVs and six short saphenous veins (SSVs) were treated and duplexed. The authors state treatment for varicose veins should primarily be guided, in the long-term, by efficacy and recurrence rates. They note the results are early but promising for mechanochemical ablation. The main theoretical advantage for ClariVein was the avoidance of thermal energy, which would allow a tumescence-free technique. The avoidance of tumescence also had a great benefit in speed of the procedure with the procedure-time cut almost in half. The authors state this has major financial implications as one could theoretically double the number of patients treated in a session. Additionally, the technique does not require any fixed equipment allowing greater degree of flexibility in where the procedure is conducted. They point out the study is limited by lack of randomization or indications for therapy and is not powered to detect whether ClariVein is equally as efficacious as the endothermal techniques. The authors also state longer follow-up is needed to see the extent of recanalization. The study concludes ClariVein is a safe and well-tolerated viable alternative to RFA and EVLT for treating superficial venous incompetence and that work in the form of a randomized controlled trial should be conducted to assess the long-term success and overall cost effectiveness of ClariVein.

In 2016, Witte et al[15] reported the midterm results of mechanochemical ablation (MOCA) for treating GSV insufficiency of 85 patients treated over a one-year period. Median age was 51.4 years. The patients were evaluated at baseline and at follow-up visits of 4 weeks, and 1, 2, and 3 years using duplex ultrasound, CEAP classification, Venous Clinical Severity Score (VCSS), the RAND-Short Form 36-Item Health Survey (RAND-SF36), and the Aberdeen Varicose Vein Questionnaire (AVVQ). Primary outcome measures were clinical and anatomic success. Anatomic success was 92%, 90%, and 87% after 1, 2, and 3 years respectively. The clinical success at 3 years was 83%. The AVVQ and RAND-SF36 scores showed an improvement at all time intervals compared to base line values. Between 12 and 36 months, however, a significant deterioration was observed in VCSS. This was accompanied by worsening of disease-specific and general QoL. The authors concluded MOCA to be effective for GSV insufficiency at midterm follow-up but clinical results decreased over time.

Polidocanol Endovenous Microfoam (PEM) Ablation

The aim of the Biemans et al[24] study (MAGNA) was to compare the anatomic success rate, frequency of complications, and health related QoL improvement of EVLA, UGFS, and surgery for the treatment of primary incompetent GSV after one year. UGFS was prepared using the Tessari-method with aethoxysclerol 3%. Patients were evaluated at three and twelve months for clinical examination and duplex ultrasound to gauge anatomic success. The authors noted 11 of the 21 patients of the UGFS group had partial obliteration with reflux. These patients did not undergo any additional treatment after the initial treatment resulted in complete relief of complaints despite persistent reflux after the one-year follow-up. The one-year results of this study showed the short-term efficacy equally high for EVLA and surgery and low for UGFS. It was noted that neovascularization was more common following surgery. All therapies were found to have significant clinical and health-related QoL improvement. The long-term efficacy of these three intervention methods was pooled in the meta-analysis by van der Velden et al[25] (NCT00529672). The conclusion was EVLA and surgery were more effective than UGFS in obliterating the GSV 5-years after intervention. UGFS was associated with substantial rates of GSV reflux as well as lower QoL scores when compared with EVLA and surgery.

The aim of the multicenter, parallel group, industry-sponsored, randomized, blinded study (VANISH-1) by King et al

[26] was to determine if a single administration of 15 milliliters (mL) or less of pharmaceutical-grade polidocanol endovenous microfoam (PEM) could alleviate symptoms and improve appearance of varicose veins in a typical population of patients with moderate to very severe symptoms of superficial venous incompetence and visible varicosities of the GSV system. The primary endpoint was patient-reported venous symptom improvement measured by change from baseline to week 8 in 7-day average VVSymQ score. The VVSymQ instrument (BTG International, Inc.) was specifically designed to measure symptoms of superficial venous incompetence and detect clinically meaningful changes in patients' symptoms following intervention. The study was funded by BTG International and several authors disclosed conflicts of interest related to this study. Two hundred and eighty-four patients underwent treatment sessions who had saphenofemoral junction incompetence, reflux (greater than 0.5 seconds on duplex ultrasound) of the GSV or other major accessory saphenous veins determined by duplex ultrasound, that were symptomatic and visible. The mean age was 49 years and mean body mass index of 28 kg/m². Two hundred and seventy-five patients completed the study to week 8. It was not possible to create placebo foam that was indistinguishable from PEM therefore; physician and ultrasonographer were unblinded to placebo. Assessors for primary and secondary endpoints were completely blinded. At week 8, VVSymQ scores for the pooled PEM group (0.5% and 1% and 2%, p less than .0001) and individual dose concentrations (p less than .001) were significantly superior to placebo. The study concluded that at week 8, a single administration of up to 15-mL, in 5-mL allocations, of PEM is a safe, effective, and convenient treatment for the symptoms of superficial venous incompetence and the appearance of visible varicosities of the GSV system. Patients could receive open-label treatment with 1% PEM; patients continued to be followed for one year.

Todd et al[27] assessed the durability of response to treatment for patients from the (VANISH-2) trial treated with polidocanol endovenous microfoam (PEM) 1% at baseline (visit 2/week 0), from visit 5/week 8 through the one year visit. Of the 221 patients who completed the one-year study visit, 56 patients were subsequently assessed for efficacy at visit 5/week 8 and the one-year study visit. Patients who reported overall improvements, in a separate questionnaire completed at one-year evaluation, were compared at visit 5/week 8 and at year one after treatment. Duplex ultrasound response was assessed as a marker of physiologic response to and durability of treatment. The authors stated significantly adverse events reported were those that would be expected during long-term follow-up of the population studied and were unrelated to treatment. Authors reported results of patient efficacy measured by patient-reported symptoms (VVSymQ score) and appearance (clinician assessment) and patient self-assessment scores at year one were as good as or better than those seen at visit 5/week 8. A small decrease in duplex ultrasound response was observed which the authors state is comparable to what has been seen at one-year with other treatments. The authors conclude the one-year data, for patients from the VANISH-2 trial support that after treatment with PEM 1%, demonstrates venous thrombus is manageable and does not result in important clinical sequelae.

The aim of the Rasmussen et al[28] study was to compare the outcome for 500 patients (580 legs) three years after treatment of varicose veins by EVLA, RFA, UGFS, or surgery by assessing recurrence, Venous Clinical Severity Score (VCSS), and QoL. The UGFS used was aethoxysclerol 3% mixed according to the Tessari method. All treatments were performed under tumescent local anesthesia. The authors report due to recanalization, significantly more patients in the UGFS group developed open refluxing GSV segments of more than 10cm compared with patients treated with other modalities. The study concluded that all treatment modalities were effective and resulted in similar improvement in VCSS and QoL; however, more recanalization and reoperations were noted after UGFS treatment.

The NHS 2015 Technology Assessment (Brittenden, et al[29]) lists the results from the CLASS parallel-group randomized control trial (RCT) without blinding that compared the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation (with delayed foam sclerotherapy to residual varicosities when required) and surgery for treatment of symptomatic varicose veins. At the time of applying for funding, the authors excluded Radiofrequency Ablation (RFA) and since then noted that EVLA and RFA are now considered to be comparable technique in terms of outcome. This is the first RCT involving foam to evaluate disease-specific quality of life (QoL) as a primary outcome measure. The primary outcome measures were disease-specific QoL with the Aberdeen Varicose Vein Questionnaire (AVVQ), generic QoL with the European Quality of Life-5 Dimensions (EQ-5D)

and Short Form questionnaire-36 items (SF-36) physical and mental component scores QoL at six months as well as cost-effectiveness measured as cost per quality-adjusted life-year (QALY) gained. Based on trial data, cost-effectiveness analysis assessed mean differences in costs and QALYs at six months and estimates of cost-effectiveness were analyzed out to five and ten years using a Markov model. Seven hundred and ninety-eight patients were recruited over 48 months between November 2008 and October 2012. The study included adult patients with symptomatic primary varicose veins CEAP classification C2 or above and those with GSV and SSV with reflux greater than one second on duplex ultrasound. The study noted recruitment difficulties which led to a revision in the target size based on an interim analysis. NHS states that did not lead to any reduction in the predefined clinically important difference in QoL but may have disadvantaged the EVLA arm, which had reduced power (foam, n=292; surgery, n=294, EVLA, n=212). After obtaining approval, the trial involved an off-label use of a licensed product, sodium tetradecyl sulphate (STS), Fibrovein®. Participants (mean age 49.0-49.7 years) were randomly assigned to all options available at each study site with seven hundred ninety-eight participants receiving treatment of which thirteen were excluded from treatment after randomization. Per the NHS, the results appear generalizable in that participants' baseline characteristics (apart from a lower-than-expected proportion of females) and post-treatment improvement in outcomes were comparable with those in other RCTs. Surgery of the main truncal veins and varicose tributaries was performed concurrently. EVLA of the main truncal veins was performed as an initial treatment with foam to residual varicosities, if required, which was done at or after 6 weeks. Foam to non-truncal varicosities was performed in 31% of patients following EVLA and in 38% randomized to foam. At six months, 80% of patients attended the follow-up appointment and completed the six-month questionnaire. The AVVQ showed the health gain with foam treatment was significantly lower than that for surgery at six-month follow-up. No differences were noted between surgery and foam in the other QoL outcome measures. The SF-36 noted EVLA had marginal superiority to foam but no differences in other QoL measures at six months. The study results indicate EVLA and surgery were broadly equivalent in terms of QoL at six months. Evaluations at six weeks yielded greater gains in QoL for EVLA than surgery and for surgery and EVLA than for foam. QoL for foam may have been impacted by the finding of residual varicose veins and the frequency of some complications being higher after foam than after either surgery or EVLA. Participants reported returning to normal activities faster after foam treatment, further identified by the BRAVVO (Behavioural Recovery After treatment for Varicose Veins) questionnaire used in the study to classify behavioral items. Independent assessment of truncal ablation rates found the foam group had significantly lower ablation rates than in the surgery and EVLA groups. The authors noted this may lead to an increased risk of developing recurrent varicose veins in those patients, with associated reduced QoL and costs of further treatment. The overall technical success rate for CLASS for EVLA and surgery were comparable at 91% and 82% respectively. The technical success rate for foam of 67% (complete and partial with no reflux) was lower than in some studies but the authors noted it was a comparable rate with two other RCTs for foam. The multicenter trial comparing the clinical effectiveness of endovenous laser ablation, foam sclerotherapy, and surgery for the treatment of varicose veins showed no clinically substantial differences in QoL between groups. Moderate differences in disease-specific QoL results support surgery over foam treatment and moderate differences in generic QoL favored laser treatment over foam. Five-year trial results are currently being evaluated to compare the cost-effectiveness of foam, surgery and EVLA, and to determine the recurrence rate following each treatment. The authors highlight the need for long-term outcome data from RCTs on QoL, recurrence rates and costs for foam and other endovenous techniques, compared against each other and against surgery.

The aim of the randomized clinical trial by Venermo et al[30] was to compare the efficacy of surgery, EVLA, and ultrasound-guided foam sclerotherapy (UGFS) in patients with primary symptomatic, uncomplicated great saphenous varicose veins (Clinical Etiologic Anatomic Pathophysiologic [CEAP] clinical grade C2-C4). The sclerosant foam was prepared with a double-syringe technique for polidocanol 1% and sodium tetradecyl sulphate (STS) 1% and 3%. The primary outcome measures were one-year occlusion rate of GSV and changes in disease-specific QoL according to the Aberdeen Varicose Vein Severity Score (AVVSS). Between November 2007 and May 2010, 214 patients met criteria and were treated. All 214 were evaluated at the one-month follow-up and 206 patients attended the one-year follow-up. The authors reported the difference in occlusion rates between UGFS and the two other treatments was significant. Also noted was the effect of GSV diameter on outcome suggesting that UGFS should not be recommended for veins larger than 6-mm in diameter.

Varicose Veins, Guidelines/Technology Assessments

The American College of Phlebology (ACP) Practice Guidelines for superficial venous disease (Rev 2016)[31] supports the use of endovenous thermal (laser and RFA) ablation techniques. ACP also supports the use of endovenous ablation techniques that are non-thermal and do not require tumescent anesthesia. The ACP Practice Guidelines for Duplex Ultrasound Imaging[32] describe minimum standards for imaging protocols and reporting as well as qualifications for those individuals performing and interpreting these studies. The guidelines state the accuracy of the non-invasive venous study depends on the knowledge, skill and experience of the technologist or physician performing the studies, and the knowledge, skill and experience of the physician interpreting the studies. The guidelines suggest minimum qualifications for the sonographer performing studies include certification or eligibility for certification by a nationally recognized certifying body.

The Guidelines and Standards of the American Society of Echocardiography (ASE) and the Society of Cardiovascular Anesthesiologists (Troianos et al[33]) provide comprehensive practice guidelines on the use of ultrasound for vascular cannulation. Recommendations are made for training, including the role of simulation. ASE notes insertion of vascular catheters is associated with complications that may occur more often with less experienced operators, challenging patient anatomy, compromised procedural settings, and the presence of comorbidity. The guidelines further state comprehensive education should include a combination of didactic lectures, live or simulated demonstrations, and mentoring by a skilled sonographer. Formal training will reduce the failure rate of ultrasound-guided cannulation and ultimately improve patient safety.

The aim of the Cochrane Review on endovenous ablation (RFA and EVLA) and foam sclerotherapy versus open surgery for great saphenous vein varices by Nesbitt et al[34] was to determine whether endovenous ablation (RFA and EVLA) have any advantages or disadvantages in comparison with open surgical saphenofemoral ligation and stripping of great saphenous vein varices. The review was of all randomized controlled trials of UGFS, EVLT, RFA, and high ligation/stripping (HL/S). The results included a total of thirteen studies with a combined total of 3081 randomized patients. Study quality was reported as generally moderate for all included studies, although no study blinded participants, researchers and clinicians or outcome assessors. Also, the review states all included studies had other sources of bias. The overall quality of the evidence was moderate due to the variations in the reporting of results, which limited meaningful meta-analyses for the majority of proposed outcome measures. QoL scores were not amenable to meta-analysis; however, QoL similarly increased in all treatment groups and complications were generally low. Despite great variation in pain reporting from the studies, pain reported was similar between treatment groups. From available RCT evidence, the review suggests UGFS, EVLT and RFA are at least as effective as surgery in the treatment of GSVs . The authors note large differences between the ways the studies reported their outcomes, which included definitions and collection time points. The differences limited the findings of the review. Nesbitt et al state more data from randomized controlled trials comparing these novel therapies to surgery is needed before their true potential is known.

In 2017, the AHRQ technology assessment (TA) on treatment strategies for lower extremity chronic venous disease (LECVD) prepared for Agency for Healthcare Research and Quality (AHRQ) by Jones et al[6] was released. The TA results regarding diagnosis of LECVD stated there was insufficient evidence to support or refute the recommendations from current clinical guidelines that duplex ultrasound should be used as the first line diagnostic test for patients being evaluated for LECVD or for those for whom invasive treatment is planned. The TA results regarding treatment of LECVD insufficiency/incompetence/reflux was no long-term difference in effectiveness between 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. Also, for patients having endovenous interventions, RFA, EVLA, and sclerotherapy treatments, improvement in QoL scores and standardized symptoms scores was noted with no significant difference between groups. When compared with patients treated with EVLA, patients treated with foam sclerotherapy had significantly less periprocedural pain but lower rates of vein occlusion and higher rates of repeat intervention, and patients treated with RFA had significantly less periprocedural pain but

less short-term improvement in Venous Clinical Severity Score (VCSS). When compared with patients with placebo, those treated with foam sclerotherapy had statistically significant improvement in standardized symptom scores, occlusion rates, and quality of life. When compared with patients treated with placebo or no compression therapy, by heterogeneous studies that compared those treated with compression therapy, those treated with compression therapy had significant improvement in standardized symptom scores and QoL. The TA concluded the available evidence for treatment of patients with LECVD is limited multiple treatment options, measured varied outcomes, and assessed disparate outcome time points. They continued that very limited comparative effectiveness data have been generated to study new and existing diagnostic testing modalities for patients with LECVD. They noted several advances in care in endovenous interventional therapy have not yet been rigorously tested, and there are very few studies on conservative measures (e.g., lifestyle modification, compression therapy, exercise training) in the literature published since 2000. Additionally, the potential additive effects of many of these therapies are not yet known. The TA concludes the presence of significant clinical heterogeneity of these results make conclusions for clinical outcomes uncertain and provides an impetus for further research to improve the care of patients with LECVD.

The European Society for Vascular Surgery (ESVS) developed clinical practice guidelines for the care of patients with chronic venous disease (CVD) in the lower extremities (Wittens et al[35]). The guidelines state the pathophysiology of CVD is characterized by reflux, obstruction, or a combination of both. The reflux in incompetent superficial veins is primarily caused by vein wall abnormalities. The reflux can be axial or segmental. The pathology in the deep veins is more complex. The guidelines list an advantage of foam sclerotherapy is its simplicity. There is no need to inject tumescent liquid; the treatment is inexpensive and easy to repeat if necessary. Complications listed for UGFS include hyperpigmentation, thrombophlebitis, matting, and pain at the injection site. Also, they note some neurologic events such as visual disturbances, migraine, and stroke have been reported. The occlusion rates of saphenous veins treated with UGFS seem to be inferior to those of veins treated with endovenous thermal ablation (EVTA). Compared with endovenous laser ablation (EVLA), patients treated with UGFS have slightly lower post-operative pain, but no difference could be found compared with RFA. The guidelines point out varicose vein recurrence following surgical intervention is a common problem for both patients and clinicians. The rates given for recurrence following either surgery or endovenous intervention are up to 35% at two-year follow-up and 65% at 11-year follow-up. Recurrence can be classified according to clinical criteria and duplex ultrasound examination. In the treatment of recurrent varicose veins, RFA and EVLA have been described as safe and effective options for treatment of recurrent varicose veins. UGFS has been used successfully but with lower success rates compared with initial laser ablation.

The Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) standards for accreditation in non-invasive vascular testing[36] provide standards for vascular laboratories. A vascular laboratory is defined as a unit performing non-invasive vascular diagnostic testing under the overall direction of a Medical Director. Technical staff report to the Medical Director and perform clinical examinations and other assigned tasks. In order to not compromise patient care, the standards state all interpreting physicians (medical staff) and practicing technologists (technical staff) must be adequately trained and experienced to interpret and perform non-invasive vascular testing respectively. The standards encourage all staff members acquire an appropriate credential in vascular testing.

The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) (Gloviczki et al[37]) jointly issued guidelines for the care of patients with varicose veins of the lower extremities and pelvis. The guidelines define spider veins or telangiectasia as veins less than or equal to 3-mm in diameter and varicose veins of the lower limbs as dilated subcutaneous veins that are greater than or equal to 3-mm in diameter measured in the upright position. The article states the mechanisms of action for sclerosing agents are the destruction of venous endothelial cells, exposure of subendothelial collagen fibers and ultimately, the formation of a fibrotic obstruction. The higher the concentration of the solution and the smaller the vein, the greater the endothelial damage. They recommend for the treatment of the incompetent GSV, endovenous thermal ablation (RFA or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee with a GRADE 1B. The SVS/AVF guidelines recommended liquid or foam sclerotherapy for telangiectasia, reticular veins, and varicose veins with a GRADE of 1B (guideline 12.1). Endovenous thermal ablation is recommended over chemical ablation with foam for treatment of

the incompetent saphenous vein with a GRADE of 1B (guideline 12.2).

The National Institute for Health and Care Excellence (NICE) varicose vein diagnosis and management guidelines[38] found the evidence comparing conventional surgery with foam sclerotherapy and endovenous thermal ablation was listed as low to very low quality. The guidelines noted survey methods are not optimal for exploring expectations and perceptions, and questionnaires may use closed and potentially leading questions. The guideline identified a high body mass index as a factor that both increased the risk of progression to more serious varicose veins and was also a factor predicting worse outcome after treatment compared with a normal body mass index. Data reviewed from trials of interventional procedures indicates the rate of clinical recurrence of varicose veins at three years is likely between 10-30%. The summary evidence suggests patients with recurrent varicose veins have a worse outcome following treatment than those being treated for primary varicose veins. The guidelines summary notes the differences in diagnostic accuracy between the two different ultrasound methods used in studies to test for venous reflux, hand-held Doppler ultrasound and Duplex ultrasound scanning. Awareness of this difference may help avoid misinterpretation of study results. The guidelines also state much of the research on the optimum treatment for varicose veins involved patients with CEAP classes C2 and C3, so little is known of the relative efficacies of treatment at the more severe stages of disease. Some studies included patients with varicose veins at a range of stages without subgrouping, which may conceal important differences in efficacy between different treatments at different stages of disease. Therefore, current treatment recommendations, which do not differentiate between patients with varicose veins at different stages, may not be equally effective for all patients. The use of CEAP to categorize the disease stages is not ideal because higher CEAP stages do not necessarily indicate greater severity. However, other methods of categorization are even more problematic. Quality-of-life measures are unlikely to reflect severity of disease because of variations in perception of symptoms. In addition, measuring the degree of venous reflux would necessitate a method of quantifying reflux in the superficial venous system in a way that adequately reflects disease severity, and such a method does not currently exist.

The NICE interventional procedures guidance on cyanoacrylate glue occlusion for varicose veins[39] states current evidence on the safety and efficacy of cyanoacrylate glue occlusion of varicose veins is limited in quantity and quality .

The focus of the Washington State Heath Care Authority, Hayes technology assessment (Hayes TA[3]) on Selected Treatments for Varicose Veins was EVLA, RFA, sclerotherapy, and ambulatory phlebectomy compared with ligation with or without vein stripping. The Hayes TA reviewed practice guidelines and found adequate evidence to support the use of EVLA, RFA, and sclerotherapy for treatment of varicose veins noting the quality of individual studies and grade of the overall evidence vary depending on the intervention being assessed. The summary of the reviewed guidelines resulted in a general recommendation of EVLA or RFA over surgery unless endovenous thermal ablation is not appropriate for the patient. Sclerotherapy and phlebectomy are also recommended in some clinical situations but not always as a first choice of treatment. Endovenous treatments are not recommended during pregnancy. Phlebectomy is often considered a concomitant treatment along with other approaches. The Hayes TA acknowledged gaps in the evidence and recommended future studies to address the methodological limitations of individual studies such as variations in outcome definitions and metrics, more consistent performance and reporting of statistical analyses, and better reporting or conduct of randomization procedures.

The U.S. Government Accountability Office 2007 Report to Congressional Committees on Medicare Ultrasound Procedures[40] considers payment reforms and technician qualification requirements. The report states factors for CMS to consider in determining whether to establish credentialing or other qualification requirements for sonographers include findings about the value of credentialing from peer-reviewed studies, MedPAC, and ultrasound-related organizations, coupled with variation in federal requirements and lack of state requirements for sonographers. Representatives from ultrasound-related professional organizations described ultrasound procedures as highly operator dependent, noting studies demonstrating the need for credentialing accreditation have been limited in number and scope with existing studies suggesting that imposing credentialing or other qualifications on

sonographers can improve the accuracy of ultrasound procedures. The report asserts professional organizations, setting requirements for sonographer' qualifications, could promote quality.

Varicose Veins, General

The size of the vein and duration of reflux correlate well with the likelihood of clinically significant disease and symptoms. Reflux duration greater than 500 milliseconds (ms), recorded with the patient standing, 2.5-cm proximal to the saphenofemoral junction, correlates with mild to moderate symptomatic incompetence. The size of the vein at this location has been correlated with the presence of significant reflux. In a cohort study, Navarro, et al[41] evaluated the relationship of GSV diameter. The GSV diameter increased significantly overall with CEAP and also increased progressively with proximity to the saphenofemoral junction. This demonstrated the GSV diameter proved to be a relatively accurate measure of hemodynamic impairment and clinical severity in a model of saphenofemoral junction and GSV incompetence, predicting not only the absence of abnormal reflux, but also the presence of critical venous incompetence, assisting in clinical decision making before considering greater saphenectomy. A GSV diameter of 5.5-mm or less accurately predicted the absence of abnormal and clinically significant reflux while GSV greater than 9.6-mm predicted both critical venous incompetence as well as the presence of abnormal and symptomatic reflux.

According to Piazza[4], varicose veins are superficial veins that have become abnormally enlarged and cause symptoms or are cosmetically distressing. Types of varicose veins listed include spider veins described as thread-like red or blue superficially visible small veins; reticular veins, which are bluish and string-like; and true varicose veins which are characterized as large rope- or worm-like veins that feel spongy to the touch and bulge out from the skin surface. Symptoms of varicose veins vary according to size and extent of the varicose changes. Risk factors for varicose veins were grouped as hormonal, lifestyle-related, acquired, and inherited, noting varicose veins can be cosmetically distressing, causing symptoms that decrease quality of life and impair ability to perform activities of daily living (ADLs). When contributing factors are not corrected and treatment not provided, varicose veins can progress in severity. Varicose veins may slightly increase the risk of deep vein thrombosis in the affected limb. Indication for treatment depends on the severity of symptoms, location and cause. Treatment options include lifestyle changes, compression stockings, nonsurgical office-based procedures and surgery. Combination of treatments may be necessary for some patients. Piazza states regardless of the procedure, lifestyle changes are crucial to ensure the best response to treatment. Sclerotherapy involves injection of a chemical causing the small veins to seal shut with most patients requiring multiple treatments for best results. Endovenous ablation is usually performed in the office with or without local anesthesia, and popularity has increased due to the less invasive nature than surgery, faster recovery time and it can be performed by a variety of techniques and providers.

The retrospective review by Weiss et al[42] looked at three different endovenous thermal ablation (EVTA) systems for GSV and SSV insufficiency over a ten year time period. This review demonstrated long-term efficacy of EVTA by three systems utilizing different energy systems and thermal targets. The authors concluded EVTA is very effective for ablation of the GSV and SSV. EVTA is comparable to surgical stripping and likely preferable to surgery. Some recanalization was noted over time; however, at 5 years post procedure there is questionable clinical significance since recanalization resulted in a much smaller vein with minimal reverse flow. Outcomes remained durable, confirmed by Duplex ultrasound, at eight-year follow-up. The authors offered caution interpreting studies only reporting six-month or one-year success as these may overestimate the success rate.

Analysis of Evidence
(Rationale for Determination)

Varicose veins, also referred to as varicosities, are a common manifestation of chronic venous insufficiency estimated

to affect up to a quarter of the American adult population. The use of endovascular and surgical techniques has increased significantly over the last decade warranting a review in how beneficiaries are treated for varicose veins. From review of literature, proper training requirements are set forth for providers to ensure services covered in this policy are consistently high quality in order to ensure patient safety.

Conservative measures (such as compression stockings, leg elevation, and treatment of concomitant medical conditions and lifestyle habits exacerbating the complaints) are sufficient treatment for early symptoms such as leg heaviness, intangible swelling, or discomfort. When conservative measures fail for a beneficiary, invasive measures are recommended, as appropriate, and include endovascular intervention (e.g., ablation) and/or surgical management (e.g., venous ligation and venous stripping).

Extensive comparison has been made between surgical removal, or interruption, of the major vein trunks (GSV, SSV) and endovascular ablative methods directed at the documented incompetent or refluxing junction. The general consensus derived from compilation of all aspects of evaluation (safety, efficiency, patient-reported outcomes, long and short-term duration of improvement as well as continued closure of the vein[s] treated) is that surgical ligation/stripping and endovenous thermal ablation have equal benefit to the beneficiary. Multiple RCTs, reviewed by CMS sponsored Technology Assessment and AHRQ studies of surgical ligation and stripping, have demonstrated long-term equivalent outcomes to endovenous catheter ablation (laser or radiofrequency) at the saphenous junction. Newer technologies have been termed ablation but do not address the junctional reflux and the etiology of the disease.

Despite the volume of research conducted on sclerotherapy techniques or methods, there is variability in the literature[8(p427)] and consequently, a variety of interpretations of the literature.[22(p448), 34(p3-4)] Accepted guidelines suggest that sclerotherapy, or the infusion of thrombus inducing fluid or foam, should not be utilized at the junction of the refluxing vein with the deep venous system, as flow rate is higher. This higher flow rate may potentially diffuse the sclerosant and potentially direct it into the deep system, rather than its remaining in the target vein affecting its occlusion. Multiple reports of sclerotherapy utilized for saphenous vein ablation have demonstrated its proficiency at thrombus occlusion of the vein at some portion of its course; however, controlled trials demonstrating safe and effective closure of a culprit vein meeting criteria for ablation with effective closure at the junction with the deep vein remain under investigation. No reviewed study presented criteria for treatment coincident with the criteria defined as medical necessity, assessed the closure of the saphenofemoral or saphenopopliteal junction or described the patient risk or debility inferred by the vein treated.

Manual or temporary compression of the junctional region adjacent to the deep vein does not allow substantial protection comparable to heat or surgical ligation of the junctional region to afford the standard of safety required for the Medicare beneficiary. Data remains insufficient to demonstrate effectiveness at junctional ablation for clinically significant reflux as described in criteria for treatment as medically necessary. According to current literature, sclerotherapy of proximal or junctional incompetence and clinically significant reflux of saphenous veins has not been demonstrated to be as effective in treating documented disease and disability as the current standard of care which is surgical ligation and stripping or endovenous thermal ablation of the saphenous vein trunk near the saphenofemoral or saphenopopliteal junction. Despite the inability to consistently compare data from endothermal ablation with the forms of sclerotherapy or non-thermal ablation listed in this policy, data presented in the available reference literature is sufficient to allow comparison with present sclerotherapy techniques and efficacy to that of standard methods of sclerotherapy, being injection or perfusion of a symptomatic vein with sufficient irritant to cause thrombosis and permanently ablate the designated symptomatic culprit vessel. Unlike heat ablation or surgical removal, vein size and configuration appear to be determinant factors of efficacy and safety. Contingent on coverage is congruency with the FDA marketing designation of the device or agent employed for non-thermal ablation. As of the time of finalization of this determination, due to this lack of congruency, Mechanical Chemical Ablation cannot be covered due to the lack of FDA marketing designation for any device or agent commercially available.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type.Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

CODE	DESCRIPTION
999x	Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

Please see Coding article for Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins, A56268

Group 1 Codes:

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

Please see Coding article for Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins, A56268

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

Please see Coding article for Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins, A56268

Group 1 Codes: N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as stated in this policy.
5. Documentation of applicable training and experience of qualified physician or NPP performing procedure must be maintained and made available upon request.
6. The patient's medical record must document all of the following:

    - Clear and definitive history and description of patient symptoms.
    - Conservative treatment(s) employed as well as diligent effort on the part of the beneficiary and provider.
    - Physical characteristics including location, number, size, level of incompetence of the vein and the **symptomatic** varicose veins being treated.
    - Photographs of pre-treatment targeted symptomatic varicose veins.
    - Process/steps used to exclude other causes of symptoms in the legs.
    - Performance of and results of appropriate tests to confirm absence of clinically significant reflux.
        - Ultrasound (US) Measurement of a superficial vein (size and reflux) must include the position of measurement relative to the junction with the deep vein and should not include the diameter of the vein at the site of a valve.

7. History of any superficial or deep venous disease or interventions as this may influence the proposed procedure.
8. Vessel(s) previously treated for varicose veins must have documentation of a recurrence of signs and symptoms specifically caused by the vessel being treated.
    - The details of the prior venous operative procedure must be described including the number, location and diameter of each vessel treated for venous insufficiency; and
    - Sclerotherapy is medically necessary to treat **symptomatic** residual veins.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Medicare recognizes multiple sclerotherapy injections may be necessary during a treatment session and that the injections may be in multiple veins in each leg. Medicare will consider the following maximum utilization of sclerotherapy services to be medically reasonable and necessary:

- Four sclerotherapy services per rolling twelve month time period per beneficiary.

Medicare expects that patients will not routinely require the maximum allowable number of services.

Sources of Information

N/A

Bibliography

Contractor is not responsible for the continued viability of websites listed.

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Associated Documents

Attachments

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Related Local Coverage Documents

Article(s)

A56268 - Coding Article for Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins

A56269 - Response to Comments: Sclerotherapy and Endovenous Non-Thermal Treatment of Varicose Veins

A55229 - Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities

LCD(s)

L35451 - Non-Invasive Peripheral Venous Studies

L34924 - Treatment of Varicose Veins and Venous Stasis Disease of the Lower Extremities

Related National Coverage Documents

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