

SURGICAL AND ABLATIVE PROCEDURES FOR VENOUS INSUFFICIENCY AND VARICOSE VEINS

Policy Number: 2014T0447N
Effective Date: September 1, 2014

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

Plan Document Language

Before using this guideline, please check enrollee's specific plan document and any federal or state mandates, if applicable. Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures.

Coverage Limitations and Exclusions

The following procedures are excluded from coverage:

- a. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.
- b. Any procedure that does not meet the criteria in the [Coverage Rationale](#) section below.
- c. Spider veins and/or telangiectasias are considered to be cosmetic and therefore excluded from coverage.
- d. Endovenous ablation (radiofrequency and/or laser) of either reticular or telangiectatic veins is not reconstructive and not medically necessary.

COVERAGE RATIONALE

I. Varicose Vein Ablative and Stripping Procedures:

A. Radiofrequency ablation, endovenous laser ablation, stripping, ligation and excision of the great saphenous vein and small saphenous veins are considered reconstructive and medically necessary when ALL of the following criteria are present (1, 2, 3 and 4):

1. Junctional Reflux (see definition section):

- a. Ablative therapy for the greater or small saphenous veins will be considered reconstructive and therefore medically necessary only if junctional reflux is demonstrated in these veins; **or**
- b. Ablative therapy for accessory veins will be considered reconstructive and medically necessary only if anatomically related persistent junctional reflux is demonstrated after the greater or lesser saphenous veins have been removed or ablated.

2. Member must have one of the following functional impairments:

- a. Skin ulceration; **or**
- b. Documented episode(s) of frank bleeding of the varicose vein due to erosion of/or trauma to the skin; **or**
- c. Documented superficial thrombophlebitis or documented venous stasis dermatitis; **or**
- d. Moderate to severe pain causing functional/physical impairment.

3. Venous Size:

- a. The greater saphenous vein must be 5.5 mm or greater when measured at the proximal thigh immediately below the sapheno-femoral junction via duplex ultrasonography

- b. The small saphenous vein or accessory veins must measure 5 mm or greater in diameter immediately below the appropriate junction.

4. Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:

- a. Greater than or equal to 500 milliseconds (ms) for the great saphenous, small saphenous or principle tributaries
- b. Perforating veins > 350 ms
- c. Some duplex ultrasound readings will describe this as moderate to severe reflux which will be acceptable.

B. Ablation of perforator veins is considered reconstructive and medically necessary when the following criteria are present:

- 1. Evidence of perforator venous insufficiency measured by recent duplex ultrasonography report (see criteria above); **and**
- 2. Perforator vein size is 3.5 mm or greater; **and**
- 3. Perforating vein lies beneath a healed or active venous stasis ulcer.

C. Endomechanical ablation of varicose veins using a percutaneous infusion catheter, such as ClariVein®, is unproven and not medically necessary for treating venous reflux.

There is insufficient evidence in the clinical literature supporting the safety and efficacy of endomechanical ablation for treating varicose veins. Further results from large, well-designed studies are needed to support the clinical utility of this approach.

II. Ligation Procedures:

A. Ligation of the great saphenous vein at the saphenofemoral junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.

Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.

B. Ligation of the small saphenous vein at the saphenopopliteal junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.

Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.

C. Ligation at the saphenofemoral junction, as a stand-alone procedure, is proven and medically necessary, when used to prevent the propagation of an active clot to the deep venous system in patients with ascending superficial thrombophlebitis who fail or are intolerant of anticoagulation therapy.

D. Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins, is unproven and not medically necessary for treating venous reflux.

Published clinical evidence has not demonstrated that the addition of saphenofemoral ligation to endovenous ablation procedures provides an additive benefit in resolving venous reflux or preventing varicose vein recurrence. Endovenous ablation is a clinically effective therapy for treating venous reflux. Adding ligation to the procedure adds clinical risk without adding clinical benefit.

DEFINITIONS

When applicable, please refer to the enrollee-specific plan document for definitions.

Accessory/Tributary Vein: Axial accessory or tributary saphenous veins indicate any venous segment ascending parallel to the greater saphenous vein and located more superficially above the saphenous fascia, both in the leg and in the thigh. These can include the anterior accessory vein, the postero-medial vein, circumflex veins [anterior or posterior], intersaphenous veins, Giacomini vein or posterior [Leonardo] or anterior arch veins.

Congenital Anomaly: A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth (2011 Generic COC).

Congenital Anomaly (for California only): A physical developmental defect that is present at birth

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving physiological function, as determined by UHC (2011 Generic COC).

Cosmetic Procedures (for California only): Procedures or services are performed to alter or reshape normal structures of the body in order to improve the Covered Person's appearance

Duplex Ultrasonography: Combines a real-time B mode scanner with built-in Doppler capability. The B mode scanner outlines anatomical structure while Doppler detects the flow, direction of flow and flow velocity.

Endovenous Ablation: A minimally invasive procedure that uses heat generated by radiofrequency (RF) or laser energy to seal off damaged veins.

Functional/Physical Impairment: A physical/functional or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

Great Saphenous Vein: The GSV originates from the dorsal arch of the foot and progresses medially and proximally along the distal extremity to join the common femoral vein.

High Quality Photograph: Ideally, a high-quality print should be in color have at least 200 pixels per inch. It must be detailed enough to show the patient's anatomy that is described in the physician's office notes. If submitted as a hard copy, the image must be on photographic paper.

Junctional Reflux: Reflux that exceeds a duration of 0.5 seconds at **either:**

- The confluence of the greater saphenous vein and the femoral vein
- The confluence of the small saphenous vein and the popliteal vein

Ligation: Tying off a vein.

Reconstructive Procedures: Reconstructive procedures when the primary purpose of the procedure is either to treat a medical condition or to improve or restore physiologic function. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance.

Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure (2011 Generic COC).

Reconstructive Procedures (for California only): Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or to create a normal appearance, to the extent possible. Covered Health Services include dental or orthodontic services that are an integral part of reconstructive surgery for cleft palate procedures.

Reticular Vein: Reticular veins are dilated dermal veins less than 4mm in diameter that communicate with either or both telangiectasia and saphenous tributaries.

Sickness: Physical illness, disease or Pregnancy. The term Sickness as used in this *Certificate* does not include mental illness or substance abuse, regardless of the cause or origin of the mental illness or substance abuse.

Small Saphenous Vein: Superficial vein of the calf.

Spectral Doppler Flow Imaging:

- examines flow at one site
- provides a detailed analysis of distribution of flow
- provides good temporal resolution, capable of examining flow waveform
- allows for calculation of velocity and indices

Spider Vein: Spider Veins/Telangiectasia are the permanent dilation of preexisting small blood vessels, generally up to 1mm in size.

Stripping: Surgical removal of superficial veins

Superficial Thrombophlebitis: Inflammation of a vein due to a blood clot in a vein just below the skin's surface.

Telangiectasia: See *spider vein*.

Varicose Veins: Abnormally enlarged veins that are frequently visible under the surface of the skin; often appear blue, bulging and twisted.

Venous Reflux/Insufficiency: Venous reflux is reversed blood flow in the veins [away from the heart]. Abnormal [pathological reflux] is defined as reverse flow that lasts beyond a specified period of time as measured by Doppler ultrasound. Normal [physiological reflux] is defined as reverse flow that lasts less than a specified period of time as measured by Doppler ultrasound. Abnormal [pathological reflux] times exceed different thresholds depending on the system of veins:

- Deep veins: 1 sec
- Superficial veins: 0.5 sec
- Perforator veins: 0.35 sec

Venous Stasis Dermatitis: A skin inflammation due to the chronic buildup of fluid (swelling) under the skin.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT [®] Code	Description
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, <i>radiofrequency</i> ; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, <i>radiofrequency</i> ; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, <i>laser</i> ; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, <i>laser</i> ; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
37204	Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous vein
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37799	Unlisted procedure, vascular surgery

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DESCRIPTION OF SERVICES

Varicose veins are enlarged veins that are swollen and raised above the surface of the skin. They can be dark purple or blue, and look twisted and bulging. Varicose veins are commonly found on the backs of the calves or on the inside of the leg. Veins have one-way valves that help keep blood flowing towards the heart. When the valves become weak or damaged and do not close properly, blood can back up and pool in the veins causing them to get larger. The resulting condition is known as venous insufficiency or venous reflux. Varicose veins may lead to complications such as pain, blood clots or skin ulcers.

Varicose veins are treated with lifestyle changes and medical procedures done either to remove the veins or to close them. Endovenous ablation therapy uses lasers or radiofrequency energy to create heat to close off a varicose vein. Vein stripping and ligation involves tying shut and removing the veins through small cuts in the skin (National Heart, Lung and Blood Institute, 2011).

Endomechanical ablation uses a specialized, rotating catheter (e.g., ClariVein) to close off a varicose vein by damaging the vessel lining prior to injecting a sclerosing agent. This technique is also referred to as mechanical occlusion-chemically assisted (MOCA), mechanico-chemical endovenous ablation (MCEA) and mechanically enhanced endovenous chemical ablation (MEECA).

CLINICAL EVIDENCE

Also see [References](#) section below.

O'Hare et al. (2008) conducted a multicenter, prospective cohort study of patients undergoing small saphenous vein surgery (SSV). Patients were evaluated at six weeks and one year after surgery. A total of 204 legs were reviewed at one year; 67 had small saphenous varicose vein stripping, 116 had saphenopopliteal junction (SPJ) disconnection only and the remainder had miscellaneous procedures. The incidence of visible recurrent varicosities at one year was lower after SSV stripping than after disconnection only, although this did not reach statistical significance. The rate of SPJ incompetence detected by duplex at one year was significantly lower in patients who underwent SSV stripping than in those who did not.

In a literature review of long-term results following high ligation supplemented by sclerotherapy, Recek (2004) found that ligation of the saphenofemoral junction alone provokes a higher recurrence rate in comparison with high ligation and stripping. The hemodynamic improvement achieved immediately after high ligation deteriorates progressively during the follow-up owing to recurrent reflux.

Wichers et al. (2005) performed a systematic review of randomized trials evaluating the safety and efficacy of medical (anticoagulants) or surgical (ligation or stripping of the affected veins) treatments of superficial vein thrombosis (SVT) for the prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE). Five studies were included. Pooling of the data was not possible due to the heterogeneity among the studies. Three studies had major methodological drawbacks limiting the clinical applicability of the results. One of the remaining (pilot) studies showed a non-significant trend in favor of high-compared to low-dose unfractionated heparin for the prevention of venous thromboembolism (VTE). The last remaining study showed a non-significant trend in favor of short-term treatment with low-molecular-weight heparin (LMWH) or a non-steroidal anti-inflammatory drug (NSAID) as compared to placebo shortly after treatment with respect to VTE, but the apparent benefit disappeared after three months of follow-up. More randomized controlled trials are needed before any evidence-based recommendations on the treatment of SVT for the prevention of VTE can be given. With the lack of solid evidence, the authors suggest treating patients with at least intermediate doses of LMWH. Surgical treatment of SVT may be considered when varicose veins are involved.

Sullivan et al. (2001) performed a systematic review of the literature evaluating surgical and medical management of above-knee superficial thrombophlebitis (AK-STP) not involving the deep venous system. Six studies were included for a total of 246 patients in the surgical arm and 88 patients in the medical arm. Surgical treatment modalities halt the progression of thrombus into the deep venous system through the saphenofemoral junction and reduce the incidence of PE. The two types of surgical treatment were ligation of the greater saphenous vein at the saphenofemoral junction or ligation in combination with stripping of the phlebitic vein. Medical therapy consisted of initial intravenous heparin followed by warfarin therapy for a duration varying between 6 weeks and 6 months. The authors offered no definitive conclusions due to reporting of varied outcomes, different follow-up criteria and the retrospective nature of the studies. The differences between the surgical and medical groups were small. The review concludes that medical management with anticoagulants is superior for minimizing complications and preventing subsequent deep vein thrombosis and pulmonary embolism development as compared to surgical treatment with ligation of the greater saphenous vein at the saphenofemoral junction or ligation and stripping.

Winterborn et al. (2004) conducted an 11 year follow-up study on the Jones et al. patient group. A cumulative total of 83 legs had developed clinically recurrent varicose veins by 11 years (62%). There was no statistically significant difference between the ligation-only and the stripping groups. Reoperation was required for 20 of 69 legs that underwent ligation alone compared with 7 of 64 legs that had additional long saphenous vein stripping. Freedom from reoperation at 11 years was 70% after ligation, compared with 86% after stripping. The presence of neovascularization, an incompetent superficial vessel in the thigh or an incompetent saphenofemoral junction on duplex imaging at 2 years postoperatively increased the risk of a patient's developing clinically recurrent veins. Results from the study indicate that stripping the long saphenous vein is recommended as part of routine varicose vein surgery as it reduces the risk of reoperation after 11 years, although it did not reduce the rate of visible recurrent veins.

Dwerryhouse et al. (1999) designed a 5-year follow-up study on the Jones et al. patient group. 78 patients (110 legs) underwent clinical review and duplex scan imaging. Sixty-five patients remained pleased with the results of their surgery (35 of 39 stripped vs. 30 of 39 ligated). Reoperation for recurrence was necessary for three of 52 of the legs that underwent stripping vs. 12 of 58 ligated legs. Neovascularization at the saphenofemoral junction was responsible for 10 of 12 recurrent veins that underwent reoperation and also was the cause of recurrent saphenofemoral incompetence in 12 of 52 stripped veins vs. 30 of 58 ligated legs. The authors concluded that stripping reduced the risk of reoperation by two thirds after 5 years and should be routine for primary long saphenous varicose veins.

Jones et al. (1996) conducted a randomized controlled trial of one hundred patients (133 legs) to determine whether routine stripping of the long saphenous vein reduced recurrence after varicose vein surgery. A two year follow-up in 81 patients (113 legs) showed that 89% of patients remained satisfied with the results of their surgery, though 35% had recurrent veins on clinical examination. Recurrence was reduced in patients who had their long saphenous vein stripped. Neovascularization was detected in 52% of limbs and was the most common cause of recurrence.

Rutgers et al. (1994) conducted a prospective randomized study comparing stripping and local avulsions with high ligation of the saphenofemoral junction combined with sclerotherapy for the treatment of greater saphenous vein insufficiency. Of 156 consecutive patients, 89 legs were randomly allocated to stripping and 92 to high ligation. Patients were followed-up at 3 months and 1, 2, and 3 years after treatment. At 3 years, 69 limbs in the stripping group (78%) and 73 limbs in the ligation group (79%) were available to follow-up. The authors found that clinical and Doppler ultrasound evidence of reverse flow in the saphenous vein was significantly less after stripping.

Eighty-nine legs with long saphenous vein (LSV) reflux and saphenofemoral junction incompetence were treated by saphenofemoral ligation and multiple avulsions. Patients were randomized to undergo additional stripping of the LSV (n = 43) or no additional treatment (n = 46). At a median of 21 months after surgery, more patients were free of recurrence when the LSV had been stripped compared with saphenofemoral ligation alone. The authors concluded that the addition of LSV stripping to saphenofemoral ligation and multiple avulsions results in a better overall outcome (Sarin, 1994).

During endovenous ablation procedures, radiofrequency or laser energy is applied to heat the vein, causing the vessel to close and eventually be absorbed by the body. This technique achieves the same effect as saphenofemoral or saphenopopliteal ligation and stripping. Adding ligation of the main trunk to the procedure has not been shown to provide an additive benefit in resolving venous reflux or preventing varicose vein recurrence.

In a systematic review, Darwood and Gough found that adjunctive saphenofemoral ligation is not necessary to achieve success with endovenous laser therapy of the greater saphenous vein

(Darwood, 2009). Similarly, a randomized controlled trial conducted by Disselhoff et al. (2008) found that the addition of saphenofemoral ligation to endovenous ablation made no difference to the short-term outcome of varicose vein treatment. Long-term follow-up at 5 years found similar results (Disselhoff et al. 2011). Further studies with larger patient populations are needed to establish the superiority of adjunctive saphenofemoral ligation in improving long-term outcomes.

Theivacumar et al. (2007) also found that saphenofemoral ligation following endovenous laser ablation was unnecessary. Persistent non-refluxing greater saphenous vein tributaries at the saphenofemoral junction did not have an adverse impact on clinical outcome 1 year after successful endovenous laser ablation of the greater saphenous vein.

ClariVein Occlusion Catheter

Bishawi et al. (2013) conducted a prospective observational multicenter study on the efficacy of mechanochemical ablation (MOCA) in patients with lower extremity chronic venous disease. A total of 126 patients were included at baseline, 81% females. The mean diameter of the great saphenous vein in the upper thigh was 7.3 mm and the mean treatment length was 38 cm. Adjunctive treatment was performed in 11% of patients during the procedure. Closure rates were 100% at one week, 98% at three months and 94% at six months. Post-procedure complications included hematoma, ecchymosis and thrombophlebitis. There were no cases of venous thromboembolism. The authors concluded that MOCA of the saphenous veins has the advantage of endovenous ablation without tumescent anesthesia. This study is limited by lack of randomization and control and short-term follow-up.

In a prospective comparison study, van Eekeren et al. (2013) evaluated postoperative pain and quality of life after radiofrequency ablation (RFA) and mechanochemical endovenous ablation (MOCA) for great saphenous vein (GSV) incompetence. Sixty-eight patients with unilateral GSV incompetence were included. Patients treated with MOCA reported significantly less postoperative pain than patients treated with RFA during the first 14 days after treatment. The lower postoperative pain score was associated with a significantly earlier return to normal activities and work. At 6 weeks, patients in both groups perceived an improved change in health status and an improved disease-specific quality of life. This study is limited by lack of randomization and control, small sample size and short-term follow-up.

In a prospective cohort study, Boersma et al. (2013) evaluated the feasibility, safety and 1-year results of mechanochemical endovenous ablation (MOCA) of small saphenous vein (SSV) insufficiency. Fifty consecutive patients were treated using the ClariVein device and polidocanol. At the 6-week assessment, all treated veins were occluded. One-year follow-up showed a 94% anatomic success rate and no major complications. The authors concluded that MOCA is a safe, feasible and efficacious technique for treating SSV insufficiency. This study is limited by lack of randomization and control, small sample size and short-term follow-up.

Elias and Raines (2012) assessed the safety and efficacy of the ClariVein® system for mechanochemical ablation of the great saphenous vein (GSV). Thirty GSVs in 29 patients were treated. At six-month follow-up, the primary closure rate was 96.7% with no adverse events reported. The authors concluded that mechanochemical ablation appears to be safe and efficacious. This study is limited by lack of randomization and control, small sample size and short-term follow-up.

In a pilot study, Van Eekeren et al. (2011) evaluated the feasibility and safety of endovenous mechanochemical ablation (MOCA) for the treatment of greater saphenous vein (GSV) incompetence. Thirty limbs in 25 patients (18 women; mean age 52 years) with GSV incompetence were treated with the ClariVein® device. Initial technical success, complications, patient satisfaction and classification by venous clinical severity score (VCSS) were assessed 6 weeks after the treatment. Initial technical success of MOCA was 100%. There were no major adverse events. Duplex ultrasonography at 6 weeks showed 26 (87%) of 30 veins were completely occluded. Three veins showed partial recanalization in the proximal and distal GSV.

One patient had full segment recanalization and was successfully retreated. The VCSS significantly improved at 6 weeks. Patient satisfaction was high, with a median satisfaction of 8.8 on a 0-10 scale. The authors concluded that endovenous MOCA is feasible and safe in the treatment of GSV incompetence. Larger studies with a prolonged follow-up are indicated to prove the efficacy of this technique.

A National Institute for Health and Care Excellence (NICE) guideline states that current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins is inadequate in quantity and quality. This procedure should only be used with special arrangements for clinical governance, consent and audit or research. This procedure should only be carried out by clinicians with specific training in this technique (NICE, 2013).

Professional Societies

Society for Vascular Surgery (SVS)/American Venous Forum (AVF)

The SVS and AVF released joint clinical practice guidelines regarding the care of patients with varicose veins (Gloviczki et al., 2011). The policy states that patients who undergo high ligation alone of the great saphenous vein (GSV) have recurrent reflux in the residual GSV. This causes new symptoms and increases the risk of reoperation.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Vein ligation surgery is a procedure and therefore not subject to FDA regulation.

The ClariVein® infusion catheter (Vascular Insights) received FDA approval (K071468) on March 20, 2008. The device is designed to introduce physician-specified medicaments into the peripheral vasculature. See the following website for more information:

http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071468.pdf. Accessed November 29, 2013.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Varicose Vein Procedures. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Treatment of Varicose Veins in Lower Extremities](#), [Varicose Veins of the Lower Extremities](#), [Varicose Veins of the Lower Extremity Treatment of](#), [Treatment of Varicose Veins of the Lower Extremity](#) and [Treatment of Varicose Veins of the Lower Extremities](#).

(Accessed November 20, 2013)

REFERENCES

Allan PL. Role of ultrasound in the assessment of chronic venous insufficiency. *Ultrasound Q*. 2001 Mar;17(1):3-10.

American Medical Association. *Current Procedural Terminology: CPT Professional Edition*. AMA Press.

Bishawi M, Bernstein R, Boter M, et al. Mechanochemical ablation in patients with chronic venous disease: A prospective multicenter report. *Phlebology*. 2013 Jul 2. [Epub ahead of print]

Boersma D, van Eekeren RR, Werson DA, et al. Mechanochemical endovenous ablation of small saphenous vein insufficiency using the ClariVein® device: one-year results of a prospective series. *Eur J Vasc Endovasc Surg*. 2013 Mar;45(3):299-303.

Chaar CI, Hirsch SA, Cwenar MT, et al. Expanding the role of endovenous laser therapy: results in large diameter saphenous, small saphenous, and anterior accessory veins. *Ann Vasc Surg*. 2011 Jul;25(5):656-61.

Chandler JG, Pichot O, Sessa C, et al. Defining the role of extended saphenofemoral junction ligation: a prospective comparative study. *J Vasc Surg.* 2000 Nov;32(5):941-53.

ClariVein website. <http://clarivein.eu/home>. Accessed November 29, 2013.

Darwood RJ, Gough MJ. Endovenous laser treatment for uncomplicated varicose veins. *Phlebology.* 2009;24 Suppl 1:50-61.

Disselhoff BC, der Kinderen DJ, Kelder JC, Moll FL. Randomized clinical trial comparing endovenous laser ablation of the great saphenous vein with and without ligation of the saphenofemoral junction: 2-year results. *Eur J Vasc Endovasc Surg.* 2008 Dec;36(6):713-8.

Disselhoff BC, der Kinderen DJ, Kelder JC, Moll FL. Five-year results of a randomised clinical trial of endovenous laser ablation of the great saphenous vein with and without ligation of the saphenofemoral junction. *Eur J Vasc Endovasc Surg.* 2011 May;41(5):685-90.

Dwerryhouse S, Davies B, Harradine K, Earnshaw JJ. Stripping the long saphenous vein reduces the rate of reoperation for recurrent varicose veins: five-year results of a randomized trial. *J Vasc Surg.* 1999 Apr;29(4):589-92.

Eklöf B, Rutherford RB, Bergan JJ, et al. Revision of the CEAP classification for chronic venous disorders: consensus statement. *J Vasc Surg.* 2004 Dec;40(6):1248-52.

Elias S, Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. *Phlebology.* 2012 Mar;27(2):67-72.

Engelhorn C, Engelhorn A, et al. Relationship between reflux and greater saphenous vein diameter. *Journal of Vascular Technology* 1997;21(3):167-72.

Gloviczki P, Comerota AJ, Dalsing MC, et al.; Society for Vascular Surgery; American Venous Forum. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* 2011 May;53(5 Suppl):2S-48S.

Goren G, Yellin AE. Primary varicose veins: topographic and hemodynamic correlations. *J Cardiovasc Surg (Torino)* 1990 Sep-Oct; 31(5):672-7.

Hayes, Inc. Search and Summary. Clarivein® occlusion catheter, nonthermal vein ablation system (Vascular Insights LLC) for varicose veins. November 2013.

Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL). 2007 ICAVL Standards. Part II: Vascular laboratory operations – peripheral venous.

Jones L, Braithwaite BD, Selwyn D, et al. Neovascularisation is the principal cause of varicose vein recurrence: results of a randomised trial of stripping the long saphenous vein. *Eur J Vasc Endovasc Surg.* 1996 Nov;12(4):442-5.

Kontothanassis D, Di Mitri R, Ferrari Ruffino S, et al. Endovenous laser treatment of the small saphenous vein. *J Vasc Surg.* 2009 Apr;49(4):973-79.

Labropoulos N, Kang SS, Mansour MA, et al. Primary superficial vein reflux with competent saphenous trunk. *Eur J Vasc Endovasc Surg.* 1999 Sep;18(3):201-6.

Labropoulos N, Kokkosis AA, Spentzouris G, et al. The distribution and significance of varicosities in the saphenous trunks. *J Vasc Surg.* 2010 Jan;51(1):96-103.

Labropoulos N, Leon L. Sapheno-femoral junction reflux in patients with a normal saphenous trunk. *Eur J Vasc Endovasc Surg.* 2004 Dec;28(6):595-9.

Labropoulos N, Tiongson J, Pryor L, et al. Definition of venous reflux in lower-extremity veins. *J Vasc Surg.* 2003 Oct;38(4):793-8.

Marston WA, Owens LV, Davies S, et al. Endovenous saphenous ablation corrects the hemodynamic abnormality in patients with CEAP clinical class 3-6 CVI due to superficial reflux. *Vasc Endovascular Surg.* 2006 Mar-Apr;40(2):125-30.

Medical Advisory Secretariat. Endovascular radiofrequency ablation for varicose veins: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2011;11(1):1-93. Available at: http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_rfa_vv_20110216.pdf. Accessed November 29, 2013.

Meissner MH. Lower extremity venous anatomy. *Semin Intervent Radiol.* 2005 Sep;22(3):147-56. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3036282/pdf/sir22147.pdf>. Accessed November, 29, 2013.

Merchant RF, Pichot O; Closure Study Group. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. *J Vasc Surg.* 2005 Sep;42(3):502-9.

National Heart, Lung and Blood Institute (NHLBI) website. Varicose veins. February 2011. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/vv/vv_what.html. Accessed November 29, 2013.

National Institute for Health and Care Excellence (NICE). IPG 435. Endovenous mechanochemical ablation for varicose veins. January 2013. Available at: <http://www.nice.org.uk/nicemedia/live/13702/62452/62452.pdf>. Accessed November 29, 2013.

Navarro TP, Delis KT, Ribeiro AP. Clinical and hemodynamic significance of the greater saphenous vein diameter in chronic venous insufficiency. *Arch Surg.* 2002 Nov;137(11):1233-7.

O'Hare JL, Vandebroek CP, Whitman B, et al. A prospective evaluation of the outcome after small saphenous varicose vein surgery with one-year follow-up. *J Vasc Surg.* 2008 Sep;48(3):669-73; discussion 674.

Proebstle TM, Gül D, Lehr HA, et al. Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. *J Vasc Surg.* 2003 Sep;38(3):511-6.

Recek C. Saphenofemoral junction ligation supplemented by postoperative sclerotherapy: a review of long-term clinical and hemodynamic results. *Vasc Endovascular Surg.* 2004 Nov-Dec;38(6):533-40.

Rohren EM, Kliever MA, Carroll BA, Hertzberg BS. A spectrum of Doppler waveforms in the carotid and vertebral arteries. *AJR Am J Roentgenol.* 2003 Dec;181(6):1695-704.

Rutgers PH, Kitslaar PJ. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. *Am J Surg.* 1994 Oct;168(4):311-5.

Sarin S, Scurr JH, Coleridge Smith PD. Stripping of the long saphenous vein in the treatment of primary varicose veins. *Br J Surg.* 1994 Oct;81(10):1455-8.

Sullivan V, Denk PM, Sonnad SS, et al. Ligation versus anticoagulation: treatment of above-knee superficial thrombophlebitis not involving the deep venous system. *J Am Coll Surg.* 2001 Nov;193(5):556-62.

Theivacumar NS, Dellagrammaticas D, Beale RJ, et al. Fate and clinical significance of saphenofemoral junction tributaries following endovenous laser ablation of great saphenous vein. *Br J Surg.* 2007 Jun;94(6):722-5.

Theivacumar NS, Darwood RJ, Gough MJ. Endovenous laser ablation (EVLA) of the anterior accessory great saphenous vein (AAGSV): abolition of sapheno-femoral reflux with preservation of the great saphenous vein. *Eur J Vasc Endovasc Surg.* 2009 Apr;37(4):477-81.

Theivacumar NS, Dellagrammaticas D, Mavor AI, et al. Endovenous laser ablation: does standard above-knee great saphenous vein ablation provide optimum results in patients with both above- and below-knee reflux? A randomized controlled trial. *J Vasc Surg.* 2008 Jul;48(1):173-8.

Theivacumar NS, Dellagrammaticas D, Mavor AI, et al. Endovenous laser ablation (EVLA) of great saphenous vein to abolish "paradoxical reflux" in the Giacomini vein: a short report. *Eur J Vasc Endovasc Surg.* 2007 Aug;34(2):229-31.

Theivacumar NS, Gough MJ. Endovenous laser ablation (EVLA) to treat recurrent varicose veins. *Eur J Vasc Endovasc Surg.* 2011 May; 41(5):691-6.

van Eekeren RR, Boersma D, Konijn V, et al. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. *J Vasc Surg.* 2013 Feb;57(2):445-50.

van Eekeren RR, Boersma D, Elias S, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. *J Endovasc Ther.* 2011 Jun;18(3):328-34.

Wichers IM, Di Nisio M, Büller HR, Middeldorp S. Treatment of superficial vein thrombosis to prevent deep vein thrombosis and pulmonary embolism: a systematic review. *Haematologica.* 2005 May;90(5):672-7.

Winterborn, RJ, et al. (2004). Causes of varicose vein recurrence: late results of a randomized controlled trial of stripping the long saphenous vein. *J Vasc Surgery.* 40(4): 634-9.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2014	<ul style="list-style-type: none"> • Revised coverage rationale and description of services; removed content/language specific to sclerotherapy now covered without need for clinical review • Updated definitions; removed definition of sclerotherapy • Updated and reformatted list of applicable CPT codes; removed 36470, 36471 and 75894 • Updated list of applicable HCPCS codes; removed S2202 • Archived previous policy version 2014T0447M