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Clinical Review Criteria
Treatment of Varicose Veins

- Radiofrequency Catheter Closure
- Sclerotherapy
- Surgical Stripping
- Trivex System for Outpatient Varicose Vein Surgery
- VenaSeal Closure System
- VNUS Closure Device

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Treatment of Varicose Veins of the Lower Extremities (L34010)
Local Coverage Article	None

For Non-Medicare Members

I. For great saphenous vein or small saphenous vein ligation, stab phlebectomy, division, stripping, radiofrequency endovenous occlusion (VNUS procedure), Endovenous Radiofrequency Ablation Treatment (ERFA) and endovenous laser ablation of the saphenous vein (ELAS) (also known as endovenous laser treatment (EVLT) all of the following criteria must be met:
   A. The patient is symptomatic and has one, or more, of the following:
      1. Pain or burning in the extremity
      2. Recurrent episodes of superficial phlebitis
      3. Non-healing skin ulceration
      4. Bleeding from a varicosity
      5. Stasis dermatitis
      6. Refractory dependent edema
   B. Vein size is 4.5 mm or greater in diameter (not valve diameter at junction)
   C. Pre-operative doppler demonstrates reflux (reflux duration of 500 milliseconds (ms) or greater in the vein to be treated).
   D. In addition all of the following are true for ERFA and laser ablation:
      1. Absence of aneurysm in the target segment.
      2. Maximum vein diameter of 12 mm for ERFA or 20 mm for laser ablation.
      3. Absence of thrombosis or vein tortuosity, which would impair catheter advancement.
      4. The absence of significant peripheral arterial diseases.

II. Sclerotherapy is covered for up to 6 months after a covered stab phlebectomy, endovenous ablation or a vein stripping. Sclerotherapy can be approved at these same venous sites if symptoms persist associated with persistent varicosities.

No evidence to support coverage for:

A. Treatment of reticular veins, spider veins or superficial telangiectasis by any technique (considered cosmetic)
B. Procedures with devices not FDA-approved

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The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Superficial venous reflux occurs when the valves that keep blood flowing out of the veins in the leg become damaged or diseased. Primary symptoms are pain, swelling and varicose veins. The basic treatment is to re-route blood flow through other healthy veins. This can be done using several techniques: stripping the greater damaged vein, using radiofrequency energy to heat and occlude the vein, and using irritant solution to obliterate the vein.

The conventional treatment is stripping of the greater damaged vein. This procedure has favorable clinical outcomes (REF), but is associated with substantial post-operative morbidity, particularly pain and bruising. Recurrent reflux is possible with the existing treatments and the risk of recurrence increases over time.

Rather than vein stripping, radiofrequency (RF) energy to heat and occlude the damaged vein. RF energy is delivered via collapsible catheter electrodes that are introduced into the vein lumen. The operator sets the target temperature, usually 85^{O}C. The temperature is monitored using a microprocessor-controlled bipolar generator. The procedure is performed on an outpatient basis, using either local or regional anesthesia.

Sclerotherapy is the treatment of veins that are distended, lengthened and tortuous (i.e. varicose veins) by the injection of an irritant solution to encourage obliteration of the veins by thrombosis and subsequent scarring.

The treatment of varicose veins and spider veins can be for either cosmetic purposes or for the improvement of clinical symptoms related to these conditions. In order to identify when the care will be covered a common set of clinical appropriateness criteria were developed.

Evidence and Source Documents

Radiofrequency Catheter Closure
Trivex
VenaSeal Clsoure System

Medical Technology Assessment Committee(MTAC)

Radiofrequency Catheter Closure in the treatment of varicose veins

BACKGROUND
Superficial venous reflux occurs when the valves that keep blood flowing out of the veins in the leg become damaged or diseased. Primary symptoms are pain, swelling and varicose veins. The basic treatment is to re-route blood flow through other healthy veins. The conventional treatment is stripping of the greater damaged vein. This procedure has favorable clinical outcomes (REF), but is associated with substantial post-operative morbidity, particularly pain and bruising. Recurrent reflux is possible with the existing treatments and the risk of recurrence increases over time. The VNUS Closure System was proposed as a minimally invasive treatment for superficial venous reflux. Rather than vein stripping, the Closure system uses radiofrequency (RF) energy to heat and occlude the damaged vein. RF energy is delivered via collapsible catheter electrodes that are introduced into the vein lumen. The operator sets the target temperature, usually 85o C. The temperature is monitored using a microprocessor-controlled bipolar generator. The procedure is performed on an outpatient basis, using either local or regional anesthesia. The VNUS Closure System received FDA approval March 1999.

08/13/2003: MTAC REVIEW
Radiofrequency Catheter Closure in the treatment of varicose veins
Evidence Conclusion: The best, published evidence on the VNUS Closure system is a small RCT with n=33 (Rautio et al., 2002). This study found that patients had less pain and fewer sick days a mean of 50 days after the Closure procedure than patients who received the stripping operation. There was no significant difference in quality of life variables. Potential sources of bias in the Rautio RCT include lack of blinding, lack of intention to treat analysis and potential confounding. In addition, the RCT did not have long-term follow-up and did not address the issue of recurrent reflux. Also available are case series data from a multi-center registry (Merchant et al., 2002). 93% of patients had complete The use of Radiofrequency Catheter Closure in the treatment of varicose veins does not meet the Kaiser Permanente Medical Technology Assessment Criteria. The following information was used in the development of this document and is provided as background only. It is not to be

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used as coverage criteria. Please only refer to the criteria listed above for coverage determinations. Occlusion after the VNUS Closure procedure. Twelve months after treatment, among the patients with data available, 94% of those with complete occlusion had varicose veins absent and 100% had reflux absent. These findings could be biased because data were missing on 20% of the patients at 12 months. Although the Rautio study suggests short-term benefit of the Closure system compared to the stripping procedure, there is insufficient evidence on long-term effectiveness.
Articles: The search yielded 12 articles. The best evidence was a recent case series taken from a multi-center registry and a small randomized controlled trial. The following studies were critically appraised: Rautio T, Ohinmaa A, Perala J. et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: A randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002;35: 958-65. See Evidence Table. Merchant RF, DePalma RG, Kabnick LS. Endovascular obliteration of saphenous reflux: A multicenter study. *J Vasc Surg* 2002;35: 1190-1196. See Evidence Table.

The use of Radiofrequency Catheter Closure in the treatment of varicose veins does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

TriVex System for Outpatient Varicose Vein Surgery

BACKGROUND
Because there are no published studies on the TriVex transluminated powered phlebectomy for outpatient varicose vein surgery, this was documented. Transilluminated phlebectomy is a minimally invasive surgical technique for removing varicose veins. The TriVex system was introduced by Smith & Nephew in 2000. The TriVex resector and TriVex illuminator are placed under the skin through small 2mm vertical incisions on either side of the varicosity. According to Smith & Nephew, “one of the key features of the TriVex system is its ability to light the area beneath the skin. For the first time, the vein is clearly visible, allowing the surgeon to quickly and accurately remove it using a powered resector and then visually confirm its complete extraction.”

08/08/2001: MTAC REVIEW
TriVex System for Outpatient Varicose Vein Surgery
Evidence Conclusion: There are no published studies on the TriVex System Transilluminated Powered Phlebectomy for outpatient varicose vein surgery. We were not given any unpublished data of sufficient quality to review as evidence. In conclusion, there is no evidence on which to base conclusions about the effect of this technology on health outcomes.
Articles: No published articles were found. Literature from the manufacturer included conference abstracts that cannot be evaluated as evidence. Conclusion: There is no evidence on which to base conclusions about the effect of this technology on health outcomes.

The use of TriVex in the treatment of Varicose Veins does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

VenaSeal Closure System for Varicose Veins

BACKGROUND
Chronic venous disorders of the lower limb are estimated to affect approximately 30 million adults or 35% of screened adults in the United States [1] and manifest most frequently like varicose veins. The mechanism underlying varicose veins can be explained by a dysfunctional valve inside the veins. The valves of the superficial veins and those of the Great Saphenous Vein (GSV) transferring blood toward the heart are defective leading to venous dilation and stasis. The accumulation of blood in the vein is responsible for the swelling, pain, chronic skin changes, spontaneous hemorrhage, leg ulcers and fatigue. The progression can be expressed by a reduction of quality of life (QoL) [2].

The management of varicose veins has undergone a shift and a number of treatment options have been described; these include surgery and minimal invasive therapies. Surgery which is represented by ligation and stripping and various surgical techniques are described and involve saphenous vein inversion and removal, high ligation of the saphenous vein, ambulatory phlebectomy, trans illuminated phlebectomy, conservative venous ligation (CHIVA), and perforator ligation. Although surgery improves symptoms and leads to patient satisfaction [3- 6], this is associated with hematoma, paresthesia and high recurrence rate [7]. Other treatments reside in thermal- based techniques including endovenous thermal ablation (EVTA) by radiofrequency ablation (RFA) or laser ablation. These techniques are believed to have long-term success (vein closure) rates of 78 to 84 percent [8-10] and necessitate tumescent anesthesia. In contrast, new technique such as venaseal closure system (VSCS) does not seem to require tumescent anesthesia, and has recently been approved for treatment of the

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incompetent GSV in the European Union, Hong Kong, and Canada [2].

The VenaSeal Closure System (VSCS) permanently treats symptomatic varicose veins of the legs by closing the affected superficial veins with a cyanoacrylate-based adhesive. The VenaSeal System is composed of a catheter, guidewire, dispenser gun, dispenser tips, and syringes. A catheter is introduced through the skin into the varicose vein and a clear liquid (adhesive) is also injected. The insertion of the catheter and the delivery of adhesive are performed under ultrasound guidance. After the delivery of the adhesive, manual compression of the affected area begins and the adhesive changes into a solid to seal the varicose vein. The system is used for patients with venous reflux disease and it seals superficial varicose veins of the legs. Treating the diseased veins generally relieves symptoms. The VenaSeal System should not be used in patients with a known hypersensitivity to the VenaSeal adhesive or cyanoacrylates, patients who have acute inflammation of the veins due to blood clots and patients with acute whole-body infection (FDA, 2015).

06/20/2016: MTAC REVIEW
VenaSeal Closure System
Evidence Conclusion: The search identified one study that compares VenaSeal Closure System (VSCS) with radiofrequency ablation (RFA). A non-randomized and a prospective studies assessing the efficacy and safety of VSCS were also identified but were not subject to evidence table since no comparison was made. Evidence Table 1: Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose) [2] This RCT aimed to demonstrate the non-inferiority of cyanoacrylate embolization (CAE) efficacy compared with radiofrequency ablation (RFA). The primary outcome was the total closure of the target great saphenous vein (GSV) defined as Doppler ultrasound examination (including color flow, compression, and pulsed Doppler) showing closure along the entire treated target vein segment with no discrete segments of patency exceeding 5 cm at the month 3 visit. Adverse events were also assessed. Patients were randomized to CAE performed with VenaSeal Sapheon Closure System or RFA. Patients returned to clinic at day 3, 1 and 3 months. Trial follow-up continues to 36 months after initial treatment. Vein closure was determined by Doppler ultrasound examination and confirmed by an independent vascular ultrasound core laboratory. On day 3, 100% of the GSVs treated were closed in both groups. At month 1, no patency of treated vein was identified with the VSCS vs. 15 patency observed with the RFA with closure rates of 100% and 86% respectively. The Venous Clinical Severity Score (VCSS) had improved by 3.5 points from baseline with no differences between groups. Aberdeen Varicose Vein Questionnaire (AVVQ) had improved by 8 points. Time trade-off (EQ-5D TTO) improved by 0.03 points with no differences between groups. Ecchymosis at day 3 was absent in significantly more subjects after VSCS than after RFA. Post treatment phlebitis was more frequent after VSCS. Most cases of phlebitis were mild. No difference was observed between the mean intraprocedural pain ratings of both groups (2.2 vs. 2.4 P=0.11). No deep vein thrombosis (DVT) or pulmonary embolism was observed. The authors concluded that VSCS was non inferior to RFA for the occlusion of symptomatic incompetent GSVs at 3 months.Nevertheless, the study had some limitations: Patients were not blinding raising the concern of placebo effect and increasing the risk of bias. The duration of follow-up was also short. In addition, the study was funded by Sapheon and some authors had financial interest with Sapheon. Although the assessment of the primary endpoint was objective, patient's pain assessment was subjective resulting in reporting bias. Thus, the results should be interpreted with caution.
Additional studies: A non-randomized study case series of 29 patients (fifty seven legs) [11] that evaluated the safety, efficacy and performance of endovenous cyanoacrylate (Sapheon Venaseal Closure System) by assessing the Great Saphenous Vein (GSV) occlusion, Venous clinical severity score (VCSS), Aberdeen Varicose Vein Questionnaire (AVVQ) and the Short Form Health Survey 36 Item (SF-36) questionnaires. Fifty seven legs were included and after one week of follow-up, obliteration was achieved in most patients. At month 1, VCSS, AVVQ and SF-36 physical and mental scores improved from 6.91, 23.66, 44.24, 54.26 to 2.43, 6.10, 43.85, and 52.50 respectively. The closure rates were 98.2% and 78.5% at week 1 and 1 year respectively. The authors conclude that VSCS was safe for the treatment of great saphenous vein reflux. A prospective study of 38 patients performed by Almeida et al [12] indicates that clinical efficacy of endovenous cyanoacrylate for closure of insufficient great saphenous veins was maintained over a period of 24 months.
Conclusion:

- Based on low quality evidence, manufacturer sponsored trial, cyanoacrylate embolization (CAE) performed with the VSCS was non inferior to radiofrequency ablation (RFA).
- There is a lack of evidence to determine whether the VenaSeal Closure System (VSCS) for varicose veins treatment is effective and safe compared to other alternative treatments.

Articles: The following article was selected for critical appraisal: Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose) See Evidence Table 1.

The use of VenaSeal Closure System of Varicose Veins does not meet the Kaiser Permanente *Medical*

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Technology Assessment Criteria.

Date Created	Date Reviewed	Date Last Revised
1992	05/04/2010 MDCRPC, 03/01/2011 MDCRPC, 01/03/2012MDCRPC, 11/06/2012MDCRPC, 09/03/2013MPC, 01/07/2014MPC, 07/01/2014MPC, 06/02/2015MPC, 05/03/2016MPC, 03/07/2017MPC	07/05/2016

MDCRPC Medical Director Clinical Review and Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34010
01/13/2016	Added CPT codes and stab phlebectomy language
06/20/2016	Added VenaSeal Closure System MTAC review

Codes

Endovenous Laser Ablation - 36478, 36479
Ligation and Excision – 37700, 37718, 37722, 37735, 37780, 37785
Sclerotherapy Telangiectasias – 36468
Radiofrequency Ablation – 36475, 36476
Laser Ablation - 36478, 36479
Sclerotherapy – 36470, 36471, 36473, 36474, S2202
Stab Phlebectomy – 37765, 37766
Subfascial Endoscopic Perforator Surgery (SEPS) – 37500, 37760, 37761

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