



**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

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**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	Billing and Coding: Treatment of Varicose Veins of the Lower Extremities (A57707)

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) or with exception of short saphenous vein 3.5 mm or greater can be ablated
 - 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.
 - E. Microfoam sclerotherapy (e.g. Varithena) can be used if patient meets criteria B (above) when laser ablation is not an option, per criteria D3 (above).

- 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. Also, sclerotherapy can be approved for 4.0 mm or greater superficial varicosities associated with spontaneous bleeding or a poorly healing ulcer.
- III. VenaSeal Closure System
 - Can be covered if all criteria above are met.

No evidence to support coverage for:

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

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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°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 Closure 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 85°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. 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 affect approximately 30 million adults or 35% of screened adults in the United States (McLafferty et al., 2008) and manifest most frequently like varicose veins. The mechanism underlying varicose veins can be explained by a defective valve inside the veins. The valves of the superficial veins and those of the Great Saphenous Vein (GSV) transferring blood toward the heart are dysfunctional leading to venous dilation and stasis. The accumulation of blood in the vein causes the swelling, pain, chronic skin changes, spontaneous hemorrhage, leg ulcers and fatigue. Evolution of the condition is marked by a reduction of quality of life (QoL) (Nick Morrison et al., 2015).

The management of varicose veins has undergone a shift and several treatment options have been described. These include surgery and minimal invasive therapies. Surgery which is represented by ligation, stripping and various other 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 (Baker, Turnbull, Pearson, & Makin, 1995; MacKenzie et al., 2002; Nelzén & Fransson, 2013; Smith, Garratt, Guest, Greenhalgh, & Davies, 1999), it can be complicated by hematoma, paresthesia and high recurrence rate (Ostler, Holdstock, Harrison, Price, & Whiteley, 2015). Other treatments encompass 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% (Carroll et al., 2014; Nesbitt, Bedenis, Bhattacharya, & Stansby, 2014; Pan, Zhao, Mei, Shao, & Zhang, 2014) 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 incompetent GSV in the European Union, Hong Kong, and Canada (Nick Morrison et al., 2015).

The VenaSeal Closure System (VSCS) 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:

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 Technology Assessment Criteria*.

01/04/2019: MTAC REVIEW

VenaSeal Closure System

Evidence Conclusion: Moderate evidence shows that VenaSeal is non-inferior and comparable to RFA in patients with moderate to severe varicosities and incompetence of the great saphenous vein on the short-term and long-term (36 months).

Articles: PubMed was searched from May 2016 through June 6, 2018 with the search terms venaseal OR venaseal closure system OR venaseal system. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded 18 articles. After screening, 12 articles were retained and assessed. [See Evidence Tables](#).

The use of VenaSeal Closure System of Varicose Veins does meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are

met:

Endovenous Laser Ablation

CPT® or HCPC Codes	Description
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Ligation and Excision

CPT® or HCPC Codes	Description
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
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg

Sclerotherapy Telangiectasias

CPT® or HCPC Codes	Description
36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk

Radiofrequency Ablation

CPT® or HCPC Codes	Description
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Laser Ablation

CPT® or HCPC Codes	Description
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Sclerotherapy

CPT® or HCPC Codes	Description
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)

36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
S2202	Echosclerotherapy

Stab Phlebectomy

CPT® or HCPC Codes	Description
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions

Subfascial Endoscopic Perforator Surgery (SEPS)

CPT® or HCPC Codes	Description
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
37760	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg

VenaSeal (chemical adhesive)

CPT® or HCPC Codes	Description
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Varithena

CPT® or HCPC Codes	Description
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
1992	05/04/2010 ^{MDCRPC} , 03/01/2011 ^{MDCRPC} , 01/03/2012 ^{MDCRPC} , 11/06/2012 ^{MDCRPC} , 09/03/2013 ^{MPC} , 01/07/2014 ^{MPC} , 07/01/2014 ^{MPC} , 06/02/2015 ^{MPC} , 05/03/2016 ^{MPC} , 03/07/2017 ^{MPC} , 01/09/2018 ^{MPC} , 12/04/2018 ^{MPC} , 12/03/2019 ^{MPC} , 12/01/2020 ^{MPC} , 12/07/2021 ^{MPC} , 12/06/2022 ^{MPC}	10/01/2019

^{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
04/03/2018	MPC approved to adopt the revised indication for varicose veins: <i>Vein size is 4.5 mm or grater in diameter (not valve diameter) & Sclerotherapy can be approved for 4.0 mm or greater superficial varicosities associated with spontaneous bleeding or a poorly healing ulcer.</i>
02/05/2019	MPC approved to adopt coverage criteria for VenaSeal Closure System; added 01/2019 MTAC review
10/01/2019	MPC approved to add coverage for Varithena
12/06/2022	Care Delivery Medical Necessity Review for Varicose Veins audit has been reviewed; prior authorization with no medical review has been awarded for another year.