

UnitedHealthcare[®] Commercial and Individual Exchange Medical Policy

Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

Policy Number: 2024T0447MM Effective Date: April 1, 2024

Instructions for Use

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Related Commercial/Individual Exchange Policies

- Cosmetic and Reconstructive Procedures
- Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome

Community Plan Policy

• Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins

Medicare Advantage Coverage Summary

 Varicose Veins Treatment and Other Vein Embolization Procedures

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

See Benefit Considerations

Varicose Vein Ablative and Stripping Procedures

The initial and subsequent radiofrequency ablation, endovenous laser ablation, Stripping, Ligation, and excision of the Great Saphenous Vein (GSV) and Small Saphenous Veins (SSV) are considered reconstructive, proven, and medically necessary when all of the following criteria are present:

- Junctional Reflux:
 - o Ablative therapy for the GSV or SSV only if Junctional Reflux is demonstrated in these veins; or
 - Ablative therapy for Accessory Veins only if anatomically related persistent Junctional Reflux is demonstrated after the GSV or SSV have been removed or ablated
- Individual must have one of the following Functional or Physical Impairments:
 - o Skin ulceration; or
 - o Documented episode(s) of frank bleeding of the Varicose Vein due to erosion of/or trauma to the skin; or
 - o Documented Superficial Thrombophlebitis; or

- o Documented Venous Stasis Dermatitis causing Functional or Physical Impairment; or
- Moderate to Severe Pain causing Functional or Physical Impairment
- Venous Size:
 - The GSV must be 5.5 mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via Duplex Ultrasonography (Navarro et al. 2002)
 - The SSV or Accessory Veins must measure 5 mm or greater in diameter immediately below the appropriate junction
- Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:
 - o Greater than or equal to 500 milliseconds (ms) for the GSV, SSV or principal tributaries
 - o Some Duplex Ultrasound readings will describe this as moderate to severe reflux which will be acceptable

Refer to the <u>Coding Clarification</u> section. Adherence to American Medical Association (AMA) coding guidance is required when requesting coverage of Endovenous Ablation procedures. Note that only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated.

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

- Evidence of perforator Venous Insufficiency measured by recent Duplex Ultrasonography report (see criteria above); and
- Perforator vein size is 3.5 mm or greater; and
- Perforating veins > 350 ms; and
- Perforating vein lies beneath a healed or active venous stasis ulcer

Ligation Procedures

The following procedure is proven and medically necessary:

 Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are intolerant of anticoagulation therapy

The following procedure is proven and medically necessary in certain circumstances:

Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency.
 For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein

Click here to view the InterQual® criteria.

The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy:

- Ligation of the GSV at the saphenofemoral junction, as a stand-alone procedure
- Ligation of the SSV at the saphenopopliteal junction, as a stand-alone procedure
- Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or Endovenous laser ablation of the main saphenous veins

Ambulatory Phlebectomy

Ambulatory phlebectomy for treating Varicose Veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ambulatory Phlebectomy, Varicose Vein for:

- Hook Phlebectomy
- Microphlebectomy
- Mini Phlebectomy
- Stab Avulsion
- Stab Phlebectomy

Click here to view the InterQual® criteria.

Other Procedures

The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy:

- Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive
- Endovenous low-nitrogen foam Sclerotherapy of incompetent GSV, lesser saphenous veins, and accessory saphenous veins
- Endovenous mechanochemical ablation (MOCA) of Varicose Veins
- Porcine bioprosthetic valve (e.g., VenoValve) implantation into the femoral vein for treatment of deep vein reflux associated with chronic Venous Insufficiency

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information	
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins		
36470	Medical notes documenting the following, when applicable:	
36471	Diagnosis	
36473	History of the medical condition(s) requiring treatment or surgical intervention	
36474	Documentation of signs and symptoms; including onset, duration, frequency, and which extremity	
36475	(right, left, or both)	
36476	 Pain or other symptoms that interfere with activities of daily living (ADL) related to vein disease, including duration 	
36478	 Functional disability(ies), as documented on a validated functional disability scale, interfering with 	
36479	the ability to stand or sit for long periods of time	
37700	Relevant medical history, including:	
37718	 DVT (deep vein thrombosis) 	
37722	o Aneurysm	
37780	o Tortuosity	
	Physical exam, including:	
	 Which extremity (right, left, or both) 	
	 Vein(s) that will be treated [e.g., Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV), etc.] 	
	 Vein diameter including the specific anatomic location where the measurement was taken (e.g., 	
	proximal thigh, proximal calf, etc.)	
	 Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction 	
	(SFJ)]	
	Reports of recent imaging studies and applicable diagnostic tests	
	 Prior non-invasive treatments of the veins that have been tried, failed, or were contraindicated; 	
	include the dates, duration, and reason for discontinuation	
	History of prior treatment complications (e.g., recurrent bleeding or significant hemorrhage)	
	including the dates of occurrence	
	History of previous relevant vein procedure(s), if applicable	
	 Proposed treatment plan with procedure code, including specific vein(s) that will be treated [e.g., Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV), etc.], which extremity (left, right, or 	
	both), and date of procedure for each vein to be treated	

^{*}For code descriptions, refer to the <u>Applicable Codes</u> section.

Definitions

When applicable, refer to the member specific benefit plan document for definitions.

Accessory/Tributary Vein: Axial accessory or tributary saphenous veins indicate any venous segment ascending parallel to the Great 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 (COC, 2018).

Congenital Anomaly (California only): A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth (COC, 2018).

Cosmetic Procedures: Cosmetic Procedures are excluded from coverage. Procedures or services that change or improve appearance without significantly improving physiological function (COC, 2018).

Cosmetic Procedures (California only): Procedures or services that are performed to alter or reshape normal structures of the body in order to improve appearance (COC, 2018).

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 or Physical Impairment: A physical or 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 (GSV): 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.

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

- The saphenofemoral junction (SFJ) Confluence of the Great Saphenous Vein and the femoral vein; or
- The saphenopopliteal junction (SPJ) Confluence of the Small Saphenous Vein and the popliteal vein.

Ligation: Tying off a vein.

Moderate to Severe Pain: The Venous Clinical Severity Score (VCSS) describes moderate pain to be daily pain or other discomfort interfering with, but not preventing regular daily activities, and severe pain to be daily pain or discomfort that limits most regular daily activities (Vasquez et al. [American Venous Forum], 2010).

Reconstructive Procedures: Reconstructive procedures when the primary purpose of the procedure is either of the following:

- Treatment of a medical condition.
- Improvement or restoration of physiologic function.

Reconstructive procedures include surgery or other procedures which are related to 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 you 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 (COC, 2018).

Reconstructive Procedures (California only): Reconstructive procedure is covered to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. The purpose of reconstructive procedure is to correct abnormal structures of the body to improve function or create a normal appearance to the extent possible (COC, 2018).

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

Sclerotherapy: Defined by Watson et al. (2017), Sclerotherapy is the intravascular injection of a chemical agent to cause endothelial damage and subsequent vascular occlusion of the target vessel (endovenous chemical ablation).

Sickness: Physical illness, disease or pregnancy. The term Sickness includes mental illness or substance-related and addictive disorders, regardless of the cause or origin of the mental illness or substance-related and addictive disorder (COC, 2018).

Sickness (California Only): Physical illness, disease or pregnancy. The term Sickness includes mental illness or substance-related and addictive disorders, regardless of the cause or origin of the mental illness or substance-related and addictive disorder (COC, 2018).

Small Saphenous Vein: Superficial vein of the calf.

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: Refer to 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 secSuperficial veins: 0.5 secPerforator veins: 0.35 sec

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

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Guidelines may apply.

Coding Clarification

- According to the American Medical Association (AMA), CPT code 37241 is specific to venous embolization/occlusion and
 excludes lower extremity venous incompetency. Coding instructions state that 37241 should not be used to request
 treatment of incompetent extremity veins. For sclerosis of veins or endovenous ablation of incompetent extremity veins,
 refer to 36468-36479 (CPT Assistant, 2014).
- Adherence to AMA coding guidance is required when requesting endovenous ablation procedures.

Per AMA coding guidance, the initial incompetent vein treated (e.g., CPT code <u>36475</u>) may only be requested once per extremity. For endovenous ablation, treatment of subsequent incompetent veins in the same extremity as the initial vein treated (e.g., CPT code <u>36476</u>), only one add-on code per extremity may be requested, regardless of the number of additional vein(s) treated (CPT Assistant, November 2016).

Therefore, only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated.

*CPT code <u>36468</u> for sclerosant treatment for spider veins is considered cosmetic; does not improve a functional, physical or physiological impairment. (2019 Amendment)

- **CPT codes 36470 and 36471 are covered for sclerotherapy up to 3 sessions per leg within a year.
- More than 3 sessions per leg within a year is considered cosmetic; does not improve a functional, physical or physiological impairment. (2019 Certificate of Coverage Amendment) Cosmetic sclerotherapy is excluded.
- A session is defined as one date of service in which sclerotherapy (36470, 36471) is performed.
- A year is defined as a rolling 12 months (365 days).

CPT Code	Description
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (e.g., polyester, ePTFE, bovine pericardium), when performed
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 (e.g., 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 (e.g., great saphenous vein, accessory saphenous vein), same leg
*36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
* *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)
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)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

CPT Code	Description
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)
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., 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 (e.g., 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)
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
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
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
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
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.

Duplex ultrasound is considered the gold standard for diagnosis of superficial venous incompetence. The CEAP (clinical, etiology, anatomy, pathophysiology) classification system is used to describe the degree of varicosity. The "C" part of CEAP classification is more useful and practical in rating the severity of Varicose Veins:

- C0: No visible or palpable signs of venous disease
- C1: Telangiectasis (Spider Veins) or Reticular Veins
- C2: Varicose Veins (diameter of vein is > 3mm)
- C3: Edema
- C4a: Pigmentation and eczema
- C4b: Lipodermatosclerosis and atrophie blanche
- C5: Healed venous ulcer
- C6: Active venous ulcer

(Lurie et al. (American Venous Forum [AVF], 2020)

Venous clinical severity scoring has been used to measure clinical improvement after treatment of Varicose Veins. Other venous severity scoring methods include Venous Severity Score, Venous Clinical Severity Score, Venous Segmental Disease Score (Lurie et al. (AVF), (2020)).

Preoperative venous duplex ultrasound is used to evaluate patients for Venous Insufficiency symptoms or suspected DVT; it can provide a road map of vein anatomy similar to contrast venography, as well as essential hemodynamic information about the presence of proximal obstruction, vein valve function, and Venous Reflux (Lin et al., 2015).

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 [NHLBI], 2014).

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 mechanochemical ablation (MOCA), mechanicochemical Endovenous Ablation (MCEA) and mechanically enhanced Endovenous chemical ablation (MEECA).

Endovascular embolization using cyanoacrylate-based adhesive (e.g., VenaSeal™ Closure System) is a minimally invasive, non-thermal and non-sclerosant procedure that does not require tumescent anesthesia. The medical adhesive is used to close the lower extremity superficial truncal veins, such as the Great Saphenous Vein, in individuals with symptomatic Venous Reflux disease.

Endovascular embolization using Endovenous foam Sclerotherapy with polidocanol Endovenous microfoam (PEM) (e.g., Varithena™ [Provensis Ltd.]), is a prescribed proprietary canister that generates a sterile, uniform, stable, low-nitrogen polidocanol 1% microfoam sclerosant intended for ultrasound-guided intravenous (IV) injection for treating venous incompetence and varicosities (Hayes, 2022). The aim of ultrasound-guided foam Sclerotherapy for Varicose Veins is to damage the endothelial surface of the vein causing scarring and leading to blockage of the treated Varicose Veins. Sclerosant, in the form of a foam, is intended to have good surface area contact with the vein walls (National Institute of Health and Care Excellence [NICE], 2013).

Benefit Considerations

Coverage Limitations and Exclusions

The following procedures are excluded from coverage:

- Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are
 considered Cosmetic Procedures and therefore excluded from coverage. 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.
- Any procedure that does not meet the criteria in the Coverage Rationale section.
- Treatments for Spider Veins and/or Telangiectasias are considered to be cosmetic and therefore excluded from coverage.
- Endovenous Ablation (radiofrequency and/or laser) of either reticular or telangiectatic veins is not reconstructive and not medically necessary and therefore excluded from coverage.

Sclerotherapy Treatment of Veins

- Cosmetic Sclerotherapy is excluded.
- Sclerotherapy up to 3 sessions per leg within a year is covered. More than 3 sessions per leg within a year is considered
 cosmetic.
- A session is defined as one date of service in which Sclerotherapy (CPT codes 36470 and 36471) is performed.
- A year is defined as a rolling 12 months (365 days).

Clinical Evidence

A single center randomized controlled trial (RCT) with a follow-up time of 10 years was completed by Eggen et al. (2021) to evaluate the long-term results of saphenofemoral ligation and stripping (SFL/S) compared with 980-nm bare fiber endovenous laser ablation (EVLA) for the treatment of great saphenous vein (GSV) incompetence. Patients with GSV incompetence were randomized to undergo SFL/S or EVLA under tumescent anesthesia. Inclusion criteria were, among others: GSV and SFJ incompetence defined as reflux lasting more than 0.5 seconds on ultrasound imaging after calf compression and release or