

VARICOSE VEINS OF THE LOWER EXTREMITIES

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Overview

Varicose veins of the lower extremities are found in the superficial venous system which includes the greater saphenous vein (GSV) and the lesser saphenous vein (LSV), and their tributaries.¹ One-way valves are present in the superficial venous system. These valves prevent backward flow of blood within the vein and keep the blood moving toward the heart. The cause of primary varicose veins is valvular incompetence, most commonly at the saphenofemoral junction. It is not entirely clear why valves malfunction. When a person with poorly functioning valves stands up, the blood flow reverses and flows down the superficial veins, when it should be flowing up, toward the heart. Pooled blood leads to venous dilation, which in turn causes greater valvular incompetence. Over time, with more venous dilation, other adjacent valves subsequently fail. Approximately 25% of the population has lower extremity varicose veins. Age is the only consistently identified risk factor. The incidence of varicose veins increases linearly with age.

Most varicose veins do not cause persistent symptoms and most people with varicose veins do not require interventional treatment. (They may, however, have concerns over the appearance of the varicose veins. Interventional treatment in the absence of symptoms or complications is cosmetic.) In some cases varicose veins may cause symptoms, such as pain, aching and heavy legs, tenderness and swelling (edema). Symptoms may worsen after standing or sitting for long periods of time. Symptomatic varicose veins are treated conservatively by elevating the feet above the level of the heart several times a day² and/or by wearing properly fitted gradient compression stockings.³ Gradient compression stockings compress the veins, decrease venous

¹ The superficial venous system connects to the deep venous system at the following locations:

- Saphenofemoral junction (SFJ): located proximally at the groin where the GSV meets the femoral vein.
- Saphenopopliteal junction (SPJ): located behind the knee where the LSV meets the popliteal vein.
- Perforator veins: these veins traverse the deep fascia of the lower extremity. A number of perforators are found in the leg.

² Simple elevation of the legs above heart level for 30 minutes three or four times per day can reduce swelling and improve circulation and may be the only treatment needed for people with mild venous insufficiency.

³ Compression stockings are classified into four grades on the basis of pressure exerted at the ankle. Stockings graded at 20-30 mm Hg are recommended for patients with varicose veins, mild edema or leg fatigue. Stockings graded at 30-40 mm Hg are useful for treating patients with severe varicosities or moderate CVI. Stockings graded at 40-50 mm Hg and greater may be



volume, and shift blood from the extremity to more central regions of the body. If symptoms are confined to below the knee, a knee-high stocking is adequate even if there are varicose veins above the knee. Patients should put the stockings on upon arising and take them off before retiring. Daily exercise and weight reduction (where appropriate) may also help to improve circulation and alleviate symptoms.

A very small number of people with varicose veins will develop secondary complications such as superficial venous thrombophlebitis (SVT) and venous stasis ulcers. SVT is a blood clot along with pain and inflammation of a segment of vein. SVT should not be confused with a deep vein thrombophlebitis (DVT), which is a blood clot in a deep vein. (DVT requires emergent treatment because of the clot's potential to travel toward the heart and lodge in the lung.) Venous stasis ulcers are ulcers arising from chronic venous insufficiency. Both SVT and venous stasis ulcers are usually managed effectively with conservative therapy.

When symptomatic varicose veins (or complications of varicose veins) fail to respond to an adequate trial of conservative therapy, interventional treatment may be necessary. Surgical ligation with or without stripping is the standard of care in the treatment of venous insufficiency of the greater and lesser saphenous veins. Treatment is typically a three-step process:

1. Control of the most proximal point of reflux, most commonly at the saphenofemoral junction, as identified by preoperative Doppler or duplex ultrasound. Ligation is the most common treatment for controlling reflux. Ligation refers to the surgical tying off of an incompetent (i.e., varicose) vein in the leg. The GSV is typically treated by high ligation at the saphenofemoral junction followed by stripping to the knee. Most commonly the LSV is ligated at the saphenopopliteal junction only.
2. Removal of the incompetent vein from circulation. The most common strategy for this is vein stripping. Stripping refers to the removal of the incompetent vein through incisions in the groin area or behind the knee.
3. Removal of varicose tributaries. Strategies for removal may include stab phlebectomy or sclerotherapy, either at the time of ligation or subsequent to.

Less invasive alternatives to surgical ligation and stripping have been developed in recent years, notably, endovenous radiofrequency therapy (EVRT) and endovenous laser therapy (EVLV). Both of these procedures can be performed in an office or outpatient setting under local anesthesia. EVRT and EVLV are similarly designed to damage the endothelium of the vein resulting in fibrosis and ultimately occlusion of a segment of the vein, thus eliminating reflux or the backflow of blood. The vein therefore need not be ligated (tied off) surgically and stripped out. Several radiofrequency and laser devices have received FDA approval.

used for patients with severe CVI. Compression therapy should not be used for patients with infection at an ulcer site until the infection is under control.

Over the years, the role of incompetent perforator veins has been investigated in patients with advanced clinical sequelae of chronic venous insufficiency (i.e., venous ulcers). Perforator veins allow blood to pass from the superficial venous system to the deep venous system. An open surgical procedure known as the Linton procedure was developed in 1938 to treat incompetent perforator veins. The Linton procedure requires a long incision through compromised skin, frequently results in non-healing surgical incisions, infection, and recurrence of ulcers, and has largely been abandoned. In 1985 an endoscopic approach to the treatment of incompetent perforator veins known as subfascial endoscopic perforator surgery (SEPS) was introduced. There is inadequate evidence with which to make a determination of efficacy of SEPS for the treatment of leg ulcers. In many of the reported case studies and randomized controlled trials, patients have undergone both SEPS and other treatments of the superficial venous system making it difficult to assess the independent contribution of either component alone. The recommended treatment for venous ulcers is greater saphenous vein ligation and stripping. The role of incompetent perforator vein ablation awaits the results of properly conducted randomized controlled clinical trials. (O'Donnell, 2008)

Definitions

Compressive sclerotherapy – is a treatment for varicose veins. Sclerotherapy is the injection of foam or liquid sclerosant into an empty vein (elevated limb). In compressive sclerotherapy, sclerotherapy is followed by post-procedure compression. (Sclerotherapy without compression is not effective in producing long-term obliteration of the incompetent vein and is considered experimental/investigational for all indications.)

Doppler auscultation – a critical part of the physical examination of the superficial venous system. Doppler auscultation permits an estimation of blood flow as well as the presence or absence of reflux in a given vein. It also traces the reflux to its most proximal point and maps the course of the incompetent vein. The indications for Doppler auscultation include (1) any vein >3 mm in diameter that traverses the thigh or calf near the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ) regions; (2) any patient with signs or symptoms of chronic venous insufficiency; or (3) any vein causing pain.

Endovenous radiofrequency therapy (EVRT) – a minimally invasive procedure used to treat incompetent saphenous veins. EVRT uses a patented radiofrequency catheter (the VNUS Closure System) which is inserted into the vein. Radiofrequency energy causes the vein to collapse and seal shut.

Lipodermatosclerosis – is caused by an excessively high venous pressure in the subcutaneous veins in the lower leg in patients with long-standing venous insufficiency. Lipodermatosclerosis is a slow process that occurs over a number of years, and two-thirds of affected patients are obese. Lipodermatosclerosis affects the skin just above the ankle, usually on the inside surface. Over time the skin becomes brown, smooth, tight and often painful. The precise mechanism of lipodermatosclerosis is not fully understood. The most important part of management is compression therapy to correct venous stasis. Unless the underlying cause is treated, the patient is at high risk of developing venous leg ulcers. Once lipodermatosclerosis is established, the skin has

been permanently and irreversibly damaged and treatment at that stage can only hope to prevent progression to an open leg ulcer.

Stab phlebectomy – is a treatment for varicose veins. This procedure involves the removal of varicose veins through small 2-3 mm incisions in the skin overlying the vein. This procedure is more effective when performed adjunct to surgical ligation of the incompetent vein.

Stasis dermatitis – Stasis dermatitis is an inflammatory skin disease that occurs on the lower extremities in patients with chronic venous insufficiency with venous hypertension. The condition rarely occurs before the fifth decade of life, except in patients with acquired venous insufficiency due to surgery, trauma, or thrombosis. Stasis dermatitis is usually the earliest sequela of venous insufficiency, and it may be a precursor to more problematic conditions, such as lipodermatosclerosis and venous leg ulceration.

Thrombophlebitis – inflammation in a vein in an area where a blood clot has formed. (Often the term thrombophlebitis is shortened to "phlebitis.") There are two types of thrombophlebitis:

1. Superficial venous thrombophlebitis (SVT) occurs when a blood clot and inflammation develop in a small vein near the surface of the skin. SVT is usually self-limiting.
2. Deep vein thrombophlebitis (DVT) occurs when a blood clot and inflammation are deep inside a vein in a leg, the lower abdomen (pelvis), or, rarely, the arm. In deep vein phlebitis, a blood clot may break away and travel to the lungs, where it may block a blood vessel (a condition known as pulmonary embolus).

Transilluminated powered phlebectomy (TIPP) – In October 2003 the FDA approved the Trivex™ System (Smith & Nephew, Inc., Andover, MA) for the resection and ablation of varicose veins. This procedure involves the use of two devices: an illuminator and a resector. The illuminator is introduced via a groin incision underneath the varicose vein so that the vein becomes visible. The resector is then inserted beneath the illuminated vein. The tip of the resector is advanced slowly, ablating the varicose vein and aspirating the fragments. TIPP has been proposed as an alternative to stab phlebectomy. The scope and quality of the clinical studies of this treatment for varicose veins are insufficient to conduct an evidence-based assessment of safety and efficacy, therefore TIPP is considered experimental/investigational.

Varicose veins – varicose veins are bulging (≥ 4 millimeters in diameter), tortuous veins of the superficial venous system. The cause of primary varicose veins is incompetent valves in the superficial venous system. Varicose veins, also called varicosities, are most common in the legs, although they can be found in other parts of the body. The term "varicose veins" does not apply to reticular veins or telangiectasias.⁴

⁴ Reticular veins are visible, dilated, bluish, subdermal, nonpalpable veins 1-3 mm. Reticular veins are often called "feeder veins" because they give rise to telangiectasias. Telangiectasias are very small (1 mm) dilated blood vessels usually found in clusters near the surface of the skin. Telangiectasias are commonly called spider veins. Reticular veins and spider veins are not associated with symptoms that significantly impair mobility or interfere with activities of daily living and their treatment is considered cosmetic.



Venous incompetence (reflux) – backward blood flow in a superficial vein due to a defective or damaged valve which results in high venous pressure. When there is sustained superficial venous hypertension, the vein eventually becomes varicose or distorted, distended and tortuous.

Policy

Preauthorization by FCHP is required. Photographs of the affected limb(s) may be required at FCHP's discretion.

FCHP will consider surgical ligation with or without stripping, endovenous radiofrequency therapy (VNUS Closure®), or endovenous laser therapy for the treatment of varicose greater or lesser saphenous veins when documentation of all the following is submitted:

1. History and physical exam findings consistent with varicose veins caused by incompetence/reflux of the superficial venous system.
2. Incompetence/reflux of the greater or lesser saphenous vein has been demonstrated by Doppler auscultation or duplex ultrasound and the varicose vein to be treated is ≥ 4 millimeters in diameter.
3. A minimum three-month trial of conservative therapy, which has included the use of properly fitted gradient compression stockings⁵ (unless medically contraindicated), has failed to relieve symptoms and/or complications directly attributable to varicose veins of the lower extremities.
4. Symptoms directly attributable to varicose veins (such as severe and persistent pain) significantly impair mobility or interfere with activities of daily living or one of the following complications of varicose veins exists:
 - a. Recurrent (more than 2) episodes of superficial venous thrombophlebitis where an incompetent superficial vein is a significant contributing factor.
 - b. Venous stasis ulceration where an incompetent superficial vein is a significant contributing factor.
 - c. Severe stasis dermatitis or lipodermatosclerosis where an incompetent superficial vein is a significant contributing factor.
 - d. Rupture and external hemorrhage of a varicose vein.

FCHP will consider adjunctive compressive sclerotherapy or stab phlebectomy for the treatment of varicose saphenous tributaries when performed at the same time as or subsequent to covered ligation with or without stripping, endovenous radiofrequency therapy, or endovenous laser therapy of the greater or lesser saphenous vein.

- Up to 3 sessions of compressive sclerotherapy per leg may be authorized (CPT codes 36470 or 36471) over a period of not more than six months following the primary procedure (i.e., saphenous ligation and stripping, EVRT or EVLT).

⁵ The most effective treatment of chronic venous insufficiency and venous ulceration is aggressive compression therapy (minimum 20 mm Hg). The disadvantages associated with compression therapy include difficulty in putting them on, especially in patients who have severe arthritis, or who are elderly or obese. Continued use of compression stockings after ulcer healing has been found to lower the incidence of recurrent venous ulceration. (Weingarten 2001)



- One session of stab phlebectomy per leg may be authorized (CPT codes 37765 or 37766), not more than six months following the primary procedure.

FCHP's Technology Assessment Committee has reviewed ligation of perforator veins (open and endoscopic) and has determined that these procedures do not meet FCHP's Technology Assessment Criteria. However, FCHP will consider coverage for ligation of perforator veins, Linton procedure (CPT code 37760, 37761) or SEPS (CPT code 37500) for Fallon Senior Plan™ members and MassHealth members in accordance with contractual obligations, when documentation of the following is submitted:

1. Duplex ultrasound has demonstrated perforator vein incompetence/reflux.
2. Venous ulceration persists despite previous treatment for incompetence of the greater saphenous vein by ligation and stripping, endovenous radiofrequency therapy, or endovenous laser therapy.

Exclusions

1. Surgical treatment of varicose veins is contraindicated in patients who cannot remain active enough to reduce the risk of post-operative deep vein thrombosis.
2. Surgical treatment of varicose veins is contraindicated during pregnancy because many varicose veins spontaneously regress after pregnancy.
3. Compressive sclerotherapy for the treatment of valvular incompetence/reflux of the saphenofemoral junction or saphenopopliteal junction or for the treatment of varicose saphenous veins is considered experimental/investigational. Compressive sclerotherapy for the treatment of incompetent perforator veins is considered experimental/investigational. Compressive sclerotherapy of varicose saphenous tributaries without concomitant or prior ligation of the greater or lesser saphenous veins is considered experimental/investigational.
4. Non-compressive sclerotherapy is not effective in producing long-term obliteration of the incompetent vein and is considered experimental/investigational for all indications.
5. Other protocols for delivering sclerotherapy, including but not limited to the COMPASS protocol are considered experimental/investigational. (COMPASS is an acronym for comprehensive objective mapping, precise image-guided injection, anti-reflux positioning, and sequential sclerotherapy.)
6. Ultrasound guidance (CPT code 76942, echosclerotherapy, HCPCS code S2202) is not medically necessary to deliver sclerotherapy.
7. Stab phlebectomy for the treatment of valvular incompetence/reflux of the saphenofemoral junction or saphenopopliteal junction or for the treatment of varicose saphenous veins is considered experimental/investigational. Stab phlebectomy for the treatment of incompetent perforator veins is considered experimental/investigational. Stab phlebectomy of varicose saphenous tributaries or perforators without concomitant or prior ligation of the greater or lesser saphenous veins is considered experimental/investigational.
8. Transilluminated powered phlebectomy (Trivex™ System, Smith & Nephew, Inc., Andover, MA) is considered experimental/investigational. The scope and quality of the clinical studies of this treatment for varicose veins are insufficient to conduct an



evidence-based assessment of safety and efficacy. There is no specific CPT/HCPCS code for this procedure. The correct CPT code to report this procedure is unlisted procedure code 37799.

9. Endovenous radiofrequency therapy for the treatment of any vein other than the greater or lesser saphenous veins, including varicose saphenous tributaries and perforator veins is considered experimental/investigational.
10. Endovenous laser therapy for the treatment of any vein other than the greater or lesser saphenous veins, including varicose saphenous tributaries and perforator veins is considered experimental/investigational.
11. Open ligation of perforator veins (e.g., Linton procedure), CPT codes 37760, 37761, for any indication including chronic venous ulcers, is considered experimental/investigational.
12. Endoscopic ligation of perforator veins (i.e., SEPS, CPT code 37500) for any indication, including chronic venous ulcers, is considered experimental/investigational.
13. Treatment for telangiectasias (spider veins) or reticular veins (CPT codes 36468 and 36469) is not covered.

Codes

Codes	Number	Description
CPT	36470	Injection of sclerosing solution; single vein
	36471	Multiple veins, same leg
	36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
	36476	Second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (Use 36476 in conjunction with 36475)
	36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
	36479	Second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (Use 36479 in conjunction with 36478)
	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



Codes	Number	Description
		graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
	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
	37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
	37766	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), one leg

* CPT codes 37500, 37760, and 37761 are covered for Fallon Senior Plan™ and MassHealth members only.

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Committee review dates:

Technology Assessment Subcommittee: 03/24/09, 05/07/09, 09/22/09, 02/23/10

Technology Assessment Committee: 11/04/03, 02/24/04, 09/28/04, 06/10/09, 09/30/09, 06/02/10

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.