



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Varicose Vein Treatments

Table of Contents

Coverage Policy	1
General Background	3
Coding/Billing Information	10
References	11
Policy History.....	18

Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

Coverage for treatment of varicose veins is dependent on benefit plan language and may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit. Under many benefit plans, treatment of varicose veins is not covered when provided solely for the purpose of altering appearance or self-esteem or to treat psychological symptomatology or psychosocial complaints related to one's appearance. In addition, some benefit plans specifically exclude coverage for the treatment of varicose veins. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage is available for the treatment of varicose veins, the following conditions of coverage apply.

CIGNA covers ambulatory phlebectomy, ligation and excision, radiofrequency ablation (RFA) or endovenous laser therapy (EVLT), as medically necessary for treatment of symptomatic saphenous varicose veins when there is documentation of ANY ONE of the following indications:

- leg ulceration(s) that is due to saphenous vein insufficiency and is refractory to conservative management
- recurrent bleeding from the saphenous vein or other varicosities
- history of a significant episode of bleeding
- documentation of **ALL** of the following:

- Doppler evaluation and/or Duplex ultrasonography of the symptomatic varicose vein demonstrating incompetence/reflux and documented vessel size ≥ 3 mm
- failure of conservative management (e.g., leg elevation, compression therapy) for six consecutive months
- at least **ONE** of the following associated clinical conditions in the affected leg:
 - pain resulting in impaired mobility or inability to perform activities of daily living
 - recurrent phlebitis or thrombophlebitis
 - refractory dependent edema
 - persistent stasis dermatitis
 - chronic cellulitis

CIGNA covers sclerotherapy as medically necessary, for the treatment of symptomatic saphenous varicose veins, performed with or without one of the other invasive varicose vein treatment listed above, for ANY the following indications:

- As an **INITIAL** treatment session, when there is documentation of **ANY** of the following:
 - leg ulceration(s) that is due to saphenous vein insufficiency and is refractory to conservative management
 - recurrent bleeding from the saphenous vein or other varicosities
 - history of a significant episode of bleeding
 - documentation of **ALL** of the following:
 - Doppler evaluation and/or Duplex ultrasonography of the symptomatic varicose vein demonstrating incompetence/reflux and documented vessel size ≥ 3 mm
 - failure of conservative management (e.g., leg elevation, compression therapy) for six consecutive months
 - at least **ONE** of the following associated clinical conditions in the affected leg:
 - pain resulting in impaired mobility or inability to perform activities of daily living
 - recurrent phlebitis or thrombophlebitis
 - refractory dependent edema
 - persistent stasis dermatitis
 - chronic cellulitis
- As a **REPEAT** treatment (up to **TWO** sessions per affected leg) when **BOTH** of the following criteria have been met:
 - persistent symptomatic varicosities remain following a medically necessary primary invasive varicose vein treatment (i.e., sclerotherapy, excision and ligation, ambulatory phlebectomy, RFA, EVLT)
 - less than 12 months time has elapsed from the primary invasive varicose vein treatment
- As treatment of symptomatic varicose tributaries, when performed in combination with a medically necessary listed varicose vein treatment

CIGNA covers subfascial endoscopic perforator surgery (SEPS) as medically necessary when ALL of the following medical necessity criteria are met:

- There is documented Doppler evaluation and/or Duplex ultrasonography of the incompetent perforator vein and it is located on the medial aspect of the calf being treated.
- There is documented failure of conservative management (e.g., leg elevation, compression therapy) for six months.
- There is documentation of at least **ONE** of the following conditions:
 - venous stasis dermatitis/ulceration
 - chronic venous insufficiency

CIGNA does not cover EITHER of the following varicose vein treatments because each is considered cosmetic in nature and not medically necessary:

- treatment of telangiectasis or varicose veins that are less than 3 mm in diameter by any method

- intense pulsed-light source (photothermal sclerosis)

CIGNA does not cover any of the following varicose vein treatments, because they are considered experimental, investigational or unproven (this list may not be all-inclusive):

- non-compressive sclerotherapy
- transdermal laser therapy
- transilluminated powered phlebectomy (TIPP, TriVex™)
- sclerotherapy or echosclerotherapy when performed for ANY of the following medical conditions:
 - as a sole treatment of varicose tributaries without associated occlusion of the saphenofemoral or saphenopopliteal junction
 - incompetence that is isolated to the perforator veins
 - as a sole treatment for reflux that occurs at the saphenous vein junction
- SEPS for the treatment of venous insufficiency as a result of post-thrombotic syndrome

General Background

Varicose veins result from weakening or incompetence of a one-way valve, leading to a retrograde flow or reflux of blood in the vessel. The varicosity may vary in size from 3–10 mm on average. Symptoms that have been reported as associated with varicose veins of the lower extremities include pain, cramping, aching, burning, throbbing, swelling and the feeling of heaviness or fatigue in the leg. Typically, symptoms are exacerbated by standing and warm weather (Hamper, et al., 2007). Saphenous varicose veins can ultimately result in intractable ulcerations and recurrent bleeding. Patients with larger varicosities (e.g., varicose veins greater than 3 mm in diameter) are more prone to thrombophlebitis and other complications than those with smaller varicosities. Chronic cellulitis may also be associated with varicosities.

The venous system of the lower extremities is separated into two main systems: the deep venous and the superficial venous systems. The two systems are connected by perforator veins. The deep venous system comprises the popliteal and femoral veins; the superficial venous system comprises the greater saphenous and lesser saphenous veins. The GSV generally measures 3–4 mm in diameter in the upper thigh. Approximately 60% of patients who have varicosities have reflux in the GSV (Hamper, et al., 2007). The lesser saphenous vein is not usually larger than 3 mm in diameter, and connects with the deep veins at the saphenopopliteal junction in the knee area.

Telangiectasis are permanently dilated blood vessels, also called spider veins, that create fine red or blue lines on the skin. They are similar to varicose veins, but are limited to the dermis and are not usually more than 3 mm in diameter. They are not typically associated with symptoms, and treatment is generally considered cosmetic in nature and not medically necessary.

Varicose veins may develop during pregnancy, although surgery or sclerotherapy is not typically performed, as the treatment is not medically necessary. Most varicosities will spontaneously resolve within 4–6 months after delivery.

Varicose veins of the upper extremity are rare; still there are a few reports in the published, peer-reviewed medical literature dealing with the management of upper extremity varicosities (Welch and Villavicencio, 1994; Duffy, et al., 1999; Lee, 2002; Bowes and Goldman, 2002). However, authors have reported successful outcomes utilizing methods of treatment similar to lower extremity varicosities (e.g., sclerotherapy, ligation and stripping, phlebectomy).

Various ultrasound technologies are used in conjunction with other noninvasive testing to determine the physiological characteristics of the varicosities, as physical exam alone may not be reliable. Duplex ultrasound, Doppler ultrasound and plethysmography may all be used to diagnose varicose veins. In most cases, once the initial vein mapping is performed, it is not essential that follow-up scanning be done for subsequent sclerotherapy sessions. It has not been demonstrated in the published medical literature that repeat Duplex or Doppler studies are essential for the successful outcome of the procedure when performed as part of a series of sclerotherapy sessions. Also, routine use of any of these tools in the absence of venous symptoms or clinical

evidence of venous insufficiency or reflux is not considered a medical necessity. Photographs or diagrams are helpful in assessing the size and extent of the varicosities.

The CEAP classification is a method commonly used to document the severity of chronic venous disease and is based on clinical presentation (C), etiology (E), anatomy (A), and pathophysiology (P) (See Table 1).

Table 1: CEAP Classification

Class	Definition
C - Clinical Classification , supplemented by "A" for asymptomatic and "S" for symptomatic presentation	Class 0: No visible or palpable signs of venous disease Class 1: Telangiectasia, reticular veins, malleolar flare Class 2: Varicose veins Class 3: Edema without skin changes Class 4: Skin changes ascribed to venous disease (e.g., pigmentation, venous eczema, lipodermatosclerosis) Class 5: Skin changes as defined above with healed ulceration Class 6: Skin changes as defined above with active ulceration
E - Etiology	Congenital, Primary, Secondary, No venous disease
A - Anatomy	Superficial, Perforator, Deep, No venous location
P - Pathophysiology	Reflux or obstruction (alone or combined); Basic or Advanced

Classification of disease starts with an initial assessment and may not be entirely completed until after surgery and histopathologic assessment. As a result, it is recommended that CEAP classification value be followed by the date of examination. Venous disease can be reclassified at any given time. It is also recommended that the level of investigation be included, with Level I representing the office visit, Level II representing noninvasive venous laboratory testing and Level III representing invasive assessment and more complex imaging studies.

Various methods of treatment, consisting of nonsurgical (conventional) and surgical approaches, have been investigated. Conservative medical practices that may be used in the management of varicose veins include leg elevation, analgesia for symptom relief and avoidance of prolonged periods of standing. Compression therapy, the use of custom-fit compression stockings with pressure gradients, is often attempted prior to stripping, ligation, sclerotherapy or other, more invasive procedures. When conservative measures fail, treatment options rely on identifying and correcting the site of reflux and on redirecting the flow of blood through veins with properly functioning valves. No single method of treatment is universally employed in the literature; the intervention selected is generally dependent upon the competency of deep and perforating veins, and the site and degree of reflux. Surgery is commonly used to treat mainstem varicose veins. Many patients require a combination of techniques to correct venous insufficiency, most of which can be performed in a single treatment session (e.g., EVLT, RFA, sclerotherapy, ligation/stripping). While staging of procedures is generally not required, repeat sclerotherapy sessions may be required for an unsuccessful vein occlusion.

Nonsurgical Approaches

Sclerotherapy: Sclerotherapy is a nonsurgical procedure used to eradicate varicose veins of the superficial venous system (greater and lesser saphenous veins). When reflux is present at the junction, sclerotherapy should be performed in addition to surgical ligation and division of the junction, promoting control of the point of reflux. Injection of the vein at its junction and of the incompetent perforating veins has been proposed as an alternative to ligation; however, the scientific literature does not support the efficacy of this procedure. Sclerotherapy has not been shown to be effective as a sole treatment of larger incompetent veins and is often used with other approaches to treat significant varicosities.

During sclerotherapy, the abnormal vein is injected with a sclerosing agent that irritates the lining of the vein, causing it to thrombose and stenose, ultimately leading to resorption into the surrounding tissue. Foam sclerotherapy, which involves the use of a sclerosing solution that has been forcibly mixed with air or gas (e.g., carbon dioxide) to create a foam agent, is often used in large-diameter vessels. According to the American Academy of Cosmetic Surgery (AACS), guidelines for sclerotherapy, foam sclerotherapy may achieve more efficient sclerosant-endothelial contact, lessening the number of treatment sessions necessary and offering more efficient results than other forms of sclerotherapy (AACS, 2003). Authors generally agree foam

sclerotherapy is a safe and effective method of treating varicose veins (Rabe, et al., 2004; Wright, et al., 2006; Kendler, et al., 2007; Uurto, et al., 2007; Subramonia and Lees, 2007; Jia, et al., 2007).

Echosclerotherapy, also referred to as ultrasound-guided sclerotherapy, employs real-time ultrasound during the sclerotherapy procedure to help locate deep or inaccessible sites. Echosclerotherapy is also performed in conjunction with injection of foam sclerosants. As with sclerotherapy in general, the need for repeat treatment sessions when utilizing this method of treatment has been reported in the literature (Barrett, et al., 2004; Darke, and Baker, 2006). Although it has been investigated as an alternative to traditional saphenous vein ligation and stripping (Min, Navarro, 2000; Bountouroglou, et al., 2006), there is insufficient evidence in the medical literature to support safety, efficacy and improvement in long-term clinical outcomes when used for this indication. Evidence consists mainly of case series with few comparative trials. The National Institute for Clinical Excellence (NICE), an organization within the United Kingdom which provides healthcare guidance, issued a procedural guidance for ultrasound-guided foam sclerotherapy as a treatment for varicose veins and concluded that the current evidence shows that it is efficacious in the short term, although evidence for long-term efficacy is limited (NICE, 2007). Overall, little evidence exists in the form of large, randomized, controlled clinical trials to support the safety, efficacy and added benefit of echosclerotherapy in managing varicose veins.

There is no consensus in the published scientific literature regarding the optimal number of sclerotherapy treatments required to reduce the symptoms associated with varicose veins and the number treatments needed to resolve symptoms varies among patients. The AACS (2003) reports sclerotherapy is the treatment of choice for varicose veins that are 2–4 mm in diameter and large areas of veins can usually be eradicated using two to three treatment sessions. Vessels 4–6 mm in diameter may be treated by sclerotherapy or ambulatory phlebectomy. Weiss et al. (1992) reported that, in some cases, four or more separate sclerosing treatments may be necessary to completely eradicate groups of varicose veins; such a course of treatment might include 1–4 treatments for a region of the leg or three treatments for a larger vein coursing several regions of the leg.

The primary aims of sclerotherapy are to prevent complications of varicose disease and relieve symptoms; cosmetic improvement in the leg's appearance is an added benefit. Treatment provided solely for cosmetic purposes is not considered a medical necessity. Sclerotherapy is a palliative solution and cannot prevent the formation of new varicosities. New varicosities may form, either because of an underlying illness or condition, or, in some cases, because of a genetic predisposition.

In compressive sclerotherapy, the most commonly performed method of sclerotherapy, compressive dressings are applied after injection of the sclerosing agent, while the limb is elevated and the vein is drained. External compression and internal decompression (e.g., walking) stimulates fibrosis, which contributes to obliteration of the entire vein wall (Labas, et al., 2003). Non-compressive sclerotherapy involves injecting a sclerosant into the non-elevated (blood-filled) vein without applying a compressive dressing. This method of therapy has not been shown to be effective in producing long-term obliteration of the incompetent veins.

Sclerosing agents currently approved by the U.S. Food and Drug Administration (FDA) to treat varicose veins of the lower extremities include sodium tetradecyl sulfate (Sotradecol[®]) and morrhuate sodium (Scleromate[™] morrhuate sodium). There is no evidence-based consensus on the optimal type, dosage or concentration of the sclerosing agent.

Transdermal Light/Laser Therapy: Photothermal sclerosis, such as PhotoDerm[®] Vasculite[™], is also referred to as intense pulsed-light source. Used as an alternative to or to complement sclerotherapy in treating small varicose veins and telangiectases (spider veins), this type of light therapy utilizes small pulses of light energy which travel through the skin, are absorbed by the blood, are then changed to heat and ultimately destroy the vein. Successful treatment requires adequate heating of the veins, and several treatments are usually required for optimal results.

Transcutaneous laser ablation, also known as transdermal laser treatment, is a type of laser therapy similar to light therapy that involves the use of a laser to treat small varicose and spider veins. Small laser pulses are delivered to the vein, causing heat, which will ultimately lead to destruction of the vein. This modality is not generally useful as a primary treatment of spider veins of the lower extremity; instead, it is employed to treat superficial vessels on the face. The treatment may result in superficial skin burns and permanent pigmentation changes.

Laser or light therapy has been indicated for the treatment of telangiectasis and cutaneous vascular lesions (Raulin, et al., 1997; Angermeier, 1999). However, evidence in the published scientific literature indicates that transdermal light/laser therapy has not been shown to be as effective for the lower extremities as for facial telangiectasis and smaller varicosities (Weiss, Dover, 2002). The vessels in the lower extremities are located deeper and have thicker surrounding tissue. Deeper vessels require a longer wavelength and longer pulse duration to damage the vessel effectively. Additionally, because spider veins and varicosities smaller than 3 mm do not usually cause symptoms, they are considered cosmetic; hence, treatment for them is not medically necessary.

Surgical Approaches

Ligation, Division and/or Excision: The traditional surgical treatment of saphenous-vein varicosities consists of surgical ligation and stripping. The saphenous vein and other smaller veins are exposed through an incision in the groin, where the veins are then ligated (i.e., tied off) with sutures. A second incision is made just below the knee or at the ankle to allow access for stripping the vein. When both ends of the vein are free, a wire-like instrument is threaded through the vein, extending up to the second incision in the groin area. The vein is then pulled (i.e., stripped) and removed from the leg. Removal of the superficial symptomatic vein restores venous circulation and provides relief of symptoms. Operative excision of the vein is most often reserved for large varicosities and for those located in the medial or anterior thigh.

Ambulatory Phlebectomy/Stab Phlebectomy: Ambulatory phlebectomy is also widely accepted as an alternative to sclerotherapy performed alone or in addition to stripping and ligation for the treatment of surface varicose veins. It is also referred to as miniphlebectomy or stab avulsion. In ambulatory phlebectomy, multiple small incisions are made, and the varicose veins are grasped with a small hook or hemostat. They are then clamped, divided and finally extracted. The entire varicosity can be extracted with multiple small incisions. Compression therapy has been shown to reduce bleeding and improve resorption following this method of treatment and is thus widely used for that purpose.

Transilluminated Powered Phlebectomy (TIPP): TIPP, which is similar to ambulatory phlebectomy, is another minimally invasive alternative to standard surgery for the treatment of symptomatic varicosities. Also known as the TriVex™ (Smith & Nephew Inc., Andover, MA) procedure, TIPP involves endoscopic resection and ablation of the superficial varicosity.

Subcutaneous transillumination and tumescent anesthesia help visualize and locate the varicosity, while subcutaneous vein ablation is performed using a powered resector to obliterate the vein. Tumescent anesthesia involves the infusion of large amounts of saline and lidocaine to reduce hemorrhage and of epinephrine to delay absorption of the lidocaine. During this procedure, the veins are marked with a marker, and a bright light is introduced into the leg through a small incision (2–3 cm) to enhance visualization of the veins. The power vein resector is then inserted to cut and remove the vein through suction.

Proponents of this method suggest that the illuminating light allows quicker and more accurate removal of the vein, leading to a more effective yet less traumatic procedure. TIPP is intended for patients who are suitable candidates for conventional ambulatory phlebectomy, and may also be used as an adjunctive method to other varicose vein treatments (e.g., ligation and stripping).

The individual components of the TriVex system were approved for use by the FDA in 1999, however since that time, several other illumination and powered-resection devices have been approved and are available for use.

Evidence evaluating TIPP for the treatment of varicose veins is primarily in the form of published reviews, comparative trials (few involving randomized groups) and both retrospective and prospective case series involving small populations and evaluating short-term outcomes (Franz and Knapp, 2008; Passman, et al., 2007; Scavee, 2006; Chetter, et al., 2006; Aremu, et al., 2004; Shamiyeh, et al., 2003; Scavee, et al., 2003; Chesire, et al., 2002; Spitz, et al., 2000). Two controlled studies specifically compared TIPP to phlebectomy (Aremu, et al., 2004; Scavee, et al., 2003), although neither of these studies were blinded. In addition, the outcomes measured in most studies include operative time, number of incisions, complications, and cosmetic satisfaction with few patient-oriented outcomes being reported. Generally, the results of these studies demonstrate that TIPP is associated with fewer incisions (Luebke, et al., 2008; Chetter, et al., 2006; Aremu, et al., 2004; Shamiyeh, et al., 2003; Scavee, et al., 2003; Spitz, et al., 2000). Operative time varies among authors and with experience. Despite reports in the published literature of a reduced number of incisions, an increase in

bruising, postoperative pain and decreased quality of life during the early postoperative period has been reported. Moreover, it has been reported in the literature that technical complications may be associated with inexperience. The published, peer-reviewed, scientific literature does not lead to strong conclusions that TIPP results in clinical outcomes (e.g., improved pain, less varicose vein recurrence) that are as good as treatment with standard conventional methods (i.e., hook phlebectomy). Furthermore, long-term safety and efficacy of the procedure has not been adequately demonstrated.

ECRI Institute published an emerging technology report (2008) evaluating TIPP for treatment of varicose veins. According to the report, the available data are promising for demonstrating the safety and efficacy of TIPP relative to hook phlebectomy and stab avulsion to treat varicose veins. However, ECRI also reported that the available evidence is inadequate to draw firm conclusions about its relative short- and long-term effectiveness, or its purported advantages over existing methods in terms of complications, operating time, pain, varicose vein recurrence, and cosmetic outcomes.

In 2004 NICE issued an Interventional Procedure Guidance for TIPP. The advisory committee indicated that, although the evidence suggested that the procedure is effective, the data are too limited to be conclusive. In addition, there are no long-term follow-up data (NICE, 2004a).

Endoluminal Radiofrequency Ablation (RFA): Radiofrequency ablation, also known as endovascular occlusion, is a treatment for symptomatic varicose veins that involves delivery of controlled radiofrequency (RF) energy through a catheter inserted into the affected vein. The heat generated by the RF energy causes the vein to contract and become occluded. The treatment is intended as a minimally-invasive alternative to standard surgery for symptomatic varicosities mainly of the greater saphenous vein. RFA has also been investigated as a treatment of incompetent perforator veins (Singh and Sura, 2008; Uchino, 2007; Roth, et al. 2007; Peden and Lumsden, 2007; Gibson, et al, 2007a), however data supporting safety and efficacy is limited and further clinical studies are needed to support widespread use for this indication.

RFA using the VNUS® Closure System is a three-part procedure that begins with imaging of the greater saphenous vein, followed by the administration of anesthesia between the vein and the skin. Next, the closure catheter is inserted into the vein, and electrodes are implanted in the venous wall. RF energy is released until the venous wall temperature reaches approximately 85 °C. The temperature is maintained for 30 seconds; then the catheter is slowly retracted, causing the entire length of the vein to collapse on it. If the assessment following treatment indicates any areas of steady flow, those areas may be re-treated, as long as the catheter is reinserted immediately (Chandler, et al., 2000; VNUS, 2000). Possible complications include vessel perforation, pulmonary embolism, phlebitis, hematoma, infection, paresthesia and skin burns (Chandler, et al., 2000; Goldman, 2000; VNUS, 2000).

Evidence in the peer-reviewed published scientific literature supports the safety and efficacy of RFA for the treatment of symptomatic varicose veins. Most early studies were small case series with short-term follow-up (Ogawa, et al., 2005; Goldman, 2002; Weiss, 2002; Goldman, 2000), and only two included direct comparisons with standard treatments (Lurie, 2003; Rautio, 2002). RFA has been shown in a prospective nonrandomized trial to be more effective than foam sclerotherapy for closure of the GSV at one year follow-up (Gonzalez-Zeh, et al., 2008). More recently, RFA has been compared to procedures such as EVLT (Almeida, et al., 2009) and has been evaluated with and without ligation of the saphenofemoral junction (Disselhoff, et al, 2008) in randomized controlled trials. Compared to EVLT, at one month following treatment, RFA was significantly superior for measures evaluating post procedure recovery and quality of life parameters. When performed with and without ligation, at two years post procedure, there was no difference in outcomes (recurrence, degree of ablation and venous clinical severity scores) from adding the ligation procedure. The short-term results of several other studies have demonstrated that the procedure effectively occludes incompetent veins following RFA treatment (Merchant and Pichot, 2006; Hinchliffe et al., 2006; Welch, 2006; Lurie, et al., 2005). Long-term occlusion rates were reported by Merchant and Pichot (2005). This group of authors collected data to evaluate the long-term treatment outcomes of endovascular RFA and to determine risk factors that affect treatment efficacy. In their study, the authors reported on five-year follow-up results of 1006 patients (1222 limbs) treated with radiofrequency obliteration (RFO). Immediate vein occlusion was achieved in 96.8% of limbs confirmed by Duplex ultrasound examination one week or less after the procedure. The vein occlusion rate at six months, one, two, three, four and five years was 89.2%, 87.1%, 88.2%, 83.5%, 84.9% and 87.2%, respectively. The absence of reflux rate was 91.3%, 88.2%, 88.2%, 88.0%, 86.6% and 83.8%, respectively. Over a five-year follow-up period, anatomical failure was identified in 185 limbs, 19 of which received reintervention. RFA also

resulted in improved pain and less bruising compared to ligation and stripping in some studies (Hinchliffe, et al., 2006). Early studies, in addition to the more recent studies cited above, do support the safety and efficacy of RFA and, RFA for the treatment of symptomatic saphenous varicosities, is considered an appropriate alternative to conventional procedures.

ECRI Institute published an evidence report evaluating endovenous radio-frequency ablation (VNUS) for the treatment of varicose veins (ECRI, 2006). After reviewing the available evidence ECRI concluded that RFA offered a less invasive alternative to surgical stripping and ligation for patients with symptomatic varicose veins. ECRI noted that patients returned to work sooner and suffered less pain and fewer infections. Nonetheless, the benefits of RFA compared to surgery were supported on follow-up periods that were short term and consisted of a few days to one month posttreatment.

In 2003 NICE issued an Interventional Procedure Guidance for RFA and reported that safety and efficacy appeared adequate to support use of the procedure as an alternative to sapheno-femoral ligation and stripping.

Endovenous Laser Therapy (EVLT): EVLT, also commonly referred to as endovenous laser ablation of the saphenous vein (ELAS), is a treatment alternative to surgical stripping of the greater saphenous vein. It is performed by threading a catheter through the greater saphenous vein and inserting an optical fiber through the catheter. The optical fiber is then connected to a surgical laser, allowing high-intensity laser light to induce photocoagulation of blood and occlusion of the vein. As the catheter is withdrawn, light pulses can be repeated at regular intervals to prevent any further blood flow through the vein. The procedure is typically used to treat larger varicose veins since catheters cannot be easily passed through a tortuous vein or a vein with several turns or bends. Small dilated branches that persist after EVLT may require additional treatments with sclerotherapy or phlebectomy (Radiological Society of North America, 2009).

The FDA has granted several approvals for ablative technologies, including: Diomed 810nm laser (Diomed, Inc.); Dornier diode laser systems (Dornier MedTech, Kennesaw, GA); Biolitec, Inc. (East Longmeadow, MA); Angiodynamics, Inc. and Vascular Solutions Inc. (Minneapolis, MN).

Evidence in the medical literature evaluating EVLT for the treatment of saphenous vein reflux consists of both retrospective and prospective case series, published reviews, and randomized controlled clinical trials (Huisman, et al., 2009; Nijsten, et al., 2009; Kalteis, et al., 2008; Darwood, et al., 2008; Desmyttrere, et al., 2007; Sharif, et al., 2007; Gibson, et al., 2007; Rasmussen, et al., 2007; Ravi, et al., 2006; Puggioni, et al., 2006; Min, et al., 2003; Ho, 2003; Chang and Chua, 2002; Proebstle, et al., 2002; Navarro and Min, 2001). There is a growing body of evidence to suggest that more minimally invasive techniques, which include both RFA and EVLT, are beneficial in the treatment of varicose veins when used alone (van den Bos, et al, 2009; Ravi et al., 2006; Sadick, 2005; Beale, et al., 2004; Teruya and Ballard, 2004; Elias and Frasier, 2004). Sample size and follow-up periods vary widely across studies; follow-up periods typically range at least one to four years on average. In some of the studies, duplex ultrasound demonstrated successful vein occlusion after initial treatment and throughout the various follow-up periods (Kalteis, et al., 2008; Gibson, et al., 2007; Desmyttrere, et al., 2007; Ravi, et al., 2006; Puggioni, et al., 2006; Min, et al., 2003). Some of the measured outcomes, such as complication rates, return to work, patient satisfaction and quality of scores, are mixed—some authors report improvement compared to traditional surgical methods while others have not. Success rates and recurrence rates have been promising with several studies supporting clinical efficacy. Van den Bos, et al. (2009) published the results of a meta-analysis demonstrating success rates of 78%, 84%, and 95% for ultrasound guided sclerotherapy, RFA and EVLT respectively, after three years. Min and associates (2003) reported a recurrence rate of less than 7% at a two-year follow-up, although the study had a significant number of patients lost to follow-up. Nonetheless, the authors noted their results were comparable or superior to those reported for other treatment options, including surgery, ultrasound-guided sclerotherapy, and radiofrequency ablation. Puggioni et al. (2006) concluded from a retrospective review that the overall success rate of endovenous ablation techniques for occluding the incompetent greater saphenous vein was 94% at one month, although the EVLT group developed more frequent postoperative complications compared to an RFA group. Ravi et al., (2006) reported that no GSV recanalization was found at three years post EVLT and that no saphenous vein could be identified in 82.5% of limbs in their study group. Closure rates at one month, one year, two year, three year and four year follow-up were reported by Desmyttrere, et al. (2007) as follows: 98.4%, 96.8%, 97.8%, 99.3% and 97.1%, respectively. Overall, much of the evidence available suggests that endovenous closure techniques are as good as or superior to conventional ligation and stripping of the greater saphenous vein.

ECRI Institute published an evidence report evaluating laser ablation of the greater saphenous vein (ECRI, 2004) and concluded that based on the available evidence endovenous laser ablation effectively occluded the greater saphenous vein for up to one year following treatment, complications were mild, and the retreatment rates were low. Data on quality of life was lacking.

NICE issued an Interventional Procedure Guidance for EVLT of the long saphenous vein. The guidance committee accepts the evidence on safety and efficacy as adequate to support the use of this procedure (NICE, 2004b). The evidence for efficacy was based on five case series with a mean follow-up of one to 17 months. Saphenous vein closure rates were between 90% and 100%. The authors noted that although procedure seems effective in occluding the vein, few studies have reported on patient-oriented outcomes such as improvement in symptoms.

A position statement issued by the Society of Interventional Radiology in December 2003 calls the use of endovenous ablation therapy, performed with either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins. The statement reports that the success rate for vein ablation ranges from 90–95% and that long-term results demonstrate recurrence rates of less than 7% at two-year follow-up. Lower rates of recurrence may be the result of the fact that imaging guidance enhances the ability to target and treat only the abnormal, incompetent venous segments. The society recommends using Duplex ultrasound prior to the procedure to map the necessary anatomy of the venous system, during the procedure for correct catheter placement and anesthetic delivery, and as necessary for follow-up. Currently, the 2003 position statement remains unchanged.

Subfascial Endoscopic Perforator Surgery (SEPS): SEPS is a minimally invasive procedure for treating chronic venous insufficiency, in which incompetent perforating veins located in the calf are believed to be a contributing factor. Incompetent perforator veins result in pooling of blood in the lower extremity area, leading to vein enlargement, pain, swelling, skin discoloration and ulcers, and typically lead to chronic venous insufficiency.

An alternative to open subfascial perforator vein surgery (i.e., the Linton procedure), SEPS is recommended for patients in whom conservative measures have failed to treat chronic venous insufficiency and ulceration. The Linton procedure has been associated with a high incidence of postoperative wound healing complications (Townsend, 2004). Direct visualization through endoscopy has been suggested as a more desirable approach than the Linton technique. During SEPS, an endoscope is inserted in an incision located away from the ulcer site, and a balloon dissection is performed. The veins are ligated with clips and subsequently dissected, reducing pressure. Authors claim that stasis ulcer healing rates and maintenance of healing at five years after SEPS are 90% for patients with normally functioning deep venous systems and 75–80% for patients with deep venous insufficiencies (Elias, Frazier, 2004; Gloviczki, et al., 1999). The overall goal of SEPS in treating chronic venous ulcers is to interrupt the incompetent perforating veins in order to decrease reflux and pressure in areas above the ankle.

Evidence in the form of randomized clinical trials and both retrospective and prospective case series support the safety and efficacy of SEPS as an alternative to open procedures when performed for the treatment of incompetent medial calf perforator veins (Nelzen, Fransson, 2007; Kianifard, et al., 2007; de Rijcke, et al., 2003; Lee, et al., 2003; Kalra and Gloviczki, 2003; Sybrandy, et al., 2001; Pierek, et al., 1997). In contrast, SEPS performed for the treatment of post-thrombotic syndrome is controversial. Studies indicate that SEPS produces poorer outcomes, specifically, less ulcer healing and higher recurrence rates when used to treat limbs with post-thrombotic syndrome than when used to treat limbs with peripheral vascular insufficiency (Gloviczki, et al., 1999). -

NICE issued an Interventional Procedure Guidance for subfascial endoscopic perforator vein surgery. One randomized controlled trial, two non-randomized comparative studies and two case series were reviewed. The NICE specialty advisors noted that based on the evidence reviewed, efficacy of the procedure is unproven and the indications are not well established. Reported complications include nerve injury and deep vein thrombosis. There was evidence to support lower wound infection rates compared to the open procedure. Length of stay was shorter for SEPS. The rate of primary ulcer healing and cumulative ulcer recurrence rates was comparable for both open and SEPS procedures. Although SEPS has been used for individuals with post-thrombotic valvular incompetence, there is evidence when used for this indication individuals may have poorer outcomes

compared with individuals with primary valvular incompetence. In summary, the advisors noted careful patient selection is particularly important and there are uncertainties regarding safety of the procedure (NICE, 2004c).

Summary

The etiology of varicose veins is multifactorial and may result in a variety of symptoms and complications. Several treatment options are available, including minimally invasive surgical methods. The two main treatment options are surgery and sclerotherapy; however, there is little published data comparing their effectiveness. The peer-reviewed scientific literature supports safety and efficacy of most procedures, and most patients benefit from treatment, although recurrences have been reported in the literature. While varicose vein surgery is a very common surgical procedure, there is no general consensus regarding the best surgical approach.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
36470	Injection of sclerosing solution; single vein
36471	Injection of sclerosing solution; 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)
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)
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
37760	Ligation of perforator veins, subfascial, radical (Linton type), with or without skin graft, open
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, one 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), one leg
37799†	Unlisted procedure, vascular surgery

†**Note:** Covered when medically necessary and used to report stab phlebectomy of varicose veins, one extremity; less than 10 incisions.

ICD-9-CM Diagnosis Codes	Description

451.0	Phlebitis and thrombophlebitis of superficial vessels of lower extremities
451.11	Phlebitis and thrombophlebitis of femoral vein (deep) (superficial)
451.19	Phlebitis and thrombophlebitis of other deep vessels of lower extremities
451.2	Phlebitis and thrombophlebitis of lower extremities, unspecified
454.0	Varicose veins of lower extremities with ulcer
454.1	Varicose veins of lower extremities with inflammation
454.2	Varicose veins of lower extremities with ulcer and inflammation
454.8	Varicose veins of the lower extremities with other complications
459.81	Unspecified venous (peripheral) insufficiency

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
36468	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
36469	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face

HCPCS Codes	Description
S2202 ^{††}	Echosclerotherapy

††Note: Experimental, investigational, or unproven and not covered when used to report echosclerotherapy provided as the sole treatment of varicose vein tributaries without associated occlusion of the saphenofemoral or saphenopopliteal junction; for incompetence that is isolated to the perforator veins; and/or as the sole treatment for reflux that occurs at the saphenous vein junction.

ICD-9-CM Diagnosis Codes	Description
454.9	Asymptomatic varicose veins

***Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/15/2007	0234	Varicose Vein Treatments
Great-West Healthcare	1/1/2007	04.202.03	Varicose Vein Treatment
	1/1/2007	04.258.02	Varicose Vein Treatment, Sclerotherapy

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.