CIGNA MEDICAL COVERAGE POLICY

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Subject **Varicose Vein Treatments**

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Hyperlink to Related Coverage Policies

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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 the following varicose vein treatments as medically necessary:

- Sclerotherapy, ambulatory phlebectomy, ligation and excision, radiofrequency ablation (RFA) or endovenous laser therapy (EVLT) for treatment of symptomatic saphenous varicose veins when there is documentation of **ANY ONE** of the following indications:
  - 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
    - 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 single, significant episode of bleeding, especially if a transfusion is required

- Sclerotherapy for treatment of symptomatic varicose tributaries, when performed in combination with the medically necessary listed treatments above.

- Subfascial endoscopic perforator surgery (SEPS) 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

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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 and may be classified as truncal or reticular. Truncal varicosities occur in the long and short saphenous veins or their major branches. Reticular veins are subcutaneous veins not belonging to the main branches of the saphenous veins. The reflux of blood in the vessels results in an elevated pressure within the vessel, causing vein distention, dilation and tortuosity. Because of the lack of muscle support in superficial veins, the dilated vein becomes visible. Incompetent valves may be caused by familial predisposition, hormonal changes associated with pregnancy or menstruation, obesity, trauma, sun damage, or increased hydrostatic pressure from prolonged standing. 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 greater saphenous vein (GSV) originates medially on the foot, extends anteromedially up the calf and thigh, and joins the common femoral vein in the groin, connecting to the deep veins at the saphenofemoral junction in the groin. 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 originates on the dorsum of the foot, passes posterior to the lateral malleolus of the ankle, and then ascends the calf posteriorly. It is not usually larger than 3 mm in diameter, and connects with the deep veins at the saphenopopliteal junction in the knee area. One-way valves are present at the junctions to ensure unidirectional flow of blood. Approximately 90% of the venous blood flow in the lower extremities is transported proximally through the deep venous system.

Various ultrasound technologies are often 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. Doppler ultrasound detects the presence of incompetent valves but is limited in its ability to determine the precise location and extent of the varicosities. Plethysmography is also limited in this regard. Duplex ultrasound is typically used for the pretreatment mapping of varicosities and can be useful in determining incompetence of the greater or lesser saphenous veins and their associated junctions or evidence of perforator disease. 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 may be helpful in assessing the size and extent of the varicosities.

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. Often they appear on the lower extremities in a spider web pattern. 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, and there are 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).

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. Various methods of treatment, consisting of nonsurgical (conventional) and surgical approaches, have been investigated. According to a survey by the Vascular Surgical Society of Great Britain and Ireland, most surgeons prefer to use sclerotherapy for primary varicose veins in the absence of superficial venous incompetence or for residual varicose veins following surgery (Galland, 1998). Surgery is commonly used to treat mainstem varicose veins.

Many patients require a combination of techniques to correct venous insufficiency. No single method of treatment is universally employed in the literature. A Cochrane review (Rigby, et al., 2004) concluded that sclerotherapy was better than surgery in terms of treatment success, complication rate and cost at one year, but surgery was better after five years. Furthermore, since the trials reviewed used a variety of outcomes, making comparisons difficult, the evidence was insufficient to preferentially recommend sclerotherapy or surgery. Elias and Frasier (2004) reported that advances in minimally invasive vein surgery such as transilluminated powered phlebectomy (TIPP), radiofrequency ablation greater saphenous vein closure (RFGSV), laser ablation of the greater saphenous vein (EVLT), subfascial endoscopic perforator surgery (SEPS) and percutaneous vein valve bioprosthesis (PVVB) may decrease operative morbidity, the number and size of incisions, operative time and recovery time. This may result in outcomes comparable to open procedures with increased patient satisfaction and effective wound healing. Percutaneous vein valve bioprosthesis is a technique, currently under clinical trials, used to correct valvular incompetence (Elias and Frasier, 2004). The intervention selected is generally dependent upon the competency of deep and perforating veins, and the site and degree of reflux.

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. Sclerotherapy 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. Few studies reported outcomes suggesting risk was significantly different, although the comparative studies reviewed consisted of small populations, and results may not be considered reliable. 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). Subramonia and Lees (2007) published a review regarding the treatment of varicose veins and stated that foam sclerotherapy is becoming established as a primary method of treating saphenous vein reflux and the superiority of foam over liquid has been clearly demonstrated. In a systematic review conducted by Jia et al., (2007) the authors stated that the risk of adverse events with foam sclerotherapy was similar to liquid sclerotherapy or surgery in most studies. Rabe et al. (2008) compared sclerotherapy utilizing standard polidocanol foam to liquid polidocanol in a randomized trial (n=108) and also concluded that foam is more efficient and equally safe for the treatment of GSV reflux. During the European Consensus Conference on Foam Sclerotherapy in Germany 2003, it was established that foam sclerotherapy is an effective method of treatment for varicose veins, and that foam sclerotherapy was more effective (i.e., better control and stronger effect) than liquid sclerotherapy (Rabe, et al., 2004; Kendler, et al. 2007). Results from clinical studies have been favorable; 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).

There is no consensus in the published scientific literature regarding the optimal number of treatments required to reduce the symptoms associated with varicose veins. The number of sclerotherapy 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 that 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.

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.

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.

It has been suggested that transcatheter Duplex ultrasound-guided sclerotherapy provides an alternative to traditional saphenous vein ligation and stripping, improves the efficacy of greater saphenous vein sclerotherapy, and demonstrates outcomes that support lower recurrence rates (Min, Navarro, 2000). Echosclerotherapy, also referred to as ultrasound-guided sclerotherapy, employs real-time ultrasound to help locate deep or inaccessible sites. Since the saphenous vein is not visible with the naked eye, sclerotherapy is typically performed in combination with ultrasonography of the deep saphenous vein and has been investigated as an alternative therapy to traditional ligation and stripping. Bountouroglou et al. (2006) evaluated ultrasound-guided sclerotherapy utilizing time for postoperative recovery, return to work and quality of life outcomes as primary measures, and frequency of complications and cost of treatment as secondary outcomes, in a prospective randomized trial. The authors compared conventional greater saphenous vein stripping and saphenofemoral junction (SFJ) ligation under general anesthesia with ultrasound-guided foam sclerotherapy (n=30) and SFJ ligation under local anesthesia (n=30). The authors reported results that were statistically significant and favored the foam treatment group: ultrasound-guided sclerotherapy combined with ligation resulted in shorter treatment time ($p<.001$), and had improved quality of life ($p<.001$) and return to work outcomes ($p<.001$) compared to the surgery-only group. Complications were similar in both groups. Nonetheless, further trials to support long-term results would be more beneficial. At present, the evidence in the published, peer-reviewed, scientific literature is insufficient to support improved long-term outcomes of sclerotherapy of the deep saphenous veins in comparison to traditional ligation and stripping. Moreover, sclerotherapy of the saphenous vein raises concern about the appropriate volume and concentration of sclerosant, as well as about the ability to provide compression postoperatively.

Echosclerotherapy is also widely performed in conjunction with injection of foam sclerosants. When injected, the sclerosing agent can be detected by an ultrasound scanner, allowing improved visibility. Barrett et al. (2004) reported in a retrospective study that 31% of the leg varicose veins required a second treatment at three months in a study of 100 patients who received ultrasound-guided foam sclerotherapy for treatment of incompetent varicose veins. Darke and Baker (2006) reported the short-term results of a prospective trial of 192 patients referred for treatment of varicose veins, including greater saphenous (GSV) and superficial saphenous (SSV). All but 11 opted for ultrasound-guided foam sclerotherapy. Evaluation six weeks after treatment indicated complete occlusion in 163 legs after one intervention and in 33 after a second intervention (six weeks later). Only one required a third intervention. The authors acknowledged a better outcome in the SSV than the GSVs, although statistical significance was only reported for method of injection. The authors concluded that in the short-term, this procedure was safe and effective. Long-term outcomes were not evaluated in this study, and there was no comparison group.

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. A total of 67 studies were reviewed. Across nine randomized controlled trials, the median rate of successful occlusion was 84%, with rates greater than 60% across all studies. The rates of recurrence and development of new veins varied across studies, ranging from 1–15% of patients at follow-up intervals of six weeks to six years (NICE, 2007). Overall, little evidence exists in the form of large, randomized, controlled clinical trials to support the safety and efficacy of echosclerotherapy in managing varicose veins.

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 is 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. The individual components of the TriVex system were approved for use by the FDA in 1999 (FDA, 2001a, 2001b). Since that time, more than 36 illumination devices and more than 500 powered-resection devices have been approved (FDA, 2001c).

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.

Evidence evaluating TIPP for the treatment of varicose veins is primarily in the form of retrospective and prospective case series. Generally, the results of these studies demonstrate that TIPP is associated with fewer incisions (Shamiyeh, et al., 2003; Scavee, et al., 2003; Spitz, et al. 2000). Operative time varies among authors and with experience. Chesire et al. (2002) prospectively evaluated the ability of transillumination to enhance

localization and the ability of powered phlebectomy to resect varicosities and reported that TIPP was safe and efficacious. Spitz et al. (2000) reported fewer adverse events compared to a historical control group of patients who underwent hook phlebectomy. However, despite encouraging results in these studies, the measured outcomes were limited and short term. Some authors reported that more experience with the technique and further well-designed clinical trials are necessary to evaluate the full value of this technique.

Aremu et al. (2004) compared TriVex to conventional varicose vein surgery in terms of pain, cosmesis, recurrence, complications and operating time.The group was randomized to conventional stab phlebectomy (n=100) or TriVex (n=88). Varicosities were graded with CEAP classification of venous disorders and clinical assessment (grades 1–3). Randomization was single-blinded. Patients completed assessment forms preoperatively and postoperatively (2, 6, 26, 52 weeks); these forms were supplemented by physicians' clinical evaluations. TriVex cases demonstrated a need for significantly fewer incisions (n=5) than did conventional stab phlebectomy cases (n=29) ($p<0.0001$). The outcomes for pain, bruising, cellulitis, numbness, nerve injury, residual veins, cosmetic score and overall satisfaction did not differ significantly between the two procedures. The authors reported that TriVex compared well after a learning curve to conventional methods in complications and recurrence, and was safe and effective (Aremu, et al., 2004). However, the results of this study were limited by short-term outcomes (52 weeks).

Chetter and colleagues (2006) conducted a randomized clinical trial comparing perioperative variables and early patient-reported subjective outcomes after TIPP compared to multiple stab incision phlebectomy (MSIP). A total of 66 patients were randomized to receive treatment; however, four withdrew from the study prior to surgery. Thirty-three patients underwent MSIP and 29 patients underwent TIPP. Patients were assessed as outpatients at one and six weeks after surgery by a blinded independent observer. The total operating time and time taken for avulsions were similar in the MSIP and TIPP groups. The TIPP group had a reduction in the number of skin incisions. The authors reported that, unlike other publications, the incidence of hematoma in this study was not increased by the use of TIPP. Furthermore, while not statistically significant, at one and six weeks' follow-up, there was a higher incidence of saphenous neuropathy in the TIPP group. Bruising was significantly greater and more prolonged in the TIPP group, which the authors reported may be due to more extensive tissue plane dissection or the effect of intraoperative tumescent solution irrigation. Both groups experienced pain in the initial postoperative period; however, the MSIP group improved at six weeks postoperative. Additionally, TIPP had a greater adverse impact on quality of life outcome measures (bodily pain, mental health, physical function, role-play, and social function) following treatment. The authors reported, however, that their observations for quality of life improvement may suggest that the full benefit of the procedure cannot be appreciated as early as six weeks postoperatively. According to the author's conclusion, in their study, TIPP was associated with fewer surgical incisions; however, TIPP was also associated with more extensive bruising, prolonged pain and reduced early postoperative quality of life outcomes.

Scavee (2006) conducted a review of the literature and examined whether the TIPP method of treatment for varicose veins demonstrated any benefit, other than reducing the number of incisions, when compared to the gold standard treatment (hook phlebectomy). The author identified nine trials in the literature: four compared TIPP to conventional surgery, and five were prospective observational studies. Of the four that compared TIPP to conventional surgery, two were randomized controlled trials, and two were prospective nonrandomized studies. Regarding complications, the rates following TIPP varied considerably and consisted primarily of ecchymosis and/or hematoma formation, nerve injury and skin perforation. The author of this review noted that most studies reported fewer incisions for TIPP compared to conventional surgery, and that most studies reported an average of three to six incisions. Regarding operating time, results varied. Some authors reported shorter operating time for TIPP; however, the author of this review observed longer operating time for TIPP compared to hook phlebectomy. With regard to cosmetic scores, outcomes were similar for both groups, although some authors reported more favorable results with conventional surgery. Residual or recurrent varicose veins varied between 9.1 and 21.2 %. While the overall patient satisfaction scores were not statistically significant, the scores had a tendency to be lower for TIPP compared to conventional methods (87% versus 91% at six weeks, respectively). This author concluded that, currently, no data clearly proved any significant statistical advantage of TIPP over the conventional treatment, except for the number of incisions. According to the author, several questions remain, including: 1) what the mid- and long-term varicose vein recurrence rates are; 2) what the rate of cutaneous nerve and potential lymphatic injury are; and 3) is return to work or physical activity improved with TIPP. Further randomized trials are needed to determine the potential benefit of the procedure.

Operative approaches combining TIPP with other procedures have been reported in the published medical literature. Passman et al. (2007) reported retrospectively on outcomes of a combined operative approach for treatment of saphenous vein insufficiency and tributary veins. Patients were stratified by operative approach: combined saphenous vein stripping–stab avulsion phlebectomy (STRIP-PHLEB) (n=79 limbs), combined saphenous vein stripping–transilluminated phlebectomy (STRIP-TPP) (n=92 limbs), and combined endovenous ablation–transilluminated phlebectomy (EVAB-TPP) (n=129 limbs). There was no difference in the overall complication rates between the STRIP-PHLEB and EVAB-TPP group, although the distribution of complications did shift with a trend toward more wound problems in the procedures involving saphenous stripping (p=NS) and more hematomas in procedures involving TPP (p<.05). The authors noted the follow-up was short-term (i.e., one to two months postoperatively), and that there were variances in documentation methods during the study period. While the authors acknowledged a shift towards performing combined approaches, they also noted a shift in the associated postoperative problems. The authors concluded that even though newer methods (EVAB TPP) offer some advantage of being less invasive, the overall risk was unchanged compared to traditional approaches, and the perceived benefit should be weighed against that risk.

A retrospective review was published by Franz and Knapp (2008) evaluating TIPP for the treatment of varicose veins over a six year period (n=400). A total of 62.6% of the patients only underwent TIPP; 37.8% underwent additional procedures which included high ligation or endovenous laser ablation. Patients were followed for twelve weeks postoperatively. Measured outcomes included operative time, intraoperative complications, stab incision ranges, postoperative complications and patient satisfaction. The mean operative time was 19.7 minutes; the majority of cases had 10-20 stab incisions, and at 12 weeks varicosities remained resolved in all patients. Twelve patients developed postoperative complications. The study lacked randomization, a control group and was retrospective in nature.

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).

Hayes conducted an evidence-based health technology assessment of TIPP for the treatment of symptomatic varicose veins and concluded that published data supporting safety and efficacy were limited (HAYES, 2002). An updated search of the literature conducted periodically by Hayes (2004–2007) reports safety, efficacy, and patient selection criteria remain unchanged from the initial report, and there is no long-term follow-up data available.

Currently, there is insufficient evidence in the medical literature to support the safety and efficacy of TIPP. 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). Most of the clinical studies are very small in sample size and some lack randomization. In addition, the outcomes measured in most studies are short-term and include operative time, number of incisions, complications, reduced pain, and cosmetic satisfaction. Despite reports in the published literature of a reduced number of incisions, some authors have also reported an increase in bruising, postoperative pain and decreased quality of life during the early postoperative period. Moreover, it has been reported in the literature that technical complications may be associated with inexperience. Subramonia and Lees, 2007, reported there was lack of adequate evidence supporting widespread use of the procedure. The published, peer-reviewed, scientific literature does not lead to strong conclusions that TIPP results in clinical outcomes that are as good as treatment with standard conventional methods (i.e., hook phlebectomy). Furthermore, long-term safety and efficacy of the procedure have not been demonstrated.

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 of the greater saphenous vein. RFA has been investigated as a treatment of incompetent perforator veins and some authors have reported promising early results in the form of case reports, case series and published articles (Uchino, 2007; Roth, et al. 2007; Peden and Lumsden, 2007; Gibson, et al, 2007a). However, due to insufficient published data supporting safety and efficacy, further clinical studies are needed to support widespread use.

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; Weiss, 1998; VNUS, 2000). Possible complications include vessel perforation, pulmonary embolism, phlebitis, hematoma, infection, paresthesia and skin burns (Chandler, et al., 2000; Goldman, 2000; VNUS, 2000).

Short- and intermediate-term outcomes have been reported by some authors; however, few authors have reported on long-term outcomes. Merchant and Pichot (2005) collected data in an ongoing multicenter prospective registry to evaluate the long-term treatment outcomes of endovascular radiofrequency ablation 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. Anatomical failure did not necessarily result in clinical failure, as most patients experienced symptom relief and remained asymptomatic despite the anatomical failure. The authors reported anatomical failure was related to pull back speed and body mass index. The authors concluded their findings support long-term efficacy and RFO as a comparable standard of care with traditional surgery.

Lurie et al. (2005) reported that RFO was associated with long-term outcomes similar to ligation and stripping. The authors conducted a two-year follow-up of the original EVOLVeS trial (Lurie, et al., 2003). Their clinical study consisted of a total of 85 patients, 45 randomly allocated to RFO and 40 who were randomly allocated to high ligation and stripping. Seventy-nine patients received treatment. Recruitment was terminated mainly due to the patient's reluctance for randomization. Immediate intraoperative success was reported in all but two cases. The recurrence rate was lower in the RFO group compared to the ligation and stripping group but was not statistically significant. Cumulative rates of recurrent varicose veins at combined one- and two-year follow-up were 14.3% for RFO and 20.9% for the ligation and stripping. There was no sign of venous disease at two-year follow-up in 33% of the RFO group and 28% of the ligation and stripping group.

Hinchliffe et al. (2006) conducted a randomized patient–controlled, double-blind study evaluating the efficacy of endoluminal ablation (VNUS) and traditional redo groin surgery (RGS) and long saphenous vein stripping (n=16). At surgery, one leg, chosen randomly, was treated with VNUS and avulsions using intraoperative Duplex control. The other leg was treated with traditional RGS, exposure of the femoral vein, stripping of the long saphenous vein and multiple avulsions. Patients completed postoperative assessment sheets for 10 days using a 10 cm visual analogue scale for self-assessment of pain and bruising. Photographs of the legs were obtained between postoperative days five and eight. Digital image analysis was used to objectively assess bruising. All patients were followed up and evaluated with Duplex scans within six weeks of operation and at one year. The authors reported the median time to perform VNUS was less than RGS (p=0.02), and patients with VNUS had less pain (p=0.02) and less bruising (p=0.02). The median visual analogue score was 1.7 for VNUS and 3.8 for RGS (p=0.02). On duplex scanning of the legs that had VNUS, 13 patients had complete occlusion of the long saphenous vein (LSV); three had partial occlusion with small sections of the vein still patent. On duplex scanning of the legs that had RGS, a total of 14 were completely stripped and two were partially stripped. The authors concluded that VNUS is better than RGS in the management of patients with recurrent LSV varicosities; the procedure was performed more quickly and with less postoperative pain and bruising compared to RGS.

Welch (2006) conducted a retrospective study assessing the efficacy of RFA alone as a treatment for symptomatic varicose veins (n=184 procedures). The patients had a Duplex examination of the treated legs within one week of the surgical procedure, at the initial follow-up visit. Patients were then scheduled for repeat visits two to three months after the RFA to assess early results, patient satisfaction, and whether or not other procedures were necessary. Patients who were not scheduled for subsequent stab phlebectomy or sclerotherapy at that time were scheduled for telephone follow-up at nine months for reassessment. The procedure was aborted in one limb (i.e., four procedures) mainly due to inability to pass the catheter. One

patient was lost to follow-up. Postoperative Duplex results demonstrated that there was complete occlusion of 143 limbs; total or partial patency of < 10 cm was present in 155 limbs. Seven of those 155 had concomitant stab phlebectomy, one was a redo ablation with concomitant stab phlebectomy, seven subsequently had sclerotherapy, and 39 later underwent stab phlebectomy. In 101 limbs, symptoms resolved and there was no other therapy. Overall, the complications were mild; 102 limbs had no adverse events. Complications included superficial thrombophlebitis, numbness, burning sensation, ecchymosis, mild pigmentation changes, pulling sensation, discomfort, and cutdown for microwire retrieval. The authors concluded that eliminating the source of venous reflux can be effective in relieving patients of the symptoms of varicose veins, and that further treatment can be deferred in many patients.

There is also some clinical evidence from earlier randomized, prospective clinical trials to suggest that RFA can effectively occlude incompetent saphenous veins and reduce the symptoms associated with varicose veins. Most of the 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). These studies, in addition to the more recent studies cited above, do support the safety and efficacy of RFA. In addition, both physicians practicing in the relevant clinical area and the medical community at large recognize RFA as in accordance with generally accepted standards of medical practice. Therefore, RFA for the treatment of symptomatic saphenous varicosities is considered appropriate for coverage when the medical necessity criteria are met.

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.

Several case series have been published evaluating EVLT. In a large, prospective case series conducted by Chang and Chua (2002), 252 greater saphenous veins were treated with endovenous laser photocoagulation (EVLP) in 149 patients. Only patients with saphenofemoral reflux documented by Duplex ultrasound were treated. All patients received surgical ligation of the saphenofemoral junction. EVLP was performed using an Nd:YAG laser. Follow-up period ranged from 12–28 months, with a mean of 19 months. In all, 141 patients with 244 legs demonstrated significant improvement ($p<0.05$). Common early complications reported included: local paresthesia in 92 legs (36.5%); ecchymosis/dyschromia in 58 legs (23.0%); superficial burn injury in 12 legs (4.8%); superficial phlebitis in four legs (1.6%); and localized hematoma in two legs (0.8%) at three weeks postoperatively. The final outcome did not include significant morbidity or mortality. All patients recovered quickly. In summary, the authors found that complications were minimized after EVLP in comparison to conventional surgery.

Min and associates (2003) reported on long-term follow-up of EVLT for greater saphenous vein reflux caused by incompetence of the saphenofemoral junction in a prospective, multicenter, uncontrolled case series. Over a three-year period, 499 veins were treated in 423 patients. Patients were evaluated at one week, one month, three months, six months, one year and yearly thereafter to assess efficacy and adverse reactions. Compression sclerotherapy was performed in nearly all patients at follow-up for treatment of associated tributary varicose veins and secondary telangiectases. Successful occlusion was documented by Doppler imaging (by absence of flow) in 490 of the 499 patients (98.2%) after initial treatment. Continued closure was reported as follows: 444 of 447 (99.3%) at three months; 390 of 396 (98.5%) at six months; 351 of 359 (97.8%) at nine months; and 310 of 318 (97.5%) at one year. One hundred and thirteen of 121 limbs (93.4%) were followed for two years. Forty subjects were followed for three years, and no new recurrences were seen in comparison to one-year results. In some patients, postoperative bruising and tightness were noted along the course of the vein. No cases of skin burn, paresthesia or deep vein thrombosis were reported. The authors stated that long-term results supported a recurrence rate of less than 7% at a two-year follow-up. Those results were comparable or superior to those reported for other treatment options, including surgery, ultrasound-guided sclerotherapy, and radiofrequency ablation. Although this study seems promising, the authors documented that a significant number of patients were lost to follow-up by the end of three years.

In 2006, Puggioni and colleagues published a retrospective review comparing saphenous closure rates and complications of endovenous laser therapy and radiofrequency ablation. During a three-year period, ablation of

the greater saphenous vein was performed on 130 limbs. RFA was the procedure of choice for 53 limbs, and EVLT was performed on 77 limbs. Other procedures performed concomitantly included avulsion phlebectomy (126 limbs), subfascial endoscopic perforator surgery (10 limbs), and small saphenous vein ablation (4 limbs). Routine postoperative duplex scanning was performed on 65 limbs between 1–23 days postoperatively to assess for thrombotic complications. The authors observed three cases of thrombus protrusion into the common femoral vein after EVLT that had resolution after treatment with anticoagulants. Occlusion of the greater saphenous vein was confirmed in 94.4% of the EVLT limbs and 90.9% of the RFA limbs. The reported complication rate was 20.8% in the EVLT group and 7.6% in the RFA group and included superficial thrombophlebitis (four EVLT), excessive pain (three each group), hematoma (one EVLT), and edema (two EVLT, one RFA). The authors concluded from their retrospective review that the overall success rate of endovenous ablation techniques for occluding the incompetent greater saphenous vein was 94% at one month. EVLT was associated with higher occlusion rates; however, they reported more frequent postoperative complications in the EVLT group compared to the RFA group. Furthermore, the authors reported that all patients undergoing endovenous procedures should also undergo early postoperative duplex scanning to rule out proximal extension of thrombus, confirm occlusion, and exclude more distal deep vein thrombosis (Puggioni, et al., 2006).

Ravi et al. (2006) published the results from a retrospective study assessing the effectiveness of endovenous treatment using endovenous laser (EVL) or radiofrequency ablation (RFA) over a three-year follow-up. A total of 981 consecutive patients with symptomatic varicose veins underwent EVL of 1149 great saphenous veins (GSV) and 101 small saphenous veins (SSV). There were 990 GSV and 1-1 SSV procedures using EVL; 159 GSVs were treated with RFA. Patients were seen at two weeks postoperatively for Duplex scan of the target vein to confirm complete occlusion, assess vein wall thickness, rule out deep vein thrombosis (DVT), or extension of a thrombus into the deep system. Patients involved in the first 200 procedures were invited to obtain a clinical examination and Duplex scan at six months and 12 months, and then annually. The Duplex scan performed within two weeks postoperatively demonstrated 39 recanalizations or incomplete occlusions of the 1149 GSVs that were treated (33 EVL, 6 RF). Of the 101 SSVs treated (all EVL), nine demonstrated SSV incompetence. The authors noted that, overall, the majority of limbs required an additional procedure at the time of EVL. Postoperative complications were few and patients reported mild discomfort. Many patients (95%) resumed normal activity two days after the procedure. None of the patients developed DVT or thrombus of the deep venous system, and there was no variability of occlusion rates with either technique. A total of 73.3% of patients were evaluated periodically for an average of three years. The authors reported that no GSV recanalization was found; no saphenous vein could be identified in 82.5% of limbs. A total of 121 patients completed the patient satisfaction questionnaire. Prior to treatment, 90% of patients reported severity of their symptoms as “moderate to severe;” after treatment 84% claimed their symptoms were diminished to “none or minimal.” Patient satisfaction, efficacy, ease of use, and overall success with RFA versus EVL were not significantly different. The authors stated that in their experience, endovenous closure techniques are superior to conventional ligation and stripping.

Desmyttrere et al. (2007) published the results of prospective cohort observational study involving 500 patients who underwent endovenous laser therapy of incompetent GSV using a 980 nm diode laser. The procedure was performed as outpatient under ultrasound guidance. Linear endovenous energy density was tuned as a function of the GSV diameters and pulse duration was adjusted for each individual GSV segment from 1.2 seconds up to 6 seconds. Concomitant ambulatory phlebectomy was performed in 98% of the patients in this series. Closure rates at one month, one year, two year, three year and four year follow-up were 98.4%, 96.8%, 97.8%, 99.3% and 97.1%, respectively. No major complications were reported.

More recently, randomized controlled trials have been published supporting efficacy of EVLT. Darwood et al. (2008) reported the results of a randomized trial of patients who underwent EVLA 1(using stepwise laser withdrawal), EVLA 2 (using continuous laser withdrawal) or surgery (saphenofemoral ligation, GSV stripping, multiple phlebectomies). The authors noted that saphenous vein reflux, the principle outcome measure, was abolished at three months in 41 of 42 legs treated with EVLA 1, 26 of 29 following EVLA 2, and 28 of 32 after surgery. At one year, continued abolition of reflux was noted 24 of 28 EVLA 1, 19 of 21 EVLA2, and 11 of 12 surgery legs. Disease specific quality of life measures were evaluated using the Aberdeen Varicose Vein Symptom Score (AVVSS) after three months and at one year. At three months following treatment, AVVSS scores were improved in all groups and were maintained at one year. Patients who underwent EVLA procedures returned to work faster compared to the surgery group. The authors noted observer or patient blinding was not possible.

Kalteis et al (2008) published early results of a randomized controlled trial comparing the use of EVLT with high ligation of the GSV(n=50) and stripping of the GSV with high ligation (n=50).The authors evaluated and compared postoperative hematoma size, quality of life scores, pain using the visual analog pain scale, and analgesic use. The results demonstrated 100% endovenous occlusion rates. Smaller hematoma formation was noted in the EVLT group. There was no difference in quality of life scores between groups and no difference in the outcome of surgery. There was also no difference in degree of comfort at 16 weeks. Patients in the EVLT group returned to work later compared to the stripping group, the authors did not attribute this to increased morbidity in the EVLT group.

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.

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).

There is a growing body of evidence indicating both RFA and EVLT are beneficial in the treatment of varicose veins (Beale, et al., 2004; Teruya and Ballard, 2004; Elias and Frasier, 2004; Sadick, 2005, Ravi et al., 2006). In 2007, Sharif et al. published the results of a case series supporting the efficacy of EVLT in the treatment and prevention of chronic venous ulcers. Much of the peer-reviewed scientific literature consists of uncontrolled case series with short-term follow-up, although the evidence available suggests that EVLT may provide effective venous occlusion with relatively few complications (Min, 2002; Proebstle, 2002; Ho, 2003; Navarro, 2001). Therefore, EVLT is considered appropriate for coverage as an alternative treatment to surgical stripping of the greater saphenous vein when the medical necessity criteria are met.

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.

In a randomized clinical study, Sybrandy and associates evaluated long-term follow-up of patients who underwent SEPS. Thirty-nine patients with venous ulceration on the medial side of the lower extremity were randomly assigned to endoscopic technique (n=20) or open technique (n=19). During the follow-up period, four patients in the SEPS group died from causes unrelated to the surgery. One patient who underwent SEPS underwent a below-knee amputation because of squamous cell cancer. The average follow-up period was 50.6 months for the open group and 46.1 months for the SEPS group. The results indicated that all 18 patients (100%) in the open group who were available for follow-up healed initially, with four recurrences (recurrence rate of 22%). In the SEPS group, 19 patients were available for follow-up, 17 of whom (89%) healed initially; two (12%) had recurrence. The authors concluded that the long-term follow-up results of endoscopic division of perforating veins are comparable to those of open division of perforating veins (Sybrandy, et al., 2001).

A small case series conducted by de Rijcke et al. indicated that SEPS is valuable in treating venous ulcers on the medial aspect of the lower leg, although not as valuable in treating venous ulcers on the lower lateral aspect of the leg. Most venous ulcers develop in the internal perimalleolar area, typically over the medial malleolus; only 10% occur over the lateral malleolus. Anatomical location of the insufficient perforating veins is an important contributing factor to the success rate of SEPS (de Rijcke, et al., 2003).

Kalra and Gloviczki (2003) reported that the available evidence supported SEPS as superior to open perforator ligation. Since ablation of superficial reflux is often performed concomitantly with SEPS, it is difficult to determine the clinical benefit produced directly by SEPS. The authors concluded that the patients, who benefit from surgical treatment and the addition of SEPS, if indicated, are those whose ulcers result from peripheral vascular insufficiency of the superficial and perforating veins, with or without deep venous insufficiency. On the basis of the data that the authors reviewed, these patients can be assured an 80–90% chance of long-term freedom from ulcer recurrence. The authors also reported that the role of SEPS and surgery is controversial in patients with post-thrombotic syndrome because only 50% of those patients can be predicted to have long-term freedom from ulcer recurrence.

Kianifard et al. (2007) reported the results of a randomized trial evaluating incompetent perforating veins following saphenofemoral ligation and stripping of the great saphenous vein (GSV), with or without SEPS (SEPS group=38 patients, non-SEPS group = 32 patients). Duplex ultrasound was performed prior to the operation, at one week, six weeks, six months, and one year following surgery. Quality of life questionnaires and visual analogue scale scores were obtained at the same time points. The study results indicated the mean total operation time for the SEPS group was longer compared to the non-SEPS group; there were no postoperative complications; there were no differences between the two groups with respect to pain, mobility or quality of life scores during follow-up. The authors noted a significantly higher proportion of patients with incompetent perforating veins in the non-SEPS group at one year ($p<0.001$). The authors acknowledged that SEPS was effective in reducing the number of incompetent perforating veins for up to one year after surgery. This study is limited by evaluation of short-term results and a small patient population.

Nelzen and Fransson (2007) reported on the results of a prospective case series involving 90 consecutive patients who underwent SEPS to evaluate healing and recurrence data for patients with open and healed venous leg ulcers. Patients were followed for an average of 77 months, with a minimum of five years. All patients were treated with SEPS; 87% had additional superficial venous surgery. The authors reported 87% of all ulcerated legs healed and three and five year recurrence rates were 8% and 18% respectively among survivors.

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).

There is some evidence in the peer-reviewed scientific literature to support the safety and efficacy of SEPS as an alternative to open procedures when performed for the treatment of medial calf perforator insufficiency (Pierek, et al., 1997; Lee, et al., 2003; Kalra, Gloviczki, 2003). 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). Therefore, SEPS remains investigational, experimental and unproven when performed for the treatment of post-thrombotic syndrome.

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

ICD-9-CM Diagnosis	Description

Codes	
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

References

1. Ahmad I, Ahmad W, Dingui M. Prevention or reversal of deep venous insufficiency by aggressive treatment of superficial venous disease. Am J Surg. 2006 Jan;191(1):33-8.

2. Almeida JI, Raines JK. Radiofrequency ablation and laser ablation in the treatment of varicose veins. Ann Vasc Surg. 2006 Jul;20(4):547-52.

3. American Academy of Cosmetic Surgery. 2003 Guidelines for sclerotherapy. Accessed September 13, 2006. Available at URL address: http:// http://www.cosmeticsurgery.org/

4. American Academy of Dermatology (AAD). New laser treatments get a leg up on unsightly veins. March 23, 2003. Accessed September 13, 2007. Available at URL address: http://www.aad.org/public/News/NewsReleases/Press+Release+Archives/Cosmetic+Dermatology+-+Aging/LegVeins.htm

5. American College of Phlebology (ACP). Phlebology: The treatment of leg veins. Accessed September 13, 2007. Available at URL address: http://www.phlebology.org/index.cfm?sector=patients&page=brochure&b=ip

6. American College of Phlebology (ACP). Sclerosing solutions. Accessed September 2004. Available at URL address: http://www.phlebology.org/docmechanism2.htm

7. Angermeier MC. Treatment of facial vascular lesions with intense pulsed light. J Cutan Laser Ther. 1999 Apr;1(2):95-100.

8. Angle N, Freischlag JA. Venous disease. In: Townsend CM Jr., Beauchamp RD, Evers BM, Mattox KL, editors. Sabiston textbook of surgery. 17th ed. Philadelphia, PA: W.B. Saunders Co.; 2004. ch 67. Copyright © 2004 Elsevier.

9. Aremu MA, Mahendran B, Butcher W, Khan Z, Colgan MP, Moore DJ, et al. Prospective randomized controlled trial: conventional versus powered phlebectomy. J Vasc Surg. 2004 Jan;39(1):88-94.

10. Baccaglini U, Pavei P, Spreafico G, Sorrentino P, Fontebasso V, Castoro C, et al. [Echo-sclerotherapy in the management of varices of the lower extremities]. Minerva Cardioangiol. 1995 May;43(5):191-7.

11. Barrett JM, Allen B, Ockelford A, Goldman MP. Microfoam ultrasound-guided sclerotherapy of varicose veins in 100 legs. Dermatol Surg. 2004 Jan 1;30(1):6-12.

12. Beale RJ, Mavor AI, Gough MJ. Minimally invasive treatment for varicose veins: a review of endovenous laser treatment and radiofrequency ablation. Int J Low Extrem Wounds. 2004 Dec;3(4):188-97.

13. Belcaro G, Cesarone MR, Di Renzo A, Brandolini R, Coen L, Acerbi G, et al. Foam-sclerotherapy, surgery, sclerotherapy, and combined treatment for varicose veins: a 10-year, prospective, randomized, controlled trial (VEDICO trial). Angiology. 2003 May 1;54(3):307-15.

14. Bergan JJ. The current management of varicose and telangiectatic veins. Surg Annu. 1993; 25:141-56.

15. Bergan JJ, Pascarella L. Severe chronic venous insufficiency: primary treatment with sclerofoam. Semin Vasc Surg. 2005 Mar;18(1):49-56.

16. Bergan J, Pascarella L, Mekenas L. Venous disorders: treatment with sclerosant foam. J Cardiovasc Surg (Torino). 2006 Feb;47(1):9-18.

17. Bountouroglou DG, Azzam M, Kakkos SK, Pathmarajah M, Young P, Geroulakos G. Ultrasound-guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins: early results of a randomized controlled trial. Eur J Vasc Endovasc Surg. 2006 Jan;31(1):93-100. Epub 2005 Oct 17.

18. Bowes LE, Goldman MP. Sclerotherapy of reticular and telangiectatic veins of the face, hands, and chest. Dermatol Surg. 2002 Jan;28(1):46-51.

19. Breu FX; Guggenbichler S. European consensus meeting on, April 4-6, 2003, Tegernsee, Germany. Dermatol Surg. 2004 May;30(5):709-17; discussion 17.

20. Bulletin of the North American Society of Phlebology, The. Insurance Advisory Committee report. J Dermatol Surg Oncol. 1992;18:609-16.

21. Chandler JG, Pichot O, Sessa C, Schuller-Petrovic, Kavnick L, Betgan J. Treatment of primary venous insufficiency by endovenous saphenous vein obliteration. Vasc Surg. 2000;34:201-14.

22. Chang CJ, Chua JJ. Endovenous laser photocoagulation (EVLP) for varicose veins. Lasers Surg Med. 2002;31(4):257-62.

23. Cheshire N, Elias SM, Keagy B, Kolvenbach R, Leahy AL, Marston W, Pannier-Fischer F, Rabe E, Spitz GA. Powered phlebectomy (TriVex) in treatment of varicose veins. Ann Vasc Surg. 2002 Jul;16(4):488-94. Epub 2002 Jun 27.

24. Chetter IC, Mylankal KJ, Hughes H, Fitridge R. Randomized clinical trial comparing multiple stab incision phlebectomy and transilluminated powered phlebectomy for varicose veins. Br J Surg. 2006 Feb;93(2):169-74.

25. Coleridge Smith P. Saphenous ablation: sclerosant or sclerofoam? Semin Vasc Surg. 2005 Mar;18(1):192-24.

26. Corabian P, Harstall C. Sclerotherapy for leg varicose veins. Alberta Heritage Foundation for Medical Research. Technology Assessment. Ip-19 Information paper. May 2004. ©Copyright Alberta Heritage Foundation for Medical Research, 2004.

27. Creton D, Uhl JF. Foam sclerotherapy combined with surgical treatment for recurrent varicose veins: short term results. Eur J Vasc Endovasc Surg. 2007 May;33(5):619-24. Epub 2007 Jan 16.

28. Darke SG, Baker SJ. Ultrasound-guided foam sclerotherapy for the treatment of varicose veins. Br J Surg. 2006 Aug;93(8):969-74.

29. Darwood RJ, Theivacumar N, Dellagrammaticas D, Mavor AI, Gough MJ. Randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous varicose veins. Br J Surg. 2008 Mar;95(3):294-301.

30. de Rijcke PA, Hop WC, Wittens CH. Subfascial endoscopic perforating vein surgery as treatment for lateral perforating vein incompetence and venous ulceration. J Vasc Surg. 2003 Oct;38(4):799-803.

31. Desmyttère J, Grard C, Wassmer B, Mordon S. Endovenous 980-nm laser treatment of saphenous veins in a series of 500 patients. J Vasc Surg. 2007 Dec;46(6):1242-7.

32. Duffy DM, Garcia C, Clarke RE. The role of sclerotherapy in abnormal varicose hand veins. Plast Reconstr Surg. 1999 Oct;104(5):1474-9; discussion 1480-1.

33. Elias SM, Frasier KL. Minimally invasive vein surgery. Mt Sinai J Med.2004 Jan;71(1):42-6.

34. Feied CF. American College of Phlebology (ACP). Venous anatomy and physiology. Accessed December 2004. Available at URL address: http://www.phlebology.org/syllabus1.htm

35. Feied C. Varicose vein treatment and endovenous laser therapy. eMedicine specialties. Dermatology, Diseases of the vessels. Updated February 15, 2007, June 24, 2008. Accessed October 2, 2008. Available at URL address: http://www.emedicine.com/med/topic2788.htm

36. Franz RW, Knapp ED. Transilluminated Powered Phlebectomy Surgery for Varicose Veins: A Review of 339 Consecutive Patients. Ann Vasc Surg. 2008 Sep 5. [Epub ahead of print.

37. Fronek H. American College of Phlebology (ACP) [website]. C.E.A.P. classification of venous disorders. 1998. Accessed January 2004. Available at URL address: http://www.phlebology.org/syllabus14.htm

38. Galland RB, Magee TR, Lewis MH. A survey of current attitudes of British and Irish vascular surgeons to venous sclerotherapy. Eur J Vasc Endovasc Surg. 1998;16:43-6.

39. Gibson KD, Ferris BL, Pepper D. Endovenous laser treatment of varicose veins. Surg Clin North Am. 2007a Oct;87(5):1253-65, xii.

40. Gibson KD, Ferris BL, Pepper D. Foam sclerotherapy for the treatment of superficial venous insufficiency. Surg Clin North Am. 2007b Oct;87(5):1285-95, xii-xiii.

41. Gloviczki P, Bergan JJ, Rhodes JM, Canton LG, Harmsen S, Ilstrup DM. Mid-term results of endoscopic perforator vein interruption for chronic venous insufficiency: lessons learned from the North American subfascial endoscopic perforator surgery registry. The North American Study Group. J Vasc Surg. 1999;29(3):489-502.

42. Goldman MP. Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow-up. Dermatol Surg. 2000;26:452-56.

43. Hamper UM, DeJong MR, Scoutt LM. Ultrasound Evaluation of the Lower Extremity Veins. Radiol Clinic North Am. 2007 May;45(3):525-47.

44. HAYES Medical Technology Directory™. Endoluminal Radiofrequency Ablation for Varicose Veins of the Leg. Lansdale, PA: HAYES, Inc.; ©2008 Winifred S. Hayes, Inc. May 2006. Updated search June 2007; June 2008.

45. HAYES Medical Technology Directory™. Endovenous laser therapy for varicose veins of the leg. Lansdale, PA: HAYES, Inc.; © 2008 Winifred S. Hayes, Inc. 2006 October. Updated search September 2007; September 2008.

46. HAYES Medical Technology Directory™. Sclerotherapy for symptomatic varicose veins. Lansdale, PA: HAYES, Inc.; © 2008 Winifred S. Hayes, Inc. 2004 Dec Updated search December 2005, December 2006; January 2008.

47. HAYES Medical Technology Directory™. Transilluminated Powered Phlebectomy for Symptomatic Varicose Veins. Lansdale, PA: HAYES, Inc.; ©2008 Winifred S. Hayes, Inc. 2002 May. Updated search July 2004, May 2005, April 2006, April 2007, Archived 2008.

48. Hinchliffe RJ, Ubhi J, Beech A, Ellison J, Braithwaite BD. A prospective randomized controlled trial of VNUS closure versus surgery for the treatment of recurrent long saphenous varicose veins. Eur J Vasc Endovasc Surg. 2006 Feb;31(2):212-8. Epub 2005 Aug 31.

49. Jia X, Mowatt G, Burr JM, Cassar K, Cook J, Fraser C. Systematic review of foam sclerotherapy for varicose veins. Br J Surg. 2007 Aug;94(8):925-36.

50. Kahle B, Leng K. Efficacy of sclerotherapy in varicose veins—prospective, blinded, placebo-controlled study. Dermatol Surg. 2004 May;30(5):723-8; discussion 728.

51. Kakkos SK, Bountouroglou DG, Azzam M, Kalodiki E, Daskalopoulos M, Geroulakos G. Effectiveness and safety of ultrasound-guided foam sclerotherapy for recurrent varicose veins: immediate results. J Endovasc Ther. 2006 Jun;13(3):357-64.

52. Kalra M, Gloviczki P. Surgical treatment of venous ulcers: role of subfascial endoscopic perforator vein ligation. Surg Clin North Am. Jun 2003;83(3):671-705.

53. Kalteis M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Pölz W, Hieller F. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: early results of a randomized controlled study. J Vasc Surg. 2008 Apr;47(4):822-9; discussion 829. Epub 2008 Mar 4.

54. Kanter A. American College of Phlebology (ACP). Technique for sclerosing varicose veins, 1998. Accessed October 2003. Available at URL address: http://www.phlebology.org/syllabus7.htm

55. Kendler M, Wetzig T, Simon JC. Foam sclerotherapy--a possible option in therapy of varicose veins. J Dtsch Dermatol Ges. 2007 Aug;5(8):648-54.

56. Kern P. Sclerotherapy of varicose leg veins. Technique, indications and complications. Int Angiol. 2002 Jun;21(2 Suppl 1):40-5.

57. Kianifard B, Holdstock J, Allen C, Smith C, Price B, Whiteley MS. Randomized clinical trial of the effect of adding subfascial endoscopic perforator surgery to standard great saphenous vein stripping. Br J Surg. 2007 Sep;94(9):1075-80.

58. Labas P, Ohradka B, Cambal M, Reis R, Fillo J. Long term results of compression sclerotherapy. Bratisl Lek Listy. 2003;104(2):78-81.

59. Lee BJ. The role of sclerotherapy in abnormal varicose hand veins. Plast Reconstr Surg. 2000 Jul;106(1):227-9.

60. Lee DW, Lam YH, Chan AC, Chung SC. Subfascial endoscopic perforator surgery for venous ulcers. Hong Kong Med J. 2003 Aug;9(4):279-82.

61. Lurie F, Cretan D, Ekloff B, Kabnick LS, Kistner RI, Pichot O, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in selected patient population (EVOLVeS Study). J Vasc Surg. 2003;Aug 38(2):207-14.

62. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomised study of endovenous radiofrequency obliteration (Closure) versus ligation and vein stripping (EVOLVeS): Two-year follow-up. Eur J Vasc Endovasc Surg. 2005 Jan;29:67-73.

63. Manfrini S, Gasbarro V, Danielsson G, Gudmunder M, Norgren L, Chandler J, et al. Endovenous management of saphenous vein reflux. J Vasc Surg. 2000;32:330-42.

64. McDonagh B, Sorenson S, Gray C, Huntley DE, Putterman P, King T, et al. Clinical spectrum of recurrent postoperative varicose veins and efficacy of sclerotherapy management using the compass technique. Phlebology. 2003;18:173-86.

65. Merchant RF, Pichot O, for the Closure Study Group. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. J Vasc Surg. 2005 Sep;42(3):502-9,discussion 509.

66. Michaels JA, Campbell WB, Brazier JE, Macintyre JB, Ratcliffe J, Rigby K. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess. 2006 Apr;10(13):1-196, iii-iv.

67. Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long term results. J Vasc Interv Radiol. 2003 Aug;14(8):991-6.

68. Min RJ, Navarro L. Transcatheter duplex ultrasound-guided sclerotherapy for treatment of greater saphenous vein reflux: preliminary report. Dermatol Surg. 2000 May;26(5):410-4; discussion 413-4.

69. Murray JD, Bergan JJ, Riffenburgh RH. Development of open-scope subfascial perforating vein surgery: lessons learned from the first 67 cases. Ann Vasc Surg. 1999 Jul;13(4):372-7.

70. National Institute for Clinical Excellence (NICE). Endovenous laser treatment of the long saphenous vein. Guidance. Issued 2004b Mar 4. Accessed October 2, 2008. Available at URL address: http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

71. National Institute for Clinical Excellence (NICE). Interventional procedure consultation document: ultrasound guided foam sclerotherapy for varicose veins. 2004 Mar. Accessed October 2, 2008. Available at URL address: http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

72. National Institute for Clinical Excellence (NICE). Radiofrequency ablation of varicose veins. Guidance. Issued September 2003. Accessed October 2, 2008. Available at URL address: http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

73. National Institute for Clinical Excellence (NICE). Subfascial endoscopic perforator surgery, Guidance. Issued 2004c June. Accessed October 2, 2008. Available at URL address: http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

74. National Institute for Clinical Excellence (NICE). Transilluminated powered phlebectomy for varicose veins, Guidance. Issued 2004a Jan. Accessed October 2, 2008. Available at URL address: http:// http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

75. National Institute for Clinical Excellence (NICE). Ultrasound guided foam sclerotherapy for varicose veins. Guidance. Issued June 2006. Re-issued May 2007. Accessed October 2, 2008. Available at URL address: http://www.nice.org.uk/search/searchresults.jsp?keywords=varicose+vein&searchType=all

76. Navarro L, Min RJ, Bon E. Endovenous laser: a new minimally invasive method of treatment for varicose veins -- preliminary observations using an 810 nm Diode Laser. Dermatol Surg. 2001; 27(2):117-22.

77. Nelzén O, Fransson I. True long-term healing and recurrence of venous leg ulcers following SEPS combined with superficial venous surgery: a prospective study. Eur J Vasc Endovasc Surg. 2007 Nov;34(5):605-12. Epub 2007 Aug 22.

78. Ogawa T, Hoshino S, Midorikawa H, Sato K. Clinical results of radiofrequency endovenous obliteration for varicose veins. Surg Today. 2005;35(1):47-51.

79. Pannier F, Rabe E. Endovenous laser therapy and radiofrequency ablation of saphenous varicose veins. J Cardiovasc Surg (Torino). 2006 Feb;47(1):3-8.

80. Passman MA, Dattilo JB, Guzman RJ, Naslund TC. Combined endovenous ablation and transilluminated powered phlebectomy: is less invasive better? Vasc Endovascular Surg. 2007 Feb-Mar;41(1):41-7.

81. Peden E, Lumsden A. Radiofrequency ablation of incompetent perforator veins. Perspect Vasc Surg Endovasc Ther. 2007 Mar;19(1):73-7.

82. Perkowski P, Ravi R, Gowda RC, Olsen D, Ramaiah V, Rodriguez-Lopez JA, Diethrich EB. Endovenous laser ablation of the saphenous vein for treatment of venous insufficiency and varicose veins: early results from a large single-center experience. Endovasc Ther. 2004 Apr;11(2):132-8.

83. Pierik EG, van Urk H, Wittens CH. Efficacy of subfascial endoscopy in eradicating perforating veins of the lower leg and its relation with venous ulcer healing. J Vasc Surg. 1997 Aug;26(2):255-9.

84. Proebstle TM, Herdemann S. Early results and feasibility of incompetent perforator vein ablation by endovenous laser treatment. Dermatol Surg. 2007 Feb;33(2):162-8.

85. Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, Rother W, Bethge S, Knop J. Endovenous treatment of the greater saphenous vein with 940-nm diode laser: thrombic occlusion after endoluminal thermal damage by laser-generated steam bubbles. J Vasc Surg. 2002;35(4):729-36.

86. Puggioni A, Kalra M, Carmo M, Mozes G, Gloviczki P. Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: analysis of early efficacy and complications. J Vasc Surg. 2005 Sep;42(3):488-93.

87. Rabe E, Pannier-Fischer F, Gerlach H, Breu FX, Guggenbichler S, Zabel M; German Society of Phlebology. Guidelines for sclerotherapy of varicose veins (ICD 10: I83.0, I83.1, I83.2, and I83.9). Dermatol Surg. 2004 May;30(5):687-93; discussion 693.

88. Rabe E, Otto J, Schliephake D, Pannier F. Efficacy and safety of great saphenous vein sclerotherapy using standardised polidocanol foam (ESAF): a randomised controlled multicentre clinical trial. Eur J Vasc Endovasc Surg. 2008 Feb;35(2):238-45. Epub 2007 Nov 7.

89. Ramelet AA. Phlebectomy. Technique, indications and complications. Int Angiol. 2002 Jun;21(2 Suppl 1):46-51.

90. Rao J, Wildemore JK, Goldman MP. Double-blind prospective comparative trial between foamed and liquid polidocanol and sodium tetradecyl sulfate in the treatment of varicose and telangiectatic leg veins. Dermatol Surg. 2005 Jun;31(6):631-5; discussion 635.

91. Raulin C, Weiss RA, Schonermark MP. Treatment of essential telangiectasias with an intense pulsed light source (PhotoDerm VL). Dermatol Surg. 1997 Oct;23(10):941-5.

92. Rautio R, Saarinen J, Laranne J, Salenius JP, Keski-Nisula L. Endovascular treatment of venous malformations in extremities: results of sclerotherapy and the quality of life after treatment. Acta Radiol. 2004 Jul;45(4):397-403.

93. Ravi R, Rodriguez-Lopez JA, Trayler EA, Barrett DA, Ramaiah V, Diethrich EB. Endovenous ablation of incompetent saphenous veins: a large single-center experience. J Endovasc Ther. 2006 Apr;13(2):244-8.

94. Ricotta JJ. What's new in vascular surgery. J Am Coll Surg. 2004 Apr 1;198(4):600-25.

95. Rigby KA, Palfreyman SJ, Beverley C, Michaels JA. Surgery for varicose veins: use of tourniquet Cochrane Database of Systematic Reviews 2002. In: The Cochrane Library, 2007, Issue 4. Copyright © 2007 The Cochrane Collaboration.

96. Rigby KA, Palfreyman SJ, Beverley C, Michaels JA. Surgery versus sclerotherapy for the treatment of varicose veins. Cochrane Database of Systematic Reviews 2004. In: The Cochrane Library, 2007 Issue 4. Copyright © 2007 The Cochrane Collaboration.

97. Roth SM. Endovenous radiofrequency ablation of superficial and perforator veins. Surg Clin North Am. 2007 Oct;87-5: 1267-84, xii.

98. Sadick NS. Advances in the treatment of varicose veins: Ambulatory phlebectomy, foam sclerotherapy, endovascular laser, and radiofrequency closure. Dermatol Clin. 2005 Jul;23(3):443-55,vi.

99. Sadick NS. Predisposing factors of varicose and telangiectatic leg veins. J Dermatol Surg Oncol. 1992;18:883-6.

100. Scavee V. Transilluminated powered phlebectomy: not enough advantages? Review of the literature. Eur J Vasc Endovasc Surge. Eur J Vasc Endovasc Surg. 2006 Mar;31(3):316-9. Epub 2005 Dec 15.

101. Scavee V, Lemaire E, Haxhe JP. Transilluminated powered phlebectomy. Mid-term clinical experience. Int Angiol. 2005 Mar;24(1):75-9.

102. Scavee V, Lesceu O, Theys S, Jamart J, Louagie Y, Schoevaerdts JC. Hook phlebectomy versus transilluminated powered phlebectomy for varicose vein surgery: early results. Eur J Vasc Endovasc Surg. 2003 May;25(5):473-5.

103. Schroeter CA, Neumann HA. An intense light source. The photoderm VL-flashlamp as a new treatment possibility for vascular skin lesions. Dermatol Surg. 1998 Jul;24(7):743-8.

104. Shamiyeh A, Schrenk P, Huber E, Danis J, Wayand WU. Transilluminated powered phlebectomy: advantages and disadvantages of a new technique. Dermatol Surg. 2003 Jun;29(6):616-9.

105. Sharif MA, Lau LL, Lee B, Hannon RJ, Soong CV. Role of endovenous laser treatment in the management of chronic venous insufficiency. Ann Vasc Surg. 2007 Sep;21(5):551-5.

106. Society for Interventional Radiology. Position statement. Endovenous ablation. 2003 Dec. Accessed September 13, 2007. Available at URL address: http://www.sirweb.org/clinical/SIR_venous_ablation_statement_final_Dec03.pdf

107. Spitz GA, Braxton JM, Bergan JJ. Outpatient varicose vein surgery with transilluminated powered phlebectomy. Vasc Surg. 2000;34(6);547-55.

108. Stirling M, Shortell CK. Endovascular treatment of varicose veins. Semin Vasc Surg. 2006 Jun;19(2):109-15.

109. Subramonia S, Lees TA. The treatment of varicose veins. Ann R Coll Surg Engl. 2007 Mar;89(2):96-100.

110. Sybrandy JE, van Gent WB, Pierik EG, Wittens CH. Endoscopic versus open subfascial division of incompetent perforating veins in the treatment of venous leg ulceration: long-term follow-up. J Vasc Surg. 2001 May;33(5):1028-32.

111. Teruya TH, Ballard JL. New approaches for the treatment of varicose veins. Surg Clin N Am. 2004 Oct;84(5):1397-417viii-ix.

112. Tisi PV, Beverley CA. Injection sclerotherapy for varicose veins. Cochrane database of systematic reviews. In: The Cochrane Library, Issue 2, 2005. ©2005 The Cochrane Collaboration.

113. Trelles MA, Allones I, Alvarez J, Velez M, Martin-Vazquez M, Trellas OR, et al. The 800-nm diode laser in the treatment of leg veins: Assessment at 6 months. J Am Acad Dermatol. 2006 Feb;54(2):282-9.

114. Uchino IJ. Endovenous laser closure of the perforating vein of the leg. Phlebology. 2007;22(2):80-2.

115. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Premarket notification 510(k). 2001a. Updated 2001 Feb 6. Accessed January 2004. Available at URL address: http://www.fda.gov/cdrh/pdf/k98216.pdf

116. Uurto I, Hannukainen J, Aarnio P. Single-center experience with foam sclerotherapy without ultrasound guidance for treatment of varicose veins. Dermatol Surg. 2007 Nov;33(11):1334-9; discussion 1339.

117. van Neer PA. Perforans varicosis: treatment of the incompetent perforating vein is important. Dermatol Surg. 2004 May 1;30(5):754-5; discussion 755.

118. VNUS Medical Technologies. Safety summary. Accessed October 2, 2008. Available at URL address: http://www.vnus.com/navigation/safety.htm

119. Weiss RA. American College of Phlebology (ACP). Radio-frequency endovenous occlusion (Closure® technique). Accessed October 2003. Available at URL address: http://www.phlebology.org/closure.htm

120. Weiss RA, Dover JS. Laser surgery of leg veins. Dermatol Clin. 2002 Jan;20(1):19-36.

121. Weiss RA. Evaluation of the venous system by Doppler ultrasound and photoplethysmography or light reflection rheography before sclerotherapy. Semin Dermatol. 1993;12:78-87.

122. Welch HJ. Endovenous ablation of the great saphenous vein may avert phlebectomy for branch varicose veins. J Vasc Surg. 2006 Sep;44(3):601-5.

123. Welch HJ, Villavicencio JL. Primary varicose veins of the upper extremity: a report of three cases. J Vasc Surg. 1994 Nov;20(5):839-43.

124. Zan S, Contessa L, Varetto G, Barra C, Conforti M, Casella F, Rispoli P. Radiofrequency minimally invasive endovascular treatment of lower limbs varicose veins: clinical experience and literature review. Minerva Cardioangiol. 2007 Aug;55(4):443-58 (abstract only).

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