APPENDIX to Varicose Vein Treatments Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Treatment of venous reflux/venous insufficiency is aimed at reducing abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment includes elevation of the extremities, graded compression, and wound care, when indicated. Conventional surgical treatment consists of identifying and correcting the site of reflux by ligation of the incompetent junction followed by stripping of the vein to redirect venous flow through veins with intact valves. While most venous reflux is secondary to incompetent valves at the saphenofemoral or saphenopopliteal junctions, reflux may also occur at incompetent valves in the perforator veins or in the deep venous system. The competence of any single valve is not static and may be pressure dependent. Accessory saphenous veins may have independent saphenofermoral or saphenopopliteal junctions that become incompetent when the greater or lesser saphenous veins are eliminated and blood flow is diverted through the accessory veins.

Treatment of venous reflux typically includes the following:

- Identification by preoperative Doppler ultrasound (US) of the valvular incompetence
- Control of the most proximal point of reflux, traditionally by suture ligation of the incompetent saphenofemoral or saphenopopliteal junction

- Removal of the superficial veins from circulation, for example by stripping of the greater and/or lesser saphenous veins
- Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (microphlebectomy) or injection sclerotherapy

Venous reflux may be categorized according to the CEAP classification, which considers the clinical, etiology, anatomic and pathologic characteristics of venous insufficiency. The CEAP classification ranges from 0 to 6, with 0 describing no visible sign of disease, while 6 describes active ulceration.

*Note the term "varicose veins" does not apply to the telangiectatic dermal veins, which may be described as "spider veins" or "broken blood vessels." While abnormal in appearance, these veins typically are not associated with any symptoms, such as pain or heaviness, and their treatment is typically considered not medically necessary. Sclerotherapy alone may be commonly used to treat telangiectactic dermal veins.

Radiofrequency ablation (RFA) is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within 1 to 2 centimeter (cm) of the saphenofemoral junction. High frequency radio waves (200 to 300 Kilohertz (kHz)) are delivered through the catheter electrode and cause direct heating of the vessel wall, causing the vein to collapse by damaging the intimal wall. The catheter is slowly withdrawn, closing the vein and resulting in fibrosis. In 1999, the VNUS® Closure™ System (a radiofrequency device) (VNUS Medical Technologies, San Jose, CA) received United States Food and Drug Administration (FDA) clearance through a 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." The VNUS Radiofrequency Surgery (RFS) and RFSFlex devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins." The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008.

Laser ablation is performed similarly; a bare-tipped laser fiber is introduced into the greater saphenous vein under US guidance; the laser is activated and slowly removed along the course of the saphenous vein. Pulses of laser light are emitted inside the vein, heating the vein wall causing it to collapse, scar and seal. In 2002, the Diomed 810 nanometer (nm) surgical laser and endovenous laser therapy (EVLT)™ procedure kit (Diomed, Inc., Andover, MA) received FDA clearance through a 510(k) process, "In addition to the already cleared indications for use: for use in the endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux."

Cryoablation uses extreme cold to cause injury to the vessel.

Sclerotherapy destroys the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or a chemical irritant), ultimately resulting in the complete obliteration of the vessel. The success of treatment depends on accurate injection of the vessel, an adequate injection volume and concentration of sclerosing solution and postprocedure compressions. Historically, larger veins and very tortuous veins were not considered to be good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex US to target refluxing vessels, luminal

compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl suflfate). The foam is produced at the time of treatment and is considered an on off-label use. A proprietary microfoam sclerosant (Varisolve, BTG PLC, London) with a controlled density and more consistent bubble sizes is being developed in Europe. In late October 2009, the sponsor submitted a request to the FDA for a protocol assessment to agree on the design, endpoints and statistical analyses for the phase III trial.

Subfascial endoscopic perforator surgery (SEPS) is a minimally invasive procedure designed to interrupt incompetent perforator veins as a treatment of chronic venous insufficiency. Guided by Duplex US, small incisions are made in the skin and the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure.

Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or microphlebectomy. This procedure uses two instruments; an illuminator which also provides irrigation, and a resector, which has an oscillating tip and can perform suction. Following removal of the saphenous vein, the illuminator is introduced via a small incision in the skin and tumescence solution (anesthetic and epinephrine) is infiltrated along the course of the varicosity. The resector is then inserted under the skin from the opposite direction, and the oscillating tip is placed directly beneath the illuminated veins to fragment and loosen the veins from the supporting tissue. Irrigation from the illuminator is used to clear the vein fragments and blood through aspiration and additional drainage holes. The illuminator and resector tips may be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or microphlebectomy. It has been proposed TIPP might result in decreased operative time, decreased complications such as bruising, and faster recovery compared to the established procedures. The TriVex system (Smith & Nephew Surgical Pty Ltd., North Ryde, New South Wales) is a device for TIPP that received FDA clearance through the 510(k) process in October 2003. According to the label, the intended use is for "ambulatory phlebectomy procedures for the resection and ablation of varicose veins."

Deep vein valve replacement is being investigated.

Compression Therapy

A 2009 Cochrane review on compression for venous ulcers included a total of 39 randomized, controlled trials (RCTs), with 47 different comparisons (O'Meara et al., 2009). Objective measures of healing were the time to complete healing, the proportion of ulcers healed within the trial period (typically 12 weeks), the change in ulcer size, and the rate of change in ulcer size. Evidence from seven trials indicated venous ulcers healed more rapidly with compression than without. Findings from six trials suggested multi-component systems (bandages or stockings) were more effective than single-component compression. In addition, multi-component systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although this meta-analysis did not include time to healing, studies included in the review reported the mean time to ulcer healing was approximately two months, while the median time to healing in other reports was three to five months.

Ligation and Stripping

Systematic literature reviews published in 2008 indicated a similar healing rate of venous ulcers with superficial vein surgery and conservative compression treatments but a reduction in ulcer recurrence rate with surgery (Howard et al., 2008; O'Donnell, 2008). In general, recurrence rates after ligation and stripping are estimated at around 20%. Jones and colleagues (1996) reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping. At one year, reflux was detected in 9% of patients, rising to 26% at two years. Rutgers and Kitslaar (1994) reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy. At two years, Doppler US demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at three years.

Endovenous Radiofrequency Ablation

In 2003, the Society of Interventional Radiography (SIR) published a position statement that considered endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins under the following conditions:

1. The endovenous treatment of varicose veins may be medically necessary when one of the following indications (A through E) is present:
    - Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching, and/or swelling during activity or after prolonged standing
    - Significant recurrent attacks of superficial phlebitis
    - Hemorrhage from a ruptured varix
    - Ulceration from venous stasis where incompetent varices are a contributing factor
    - Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above) and

2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings and;

3. The patient's anatomy is amenable to endovenous ablation.

In a joint statement published in 2007, the American Venous Forum and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency (Kundu et al., 2007). The document recommended reporting in clinical studies should include the symptoms of venous disease, history of disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted potential candidates for endovenous ablation may include patients with reflux in an incompetent greater saphenous vein or smaller saphenous vein or in a major tributary branch of the greater or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory greater saphenous vein. The presence of reflux in these veins is important to document using Duplex US imaging, and the US criteria used to define reflux should be indicated. It was also stated in current practice, most vascular laboratories considered the presence of venous flow reversal

greater than 0.5 to 1.0 seconds with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

In 2008, Luebke and colleagues reported on a meta-analysis of eight studies that included a total of 224 patients who underwent endovenous RFA and 204 patients who underwent stripping. There was no significant difference between RFA and surgery in immediate or complete greater saphenous vein occlusion, incomplete greater saphenous vein closure, freedom from reflux, recurrent varicose veins, recanalization, or neovascularization between the two treatments. There were significant reductions in tenderness and ecchymosis at one week and fewer hematomas at 72 hours, one week, and three weeks with RFA. Quality-of-life results, including return to normal activity and return to work, favored RFA over surgery. The authors noted rates of recanalization, retreatment, occlusion, and reflux may alter with longer follow-up and further RCTs with longer follow-up are needed.

Long-term outcomes of endovenous RFA were reported from the Closure Study Group clinical registry in 2005 (Merchant & Pichot, 2005). Thirty-four centers (1,006 patients, 1,222 limbs) participated in the registry, with 12 centers contributing five-year data (406 limbs). The registry included data on the treatment of 52 lesser saphenous veins and 16 accessory saphenous veins. Follow-up at one week showed a 97% anatomical success rate and a decrease in pain in 50% (from 85% to 30%) of patients. An additional 162 failures were identified over the five-year follow-up, 129 veins were found to have recanalization, and 33 limbs had reflux in the groin. Logistic regression analysis (risk factors of gender, age, body mass index (BMI), vein diameter, and catheter pullback speed) showed BMI was associated with long-term failure. The rate of pull-back speed of the catheter during treatment was associated with failure to occlude or recanalization.

Endovenous Laser Ablation

A systematic review of endovenous laser ablation (EVLA) versus surgery was published in 2009 by Hoggan and associates. Fifty-nine studies were included, with seven studies that directly compared EVLA and surgery. Randomized and non-randomized studies directly comparing outcomes for EVLA or surgery were included for the assessment of safety or effectiveness, while case series with a minimum patient population of 100 were included for the assessment of safety alone. For all studies, it was calculated 5,759 patients (6,702 limbs) were treated with EVLA and 6,395 patients (7,727 limbs) underwent surgery. Few differences were apparent between treatments with respect to clinical effectiveness outcomes, although long-term follow-up was lacking. Non-clinical effectiveness outcomes generally favored EVLA over surgery in the first two months after treatment. The authors concluded while EVLA offered short-term benefits and appeared to be as clinically effective as surgery up to 12 months after treatment, clinical trials with a minimum of three years follow-up were required to establish the enduring effectiveness of EVLA.

In 2009 Theivacumar et al., reported two-year follow-up from 118 consecutive patients treated with either EVLA (69 limbs) or ligation and stripping (n = 60 limbs). Sixty-eight patients agreed to be randomized to treatment; the remainder declined randomization but received one of the two treatments and agreed to follow-up. The rationale for the selection of treatment in the non-randomized population was not described. Rates of clinical recurrence (7%) were similar in the

two treatment groups at two years. Recanalization of the residual greater saphenous vein, reflux in the accessory greater saphenous vein, and reflux in incompetent perforator veins accounted for the majority of cases of clinical recurrence (6%) in both groups. Neovascularization was observed in only 1% of limbs treated with endoluminal ablation and 18% of limbs treated with ligation and stripping (2% were clinically significant at two years). Early neovascularization has been associated with clinical recurrence at five years.

Rasmussen et al., (2010) randomized 121 patients (137 legs) to EVLA (n = 69) or to ligation and stripping (n = 68). The incidence of clinical recurrence was found to increase gradually from six months onward. At two-year follow-up, outcomes were similar between the two groups. In the EVLA group, there were three (4%) technical failures, 18 (26%) clinical recurrences, six (8%) cases of reflux into the anterior accessory saphenous vein, two (3%) cases of reflux in the groin, and seven (10%) cases of reflux in perforator veins. In the ligation and stripping group, there were two (3%) technical failures, 25 (37%) recurrences, three (4%) cases of reflux in the accessory vein, three (4%) cases of reflux in the groin, and 15 (22%) cases of reflux in perforator veins. Another trial compared EVLA with ligation and stripping in 200 limbs (100 in each group) (Christenson et al., 2010). At one-year follow-up, 98% of the limbs were reported to be free of symptoms. At two-year follow-up, the EVLA group had two veins completely reopened and five partially reopened, which was significantly greater than in the ligation and stripping group.

Endovenous Cryoablation

Klem and colleagues (2009) reported on a randomized trial that found endovenous cryoablation (n = 49) to be inferior to conventional stripping (n = 245) for treating patients with symptomatic varicose veins. The percentage of patients with greater saphenous veins remaining was 44% in the endovenous cryoablation group and 15% in the conventional stripping group. The Aberdeen Varicose Vein Questionnaire also showed better results for conventional stripping (score of 11.7) in comparison with cryoablation (score of 8.0). There were no differences between the groups in Short-Form-36 (SF-36) subscores, and neural damage was the same (12%) in both groups.

Sclerotherapy

In 2009 the National Institute for Health and Clinical Excellence updated their US-guided foam sclerotherapy for varicose veins. The guidance stated:

> …evidence on US-guided foam sclerotherapy for varicose veins shows that it is efficacious in the short term. The evidence on safety includes systemic side effects in some patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit. In addition, evidence of long-term efficacy is limited, and clinicians are encouraged to collect longer-term follow-up data.

More recent randomized trials using US-guided foam sclerotherapy of the greater saphenous vein (with or without ligation) showed high variability in success rates between centers (ranging from 25% to 100%) and a decline in success rates from 85% at 3-week follow-up to 53% at two years (Jia et al., 2007; Ouvry et al., 2008; Rabe et al., 2008). Other studies indicated efficacy rates ranging from 12% to 76% for liquid sclerosant and from 57% to 84% for foam sclerosant (Hamel-Desnos & Allaert, 2009).

A systematic review from 2008 found foam sclerotherapy of varicose veins was associated with a higher recurrence rate in patients with saphenofemoral incompetence compared to the rates of EVLT or RFA, while a 2009 systematic review suggested outcomes from sclerotherapy are worse than those of surgery (ligation and stripping) for saphenous vein reflux (Leubke & Brunkwall, 2008; Leopardi et al., 2009). Although long-term sequelae have not been reported, transient adverse effects have been found in up to 8% of patients, including visual disturbance, migraine, shortness of breath, dizziness, and numbness (Smith, 2009). Bubbles appeared in the right heart between nine and 59 seconds after injection, and emboli have been detected in the middle cerebral artery following sclerotherapy of saphenous trunks and varices (Smith, 2009). Deep venous occlusion after US-guided sclerotherapy has also been reported; risk was found to be greater when treating veins 5 millimeter (mm) in diameter or greater (odds ratio (OR): 3.7) and injecting 10 milliliter (mL) or more of foamed sclerosant (OR: 3.6) (Myers & Jolley, 2008).

Blaise et al., (2010) reported three-year follow-up from a multicenter double-blind randomized trial (143 patients) that compared treatment of the greater saphenous vein with either 1% or 3% polidocanol foam. Additional treatment with foam sclerotherapy was carried out at six weeks, three and six months if required to abolish persistent venous reflux. There were 49 additional injections in the 1% polidocanol group and 29 additional injections in the 3% group. At three-year follow-up, venous reflux was observed in 21% of patients in the 1% group and 22% of patients in the 3% polidocanol group.

Treatment of Tributary Varicosities

Sclerotherapy and Phlebectomy

Early studies established ligation and stripping as the gold standard for the treatment of saphenofemoral incompetence based on improved long-term recurrence rates, with sclerotherapy used primarily as an adjunct to treat varicose tributaries. A 2006 Cochrane Review, based primarily on RCTs from the 1980s, concluded, “The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins” (Tisi et al., 2006). Sclerotherapy and phlebectomy are considered appropriate in the absence of reflux of the saphenous system, (e.g., post- or adjunctive treatment to other procedures such as surgery) (Leopardi et al., 2009).

A small proportion of patients may present with tributary varicosities in the absence of saphenous reflux. In a study by Michaels et al., (2006) it was found that in 1,009 patients recruited for a RCT, 64 patients had minor varicose veins without reflux, 34 of whom agreed to be randomized to sclerotherapy or conservative treatment. At baseline, 92% had symptoms of heaviness, 69% had cosmetic concerns, 53% reported itching, and 30% reported relief of symptoms through the use of compression hosiery. At one year follow-up, there was an improvement in clinicians' assessment of the anatomical extent of varicose veins, with 85% of patients in the sclerotherapy group improved compared to 29% of patients in the conservative-therapy group. Symptoms of aching were better or eliminated in 69% of the sclerotherapy group and 28% of the group treated with conservative therapy. Cosmetic concerns were improved in 85% of the sclerotherapy patients and 14% of controls.

Transilluminated Powered Phlebectomy

A 2008 meta-analysis included five studies comparing TIPP with conventional surgery (Luebke & Brunkwall, 2008). Results showed a significant advantage of TIPP over the conventional treatment for number of incisions, mean cosmetic score, and duration of the procedure. However, TIPP also increased the incidence of hematoma and resulted in worse mean pain scores. Included in the meta-analysis was a randomized clinical trial by Chetter et al., (2006) that compared TIPP (n = 29) with a multiple stab incision procedure (n = 33). A single surgeon performed all but two of the procedures, and there was no difference in operating time. Patients treated with TIPP had an average of five incisions, compared with 20 for the multiple stab procedure. However, blinded evaluation revealed bruising or discoloration was higher for the TIPP group at both one and six weeks after surgery. At six weeks after surgery, patients in the TIPP group showed no improvement in pain (-2 points on the Burford pain scale), while patients in the multiple stab incision group had a significant improvement in pain score compared with presurgical baseline (-20 points). At six weeks after surgery, quality-of-life measures had improved in the multiple stab incision group but not in the TIPP group. Therefore, although TIPP had the advantage of fewer surgical incisions, in this single-center study, it was associated with a more prolonged recovery due to more extensive bruising, prolonged pain, and reduced early postoperative quality of life. The current literature does not show an advantage of TIPP over conventional treatment.

Treatment of Perforator Reflux

A systematic literature review published in 2008 indicated insufficient evidence for the role of incompetent perforator vein surgery (O'Donnell, 2008). These conclusions were based on four RCTs published since 2000 that compared superficial vein surgery with conservative therapy in advanced chronic venous insufficiency (CEAP classification (clinical, etiologic, anatomic, pathologic characteristics) category C5/6). The four trials included two level I (large subject population) and two level II (small subject population) studies. Two of the trials combined surgical treatment of the incompetent perforator veins with concurrent or prior treatment of the superficial saphenous veins; the other two treated the greater saphenous vein alone. The two randomized studies in which the greater saphenous vein alone was treated (including the effect of surgery and compression on healing and recurrence (ESCHAR) trial) showed a significant reduction in ulcer recurrence in comparison with conservative therapy (Barwell et al., 2004; Gohel et al., 2007). In addition, treatment of the great saphenous vein alone was reported to improve perforator function. One study showed reversal of perforator vein incompetence (41% of 68 previously incompetent perforators) was more common than new perforator vein incompetence (22% of 183 previously competent perforators) following superficial vein surgery (Blomgren et al., 2005). O'Donnell (2008) discussed additional (lower quality) evidence to suggest deep venous valvular involvement rather than incompetent perforators in venous insufficiency. Thus, although incompetence of perforator veins is frequently cited as an important etiologic factor in the pathogenesis of venous ulcer, current evidence does not support the routine ligation or ablation of perforator veins.

Subfascial Endoscopic Perforator Surgery

In 2004, Tenbrook and colleagues published a review of the literature of SEPS, which included 19 case series and one randomized trial. In total, the reviewed studies included 1,031 patients with 1,140 treated limbs. The authors concluded SEPS was associated with excellent results in terms of ulcer healing and prevention of recurrence. However, the authors also noted randomized

trials were required to define the relative contributions of compression therapy, superficial venous surgery, and SEPS in the management of severe venous disease. A 2009 meta-analysis of SEPS for chronic venous insufficiency concluded that “Its [SEPS] use should not be employed routinely and could only be justified in patients with persistent ulceration thought to be of venous origin, and in whom any superficial reflux has already been ablated and post-thrombotic changes excluded" (Luebke & Brunkwall, 2009). The authors also stated “introduction of less invasive techniques for perforator vein ablation, such as US-guided sclerotherapy or radiofrequency ablation may diminish the role of SEPS in the future."

A 2008 review of procedures for management of varicose veins recommended Duplex-guided foam sclerotherapy, microincision phlebectomy, or thermal ablation using a new short RF catheter for the treatment of symptomatic residual perforator vein incompetence (Hirsch & Dillavou, 2008). Ablation of incompetent perforator veins with laser or RFA had been shown to be technically feasible, although no studies had been identified that showed an improvement in clinical outcomes (e.g., ulcer healing or recurrence) (Chetter et al., 2006; Luebke & Brunkwall, 2008; Leopardi et al., 2009; Smith, 2009). One study published in 2010 on EVLA for perforating veins examined 33 patients with a CEAP classification of 4 (skin changes), 5 (healed ulcer) or 6 (active ulcer) (Hissink et al., 2010). All incompetent saphenous trunks were treated simultaneously (63% of limbs). At three-month follow-up, occlusion was achieved in 78% of the perforating veins. Five patients (15%) had active ulcers at baseline; four of the five ulcers had healed by six weeks after EVLA. Evidence regarding the treatment of perforator veins with US-guided sclerotherapy is limited, and there is a risk of deep venous occlusion (Myers & Jolley, 2008).

In 2009, the American College of Radiology published appropriateness criteria for the treatment of lower-extremity venous insufficiency (Silberzweig et al., 2009). The following is a summary of treatment options:

Compression Stockings: Graduated compression stockings are routinely used to control venous insufficiency symptoms. They provide external support that can constrict dilated veins and restore competence to incompetent valves. Compression stockings are particularly helpful during pregnancy, and they are frequently used following venous ablation treatment.

Surgery: Great saphenous vein stripping with branch ligation had historically been the primary treatment option for venous insufficiency. The great saphenous vein is ligated near the groin. Ligation alone can preserve the vein for subsequent harvesting in case of arterial bypass; however, ligation alone has proven unsatisfactory for preventing the occurrence of reflux, so it is often supplemented by vein stripping. Ambulatory phlebectomy is primarily used to treat surface varicose veins. It can be performed as an adjunct to endovenous ablation or stripping. This procedure involves making tiny punctures or incisions through which the varicose veins are removed. Other surgical methods to treat venous insufficiency have been described, including SEPS for treating venous ulcers and valvular surgery for treating reflux caused by incompetent valves of the deep veins.

Injection Sclerotherapy: Injection sclerotherapy is a common treatment for telangiectasias and can be used to treat smaller varicose veins. The sclerotherapy solution can be in liquid form or

can be injected as "foam" (mixed with a gas such as air). Sclerotherapy has not been shown to have long-term effectiveness for large veins, such as the great saphenous vein.

Endovenous Ablation: Endovenous ablation is a minimally invasive alternative to surgery. It is a percutaneous procedure that can be used to treat the greater saphenous vein, small saphenous vein and other superficial veins. Endovenous ablation uses RFA or laser energy (EVLA) applied inside the vein to cause occlusion. Small prospective trials comparing EVLA and RFA with conventional surgery in patients with great saphenous vein reflux have shown favorable results. One study demonstrated EVLA is comparable to surgery in abolishing reflux and improving disease-specific quality of life and it allows earlier return to normal activity. A recent systematic literature review comparing the safety and efficacy of EVLA and surgery involving saphenous ligation and stripping as treatments for varicose veins showed few differences in clinical effectiveness outcomes, although long-term follow-up was lacking. A meta-analysis suggested EVLA and RFA are at least as effective as surgery in treating lower-extremity varicose veins. After three years, the estimated pooled success rates for treatment were 78% for surgical stripping, 77% for foam sclerotherapy, 84% for RFA, and 94% for laser therapy.

Adjunctive Treatments: Adjunctive treatments may be required to help eliminate venous insufficiency. Patients with venous insufficiency and associated venous occlusion or stenosis of the common iliac vein (e.g., May-Thurner syndrome) may require venous recanalization with angioplasty and stenting to achieve a patent conduit for venous return. Patients with pelvic venous insufficiency may need percutaneous embolization of the ovarian veins. Patients with deep venous thrombosis are typically treated with anticoagulation to reduce the risk of thrombus propagation, embolization, and post-thrombotic syndrome. One study suggested endovenous ablation of the saphenous vein could be considered as a viable treatment alternative in patients with venous insufficiency and previous deep venous thrombosis.

Complications: All forms of lower-extremity venous insufficiency treatment are subject to recurrence. Additional risks of vein ligation and stripping surgery include: anesthetic risk, scarring, pain, bleeding, deep venous injury or thrombosis, nerve injury, and infection. Complications of the endovenous ablation procedure include bruising, swelling, transient numbness, and rarely deep venous thrombosis.

In summary, although RCTs with longer follow-up are needed to evaluate long-term durability, and repeat treatments may be required, evidence indicates endovenous treatment of saphenous veins with radiofrequency or laser ablation improves short-term clinical outcomes (e.g., pain and return to work) in comparison with surgery. In contrast, results from a RCT of cryoablation indicated this therapy is inferior to conventional stripping. Sclerotherapy as the sole treatment of saphenofemoral or saphenopopliteal reflux has not been demonstrated to be as effective as available alternatives.

The literature indicated sclerotherapy of tributaries following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins may be considered medically necessary. Evidence is insufficient to evaluate the health benefit of sclerotherapy as a sole treatment of varicose tributaries without prior or concurrent treatment of the saphenous veins. No studies have been identified that compare radiofrequency or laser ablation of tributary veins with standard procedures (stab phlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy is

effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion.

The literature indicated routine ligation/ablation of incompetent perforator veins is not medically necessary for the treatment of varicose veins/venous insufficiency at the time of superficial vein procedures. However, when combined superficial vein procedures and compression therapy have failed to improve symptoms (e.g., ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (e.g., deep vein valve replacement). Therefore, treatment of incompetent perforator veins may be considered medically necessary in this specific situation.

Comparative studies are needed to determine the most effective method of ligating/ablating incompetent perforator veins. Subfascial endoscopic perforator surgery has been shown to be as effective as the Linton procedure with a reduction in adverse events. Although only one case series has been identified showing an improvement in health outcomes, endovenous ablation with specialized laser or radiofrequency probes has been shown to effectively ablate incompetent perforator veins with a potential decrease in morbidity in comparison with surgical interventions. For sclerotherapy, concerns have been raised about the risk of deep vein occlusion and evidence is currently insufficient to evaluate the safety or efficacy of this treatment for incompetent perforator veins.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	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

Type	Number	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	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; 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	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; 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), including skin graft, when performed, open,1 leg
	37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
	37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions

Type	Number	Description
	37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
	37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
HCPC	S2202	Echosclerotherapy
ICD9 Procedure		
	38.5	Ligation and stripping of varicose veins
	38.59	Ligation and stripping of lower limb varicose veins
	39.92	Injection of sclerosing agent into vein
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

Definitions

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
10/11/2000	New Policy Adoption	Medical Policy Committee
2/26/2002	Coding Update	Administrative Review
10/29/2002	Coding Update	Administrative Review
9/1/2003	Policy Revision	Medical Policy Committee
5/1/2006	Policy Revision	Medical Policy Committee
8/1/2006	Policy Revision	Medical Policy Committee
6/28/2007	BCBSA Medical Policy adoption	Medical Policy Committee

Effective Date	Action	Reason
12/10/2008	Policy Title Revision, criteria revised, BCBSA Medical Policy Adoption	Medical Policy Committee
9/3/2009	Administrative Review	Administrative Review
7/1/2011	Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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