

MEDICAL POLICY – 7.01.519

Treatment of Varicose Veins/Venous Insufficiency

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RELATED MEDICAL POLICIES:

10.01.514 Cosmetic and Reconstructive Services

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Introduction

Varicose veins are swollen, twisted veins that are visible just below the skin. They most often occur in the legs but can develop in other parts of the body. Veins have valves that keep the blood moving toward the heart. If the valves are weak or damaged, blood can pool in the veins. It's this pooling that causes the veins to swell and appear twisted. Most varicose veins do not result in physical symptoms. On occasion, they can cause symptoms such as pain, an achy feeling, bleeding, or skin ulcers (sores). Varicose veins usually can be treated without surgery by activities such as exercising, raising the legs, or wearing compression stockings. This policy describes when varicose vein surgery or other procedures may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

| Procedures | Medical Necessity |
|--|--|
| <p>Vein ablation procedures:</p> <ul style="list-style-type: none"> • Surgery (ligation and stripping) • Thermal ablation (radiofrequency or laser) • Chemical ablation (microfoam sclerotherapy) <p>(36465, 36466, 36475, 36476, 36478, 36479, 37700, 37718, 37722, 37735, 37780, 37785)</p> | <p>Surgery (ligation and stripping), thermal ablation (radiofrequency or laser), or chemical ablation (microfoam sclerotherapy, eg, Varithena) may be considered medically necessary for treatment of symptomatic varicose veins (<u>great or small saphenous veins</u>)/venous insufficiency when the following criteria have been met:</p> <ul style="list-style-type: none"> • There is moderate to severe (greater than 0.5 second) saphenous reflux documented on venous studies and CEAP [Clinical-Etiology-Anatomy-Pathophysiology] class C2 or greater (see Definition of Terms) <p>AND</p> <ul style="list-style-type: none"> • There is documentation of ONE or more of the following four indications: <ul style="list-style-type: none"> ○ Ulceration secondary to venous stasis, or ○ Recurrent superficial thrombophlebitis, or ○ Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity, or ○ Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux along with both of the following: <ul style="list-style-type: none"> ▪ These symptoms significantly interfere with activities of daily living, and ▪ Conservative management, including compression therapy (see Definition of Terms) for at least 3 months, has not improved the symptoms <p>Note: If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work.</p> <p>Treatment of <u>great or small saphenous veins</u> by surgery, thermal ablation (radiofrequency or laser), or chemical ablation (microfoam sclerotherapy) that does not meet the criteria described above is considered not medically necessary.</p> |



| Procedures | Medical Necessity |
|------------|---|
| | <p>Surgery (ligation and stripping), thermal ablation (radiofrequency or laser), or chemical ablation (microfoam sclerotherapy (eg, Varithena) may be considered medically necessary for treatment of symptomatic <u>accessory saphenous veins</u> /venous insufficiency when ALL of the following criteria have been met:</p> <ul style="list-style-type: none"> • Incompetence of the accessory saphenous vein is isolated <p>OR</p> <ul style="list-style-type: none"> • The great or small saphenous veins have previously been eliminated (at least 3 months) <p>AND</p> <ul style="list-style-type: none"> • There is moderate to severe (greater than 0.5 second) accessory saphenous reflux documented on venous studies <p>AND</p> <ul style="list-style-type: none"> • There is documentation of ONE or more of the following four indications: <ul style="list-style-type: none"> ○ Ulceration secondary to venous stasis, or ○ Recurrent superficial thrombophlebitis, or ○ Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity, or ○ Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux along with both of the following: <ul style="list-style-type: none"> ▪ These symptoms significantly interfere with activities of daily living, and ▪ Conservative management, including compression therapy (see Definition of Terms) for at least 3 months, has not improved these symptoms. <p>Note: If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work</p> <p>Treatment of <u>accessory saphenous veins</u> by surgery, thermal ablation (radiofrequency or laser), or chemical ablation</p> |



| Procedures | Medical Necessity |
|---|--|
| | <p>(microfoam sclerotherapy (eg, Varithena) that does not meet the criteria described above is considered not medically necessary.</p> <p>Thermal ablation (radiofrequency or laser) of tributary veins is considered investigational</p> |
| <p>Vein ablation procedures:</p> <ul style="list-style-type: none"> • Stab avulsion • Hook phlebectomy • Sclerotherapy • TIPP* <p>(36470, 36471, 37765, 37766, 37799)</p> <p>Note: *TIPP-Transilluminated powered phlebectomy</p> | <p>Phlebectomy (stab avulsion, hook phlebectomy, or TIPP) or initial* sclerotherapy as a component of the treatment of symptomatic varicose tributaries when performed either at the same time or following prior treatment (surgical, radiofrequency, or laser) of the saphenous veins is considered medically necessary.</p> <p>Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins is considered investigational.</p> <p>Note: *Initial sclerotherapy for these indications is limited to a maximum of 3 sclerotherapy treatment sessions per leg.</p> <p>For sclerotherapy treatment requests after ablation (surgical, radiofrequency, or laser) of the saphenous veins, when performed for the treatment of residual or recurrent symptoms, there must be 3 months of conservative management, including compression therapy (see Definition of Terms) after the most recent varicose vein procedure, which has not successfully treated the patient’s symptoms.</p> <p>Note: If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux, despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work.</p> <p>Any other techniques, other than stab avulsion, hook phlebectomy, sclerotherapy (liquid or foam), or TIPP, for the treatment of symptomatic varicose tributaries, when performed either at the same time or following prior</p> |



| Procedures | Medical Necessity |
|---|---|
| | <p>treatment of saphenous veins, is considered investigational.</p> <p>Sclerotherapy techniques, other than microfoam sclerotherapy (eg, Varithena), of great, small, or accessory saphenous veins is considered investigational.</p> <p>Sclerotherapy of perforator veins is considered investigational.</p> <p>Stab avulsion, hook phlebectomy, or TIPP of perforator, great or small saphenous, or accessory saphenous veins is considered investigational.</p> |
| <p>Ultrasound guidance</p> | <p>It should be noted that the bulk of the literature discussing the role of ultrasound guidance refers to sclerotherapy of the saphenous vein, as opposed to the varicose tributaries. When ultrasound guidance is used to guide sclerotherapy of the varicose tributaries, it would be considered either not medically necessary or incidental to the injection procedure.</p> |
| <p>Vein ablation procedures:</p> <ul style="list-style-type: none"> • Surgery (ligation)/SEPS • Thermal ablation (radiofrequency, laser) <p>(37500, 37760, 37761)</p> | <p>Surgical ligation (including subfascial endoscopic perforator surgery [SEPS] or thermal ablation (radiofrequency or laser) of incompetent perforator veins may be considered medically necessary as a treatment of leg ulcers associated with chronic venous insufficiency when ALL of the following criteria have been met:</p> <ul style="list-style-type: none"> • There is documented perforator reflux (greater than 0.5 second) on venous studies; and • The superficial saphenous veins (great, small, accessory saphenous and symptomatic varicose tributaries) have been previously eliminated; and • Ulcers have not resolved following combined superficial vein treatment and compression therapy (see Definition of Terms) for at least 3 months; and • The venous insufficiency is not secondary to deep venous thromboembolism <p>Note: If compression therapy is successful, it should be continued for as long as it is working. Failure of conservative therapy is defined as pain, swelling, itching, burning, or other symptoms associated with vein reflux,</p> |



| Procedures | Medical Necessity |
|-------------------------------|---|
| | <p>despite conservative therapy, severe enough to require daily pain medicines and causing inability to manage daily activities at home or at work</p> <p>Ligation or ablation of incompetent <u>perforator veins</u> performed concurrently with superficial venous surgery is not medically necessary.</p> |
| Telangiectasia (36468) | Treatment, by any method, of small telangiectasia such as spider veins (1mm or less), superficial reticular veins (1-2 mm), angiomata, and hemangiomata is considered cosmetic. |

| Treatment | Investigational |
|--|--|
| <p>Other techniques</p> <p>(36473, 36474, 36482, 36483, 37799)</p> | <p>The following techniques are considered investigational for the treatment of any vein(s):</p> <ul style="list-style-type: none"> • Cyanoacrylate adhesive (eg, VenaSeal™ Closure System) • Endovenous cryoablation • Mechanochemical ablation (eg, MOCA, ClariVein™ Catheter) <p>Note: This list may not be all inclusive.</p> |

| Documentation Requirements |
|---|
| <p>Review of this procedure requires the provider to specifically indicate the following in the clinical notes submitted with the request:</p> <ul style="list-style-type: none"> • Specific procedures to be performed, including the CPT code (s) <p>AND</p> <ul style="list-style-type: none"> • Specific vein to be treated for each CPT code and whether the proposed treatment is to the left leg, right leg, or both legs <p>Additionally, written documentation in the medical record must include:</p> <ol style="list-style-type: none"> 1. CPT codes for the procedures being requested, and the name of the vein to be treated with each CPT code 2. Copy of the venous studies (ultrasound studies evaluating blood flow in the veins) 3. CEAP (Clinical-Etiology-Anatomy-Pathophysiology) class C2 or greater (Clinical classification, large varicose veins) 4. One or more indications: <ul style="list-style-type: none"> ○ Ulceration secondary to venous stasis (leg ulcers caused by poor blood flow in the veins) |



Documentation Requirements

- Recurrent superficial thrombophlebitis (recurrent blood clots or inflammation in a small veins near the surface of the skin)
- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity (bleeding from a varicose vein)
- Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux (pooling of the blood caused by valves that don't work correctly)

AND

- These symptoms significantly interfere with activities of daily living
- Conservative management including compression therapy for at least 3 months has not improved the symptoms

Coding

| Code | Description |
|------------|---|
| CPT | |
| 0524T | Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring (new code effective 1/1/19) |
| 36465 | Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein) (Varithena) |
| 36466 | Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg (Varithena) |
| 36468 | Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk |
| 36470 | Injection of sclerosing solution; single vein |
| 36471 | Injection of sclerosing solution; multiple veins, same leg |
| 36473 | Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated |
| 36474 | Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated |



| Code | Description |
|-------|--|
| | in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) |
| 36475 | Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated |
| 36476 | Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; 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) |
| 36482 | Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated |
| 36483 | Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) |
| 37500 | Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS) |
| 37700 | Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions |
| 37718 | Ligation, division, and stripping, short saphenous vein |
| 37722 | Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below |
| 37735 | Ligation and division and complete stripping of long and 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 |
| 37761 | Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg |
| 37765 | Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions |



| Code | Description |
|-------|---|
| 37766 | Stab phlebectomy of varicose veins, 1 extremity; more than 20 stab incisions |
| 37780 | Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure) |
| 37785 | Ligation, division, and/or excision of varicose vein cluster(s), one leg |
| 37799 | Unlisted procedure, vascular surgery (eg, MOCA ClariVein, TRIVEX System) |

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Accessory saphenous veins: Veins that travel in parallel with the greater and lesser saphenous veins and are generally 2 to 2.5 mm in their normal state.

Clinical-Etiologic-Anatomic-Pathophysiology (CEAP) classification system: The standard classification of venous disease considers the clinical, etiologic, anatomic, and pathologic (CEAP) characteristics of venous insufficiency. See table below.

| Class | Clinical Classification |
|-------|--|
| C0 | No visible or palpable signs of venous disease |
| C1 | Telangiectasies or reticular veins |
| C2 | Varicose veins |
| C3 | Edema |
| C4a | Pigmentation and eczema |
| C4b | Lipodermatosclerosis and atrophie blanche |
| C5 | Healed venous ulcer |
| C6 | Active venous ulcer |
| S | Symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction |
| A | Asymptomatic |



Compression Therapy: Compression hosiery or stockings are often the first line of treatment for varicose veins. Compression stockings are generally thought to be effective in a range of 20 mmHg to 40mmHg. The Society for Vascular Surgery/American Venous Forum recommends compression therapy of 20-30 mmHg for patients with symptomatic varicose veins. Compression stockings of 20-30mmHg are available over the counter without a prescription.

Greater/long saphenous vein: Superficial vein running the entire length of the leg and is generally 3 mm in its normal state. A typical GSV contains an average of 7 valves throughout its entire length, and it is the most common superficial vein to develop venous reflux.

Lesser (small)/short saphenous veins: Superficial vein of the calf and is generally 2.5 mm in its normal state. The small saphenous vein originates at the back of the ankle near the outer malleous bone, and usually runs up the back of the lower leg to the popliteal vein behind the knee.

Moderate to severe reflux: In current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

Perforator veins: These connect superficial veins to deep veins. They contain one-way valves to direct the blood from the superficial system to the deep system and are generally less than 3mm in their normal state.

Stab avulsion: This technique is also known as stab/hook phlebectomy. Stab avulsion results in removal of the varicose veins through incisions that are 2-3 mm in length. The veins are hooked with a tiny hook-like instrument and pulled out. The wounds are closed with tapes, not sutures, and the leg is wrapped in elastic compression support. Once healed, the incision sites are almost invisible.

Telangiectasia/spider veins: Very small (≤ 1 mm in diameter) thread veins found commonly just under the surface of the skin, usually not distorting skin or surrounding tissues. These are not considered varicose veins.

Tributary veins: Veins that empty into a larger vein.

Evidence Review



Description

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgery, thermal ablation, and sclerotherapy. The application of each modality is influenced by the severity of the symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent) treatments.

Background

Venous Reflux/Venous Insufficiency

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory, or duplicate, veins that travel in parallel with the great and small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins. Varicose veins with visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification of venous disease considers the clinical, etiologic, anatomic, and pathologic characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

Treatment

Treatment of venous reflux/venous insufficiency seeks to reduce abnormal pressure transmission from the deep to the superficial veins. Conservative medical treatment consists of 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 the deep venous system. The competence of any single valve is not static and may be pressure-dependent. For example, accessory saphenous veins may have independent



saphenofemoral or saphenopopliteal junctions that become incompetent when the great or small saphenous veins are eliminated, and blood flow is diverted through the accessory veins.

Treatment of Saphenous Veins and Tributaries

Saphenous veins include the great and small saphenous and accessory saphenous veins that travel in parallel with the great or small saphenous veins. Tributaries are veins that empty into a larger vein. Treatment of venous reflux typically includes the following:

- Identification by preoperative Doppler ultrasonography 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 vein from circulation, eg, by stripping of the great and/or small saphenous veins
- Removal of varicose tributaries (at the time of the initial treatment or subsequently) by stab avulsion (phlebectomy) or injection sclerotherapy.

Minimally invasive alternatives to ligation and stripping have been investigated. They include sclerotherapy, transilluminated-powered phlebectomy, and thermal ablation using cryotherapy, high frequency radio waves (200–300 kHz), or laser energy.

Thermal Ablation

Radiofrequency ablation (RFA) is performed using a specially designed catheter inserted through a small incision in the distal medial thigh to within 1 to 2 cm of the saphenofemoral junction. The catheter is slowly withdrawn, closing the vein. Laser ablation is performed similarly; a laser fiber is introduced into the great saphenous vein under ultrasound guidance; the laser is activated and slowly removed along the course of the saphenous vein. Cryoablation uses extreme cold. The objective of endovenous techniques is to injure the vessel, causing retraction and subsequent fibrotic occlusion of the vein. Technical developments since thermal ablation procedures were initially introduced include the use of perivenous tumescent anesthesia, which allows successful treatment of veins larger than 12 mm in diameter and helps to protect adjacent tissue from thermal damage during treatment of the small saphenous vein.



Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately occluding the vessel. Treatment success depends on accurate injection of the vessel, an adequate injectate volume and concentration of sclerosant, and compression. Historically, larger veins and very tortuous veins were not considered good candidates for sclerotherapy due to technical limitations. Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are commonly produced by forcibly mixing a gas (eg, air or carbon dioxide) with a liquid sclerosant (eg, polidocanol or sodium tetradecyl sulfate). The foam is produced at the time of treatment.

Endovenous Mechanochemical Ablation (MCA)

Endovenous mechanochemical ablation uses both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, and results in less pain and risk of nerve injury without the need for the tumescent anesthesia used with endovenous thermal ablation techniques (radiofrequency ablation [RFA] and endovenous laser treatment [EVLT]).

Cyanoacrylate Adhesive for Embolization (CAE)

A cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (ie, polymerizes into a solid material on contact with body fluids or tissue). The adhesive is gradually injected along the length of the vein in conjunction with ultrasound and manual compression. The acute coaptation halts blood flow through the vein until the implanted adhesive becomes fibrotically encapsulated and establishes chronic occlusion of the treated vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and to seal surgical incisions or other skin wounds.



Transilluminated Powered Phlebectomy (TIPP)

Transilluminated powered phlebectomy (TIPP) is an alternative to stab avulsion or hook phlebectomy. This procedure uses 2 instruments: an illuminator which also provides irrigation, and a resector, which has an oscillating tip and suction pump. 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 then be repositioned, thereby reducing the number of incisions needed when compared with stab avulsion or hook phlebectomy. It has been proposed that transilluminated powered phlebectomy might decrease surgical time, decrease complications such as bruising, and lead to a faster recovery than established procedures.

Treatment of Perforator Veins

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally treated with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may occasionally be used to close incompetent perforator veins that cannot be reached by less invasive procedures.

Subfascial endoscopic perforator surgery is a less-invasive surgical procedure for the treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin, and the perforating veins are clipped or divided by endoscopic scissors. The surgery can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and radiofrequency ablation has also been reported.



Review of Evidence

Conventional Treatment of Saphenous Reflux

Compression Therapy

A Cochrane review by O'Meara et al (2009) evaluated compression for venous leg ulcers included 39 RCTs with 47 different comparisons.¹ This review was updated in 2012 and included 48 RCTs with 59 different comparisons.² Most RCTs were small. 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 8 trials indicated that venous ulcers healed more rapidly with compression than without. Findings suggested that multicomponent systems (bandages or stockings) were more effective than single-component compression. Also, multicomponent systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents. Although these meta-analyses did not include time to healing, studies included in the review reported that the mean time to ulcer healing was approximately 2 months, while the median time to healing in other reports was 3 to 5 months.

A Cochrane review by Shingler et al (2011) assessed compression stockings as initial treatment for varicose veins in patients without venous ulceration.³ Selected were 7 studies involving 356 participants with varicose veins without healed or active venous ulceration (CEAP [Clinical, Etiology, Anatomy, Pathophysiology] class C2-C4). Six studies compared different types or pressures of stockings. Subjectively, participants' symptoms improved, but results were not compared with a control arm. Due primarily to inadequate reporting, the methodologic quality of the selected trials was unclear. Meta-analyses were not performed due to inadequate reporting and suspected heterogeneity. Reviewers concluded that there was insufficient high-quality evidence to determine whether compression stockings were effective as the sole and initial treatment of varicose veins in patients without venous ulceration, or whether any type of stocking was superior to another type.

Ligation and Stripping

Systematic literature reviews have 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.^{4,5} In general, recurrence rates after ligation and stripping are estimated at 20% in short-term follow-up. Jones et al (1996) reported on the results of a trial that randomized 100 patients with varicose veins to ligation alone or ligation plus stripping.⁶ At



1 year, reflux was detected in 9% of patients, rising to 26% at 2 years. Rutgers and Kitslaar (1994) reported on the results of a trial that randomized 181 limbs to ligation and stripping or to ligation plus sclerotherapy.⁷ At 2 years, Doppler ultrasound demonstrated reflux in approximately 10% of patients after ligation and stripping, increasing to 15% at 3 years.

Summary of Evidence

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive endovenous thermal ablation (radiofrequency or laser), the evidence includes randomized controlled trials (RCTs) and systematic reviews of controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity (TRM). There are a number of large RCTs and systematic reviews of RCTs assessing endovenous thermal ablation of the saphenous veins. Comparison with the standard of ligation and stripping at 2- to 5-year follow-up has supported the use of both endovenous laser ablation and radiofrequency ablation (RFA). Evidence has suggested that ligation and stripping lead to more neovascularization, while thermal ablation leads to more recanalization, resulting in similar clinical outcomes for endovenous thermal ablation and surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive microfoam sclerotherapy, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For physician-compounded sclerotherapy, there is high variability in success rates and some reports of serious adverse events. By comparison, rates of occlusion with the microfoam sclerotherapy (polidocanol 1%) approved by the Food and Drug Administration are similar to those reported for endovenous laser ablation or stripping. Results of a noninferiority trial of physician-compounded sclerotherapy have indicated that, once occluded, recurrence rates at 2 years are similar to those of ligation and stripping. Together, this evidence indicates that the more consistent occlusion with the microfoam sclerotherapy preparation will lead to recurrence rates similar to ligation and stripping in the longer term. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Based on the available evidence, clinical input obtained in 2015, and clinical practice guidelines, the use of endovenous RFA, endovenous laser ablation, and microfoam sclerotherapy are considered to improve outcomes when used in the saphenous veins. For treatment of saphenous tributaries at the same time or following treatment of the saphenous vein, stab



avulsion, hook phlebectomy, sclerotherapy, or transilluminated powered phlebectomy improve outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive mechanochemical ablation, the evidence includes two RCTs and case series. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Mechanochemical ablation is a combination of liquid sclerotherapy with mechanical abrasion. Potential advantages of this procedure compared with thermal ablation are that mechanochemical ablation does not require multiple needle sticks with tumescent anesthesia and may result in less pain during the procedure. One RCT with high loss to follow-up has been published, and a larger RCT is comparing mechanochemical ablation with RFA has reported early results. These short-term results have suggested that intraprocedural pain is lower with mechanochemical ablation than with RFA. However, liquid sclerotherapy is not as effective as thermal ablation techniques for saphenous veins, and mechanochemical ablation has been assessed in relatively few patients and for short durations. Longer follow-up in larger RCTs is needed to evaluate its efficacy and durability compared with established procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cyanoacrylate adhesive, the evidence includes an RCT and a prospective cohort. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Evidence assessing cyanoacrylate adhesive for the treatment of varicose veins and venous insufficiency includes a multicenter noninferiority trial with initial 3 months of follow-up and subsequent reports with follow-up through 24 months. The short-term efficacy of cyanoacrylate adhesive has been shown to be noninferior to RFA at three months; the loss to follow-up in the further follow-up studies limits the confidence in this outcome. A prospective cohort reported high closure rates at 30 months but also had a high loss to follow-up. Adequately powered trials with adequate follow-up are needed to determine the durability of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs and multicenter series. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.



Varicose Tributary Veins

For individuals who have varicose tributary veins who receive ablation (stab avulsion, sclerotherapy, or phlebectomy) of tributary veins, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has shown that sclerotherapy is effective for treating tributary veins following occlusion of the saphenofemoral or saphenopopliteal junction and saphenous veins. No studies have been identified comparing RFA or laser ablation of tributary veins with standard procedures (microphlebectomy and/or sclerotherapy). Transilluminated powered phlebectomy is effective at removing varicosities; outcomes are comparable to available alternatives such as stab avulsion and hook phlebectomy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Perforator Veins

For individuals who have perforator vein reflux who receive ablation (eg, subfascial endoscopic perforator surgery) of perforator veins, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The literature has indicated that the routine ligation or ablation of incompetent perforator veins is not 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 (ie, ulcers), treatment of perforator vein reflux may be as beneficial as any alternative (eg, deep vein valve replacement). Comparative studies are needed to determine the most effective method of ligating or 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 compared with surgical interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in [Table 1](#).



Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|----------------------------|--|---------------------------|------------------------|
| Ongoing | | | |
| NCT03392753 | Mechanochemical Ablation Compared to Cyanoacrylate Adhesive | 180 | Nov 2019 |
| NTR4613^a | Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial) | 160 | Apr 2020 |
| NCT01936168 | Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA) | 460 | Dec 2020 |
| NCT02627846 | A Randomised Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein®) in the Management of Superficial Venous Insufficiency (LAMA) | 140 | Sep 2030 |

NCT: national clinical trial. NTR: Netherlands Trial Registry.

^a Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies while this policy was under review in 2015. There was no agreement on the need to treat varicose tributaries to improve functional outcomes in the absence of saphenous vein disease. Input was also mixed on the use of mechanochemical ablation and cyanoacrylate adhesive.



Practice Guidelines and Position Statements

Society for Vascular Surgery and American Venous Forum

The Society for Vascular Surgery and the American Venous Forum (2011) published joint clinical practice guidelines.⁵⁷ **Table 2** provides the recommendations.

Table 2. Guidelines on Management of Varicose Veins and Associated Chronic Venous Diseases

| Recommendation | Grade ^a | SOR | QOE |
|---|--------------------|------------------|----------------------|
| Compression therapy for venous ulcerations and varicose veins | | | |
| Compression therapy is recommended as the primary treatment to aid healing of venous ulceration | 1B | Strong | Moderate |
| To decrease the recurrence of venous ulcers, ablation of the incompetent superficial veins in addition to compression therapy is recommended | 1A | Strong | High |
| Use of compression therapy for patients with symptomatic varicose veins is recommended | 2C | Weak | Low |
| Compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation is not recommended | 1B | Strong | Moderate |
| Treatment of the incompetent great saphenous vein | | | |
| Endovenous thermal ablation (radiofrequency or laser) is recommended over <ul style="list-style-type: none"> • Chemical ablation with foam or • High ligation and stripping due to reduced convalescence and less pain and morbidity. Cryostripping is a technique that is new in the United States, and it has not been fully evaluated. | 1B 1B | Strong Strong | Moderate Moderate |
| Varicose tributaries | | | |
| Phlebectomy or sclerotherapy are recommended to treat varicose tributaries | 1B | Strong | Moderate |
| Transilluminated powered phlebectomy using lower oscillation speeds and extended tumescence is an alternative to traditional phlebectomy | 2C | Weak | Low |
| Perforating vein incompetence | | | |
| Selective treatment of perforating vein incompetence in patients with simple varicose veins is not recommended | 1B | Strong | Moderate |
| Treatment of pathologic perforating veins (outward flow of ≥ 500 ms duration, with a diameter of ≥ 3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6) is recommended | 2B | Weak | Moderate |



QOE: quality of evidence; SOR: strength of recommendation.

^a Grading: strong = 1 or weak = 2, based on a level of evidence that is either high quality = A, moderate quality = B, or low quality = C.

Society of Interventional Radiography (SIR)

The Society of Interventional Radiography (2003) 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:⁵⁸

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

AND

2. A trial of conservative, nonoperative 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, American Venous Forum and Society of Interventional Radiography (2007) recommended reporting standards for endovenous ablation for the treatment of venous insufficiency.⁵⁹ They recommended that 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 that potential candidates for endovenous ablation may include patients with reflux in an incompetent great saphenous vein



or smaller saphenous vein or a major tributary branch of the great 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 ultrasound imaging, and the ultrasound criteria used to define reflux should be indicated. It was also stated that in current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 to 1.0 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

National Institute for Health and Care Excellence

The NICE (2013) updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins.⁶⁰ NICE stated that:

“1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but significant risks of foam embolization (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.

1.2 During the consent process, clinicians should inform patients that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischaemic attacks and stroke.”

The NICE (2016) revised its guidance on endovenous mechanochemical ablation, concluding that “Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure....”⁶¹

The NICE (2013) published guidance on the diagnosis and management of varicose veins in the leg.⁶² The NICE (2015) published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins.⁶³ Five-year trial results are currently being evaluated.

Medicare National Coverage

There is no national coverage determination.



Regulatory Status

In 2015, the VenaSeal® Closure System (Sapheon, a part of Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (P140018) process for the permanent closure of clinically significant venous reflux through endovascular embolization with coaptation. The VenaSeal® Closure System seals the vein using a cyanoacrylate adhesive agent. FDA product code: PJQ.

In 2013, Varithena™ (formerly Varisolve®), a sclerosant microfoam made with a proprietary gas mix, was approved by the FDA under a new drug application (205-098) for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein system above and below the knee.

The following devices were cleared for marketing by the FDA through the 501 (k) process for endovenous treatment of superficial vein reflux:

- In 1999, the VNUS® Closure™ system, a radiofrequency device, was cleared by the FDA through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." In 2005, the VNUS RFS™ and RFS*Flex*™ devices were cleared by the FDA for "use in vessel and tissue coagulation including, treatment of incompetent (ie, refluxing) perforator and tributary veins." In 2008, the modified VNUS® ClosureFAST™ Intravascular Catheter was cleared by the FDA through the 510(k) process. FDA product code: GEI.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit was cleared by the FDA through the 510(k) process, "... for use in the endovascular coagulation of the great saphenous vein of the thigh in patients with superficial vein reflux." FDA product code: GEX.
- In 2005, a modified Erbe Erbokryo® cryosurgical unit (Erbe USA) was approved by the FDA for marketing. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs. FDA product code: GEH.
- In 2003, the Trivex® system (InaVein), a device for transilluminated powered phlebectomy (TIPP) was cleared by FDA through the 510(k) process for "ambulatory phlebectomy procedures for the resection and ablation of varicose veins." FDA product code: DNQ.
- In 2008, the ClariVein® Infusion Catheter (Vascular Insights) was cleared by the FDA through the 510(k) process (K071468) for mechanochemical ablation. FDA determined that this device was substantially equivalent to the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive,



stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature. FDA product code: KRA.

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History

| Date | Comments |
|----------|--|
| 12/11/12 | Replace policy. Formatting changed to now organize procedures by type of vein. Policy statement extensively revised with additional medically necessary criteria for each procedure. Sclerotherapy now considered medically necessary only for accessory and tributary veins. Policy on hold for provider notification; the effective date is May 19, 2013. |
| 04/08/13 | Policy statement clarification. In criteria for sclerotherapy of accessory saphenous veins when not done concurrently with other listed treatments, the moderate to severe saphenous reflux criterion has been removed. To clarify the definition of "symptomatic" for treatment of tributaries not done concurrently with other listed treatments, specific criteria added for stab avulsion, hook phlebectomy, sclerotherapy or transilluminated powered phlebectomy treatment of tributaries. Tributary criterion for moderate to severe saphenous reflux, when not done concurrently with other listed |



| Date | Comments |
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| | treatments, has been removed. |
| 06/14/13 | Minor clarification. Hook phlebectomy clarified to indicate that it is also known as stab phlebectomy or micro-phlebectomy. |
| 10/14/13 | Replace policy. CPT codes for sclerotherapy (36468, 36469, 36470, 36471), TIPP (37765 or 37766, stab avulsion (37765, or 37799), etc. added to Policy Guidelines section. |
| 02/27/14 | Update Related Policies. Add 10.01.514. |
| 06/09/14 | Interim update. Criteria for vein size removed from policy statement. Minor edit to change definition of "moderate to severe reflux" to greater than 0.5 second. Coding update: ICD-9 and ICD-10 diagnosis and procedure codes removed – these are not utilized for adjudication. |
| 02/10/15 | Annual Review. Policy updated with literature review through September 23, 2014; reference 8-9, 18, 24 33 added and some references removed; policy statement revised to allow sclerotherapy as medically necessary when criteria are met. Information added regarding FDA approval of Varithena sclerotherapy. Documentation requirements added to Policy Guidelines. |
| 05/12/15 | Interim Update. Policy statement clarified: Treatment of tributaries by sclerotherapy, stab avulsion, stab/hook phlebectomy or transilluminated powered phlebectomy may now be considered medically necessary up to 10 days after saphenous veins have been treated. Definition of moderate to severe saphenous reflux and abbreviation "TIPP" added to the policy statement. |
| 06/09/15 | Interim Update. Policy statement clarified: TRIVEX listed as an example of TIPP. Exercises and pain relievers removed from conservative management requirement. TRIVEX manufacturer website added to Reference section. CPT codes 76942, 93970-71 and HCPCS code S2202 removed; these are not reviewed. |
| 11/10/15 | Interim Update. Policy updated with clarification to coverage criteria for the accessory saphenous vein, indicating parameters around treatment of the greater or lesser saphenous veins and the presence of reflux. |
| 01/12/16 | Annual Review. Added statement that cyanoacrylate adhesive/embolization (CAE) (eg, VenaSeal closure system) and endovenous mechanochemical ablation (MOCA) (eg ClariVein) of any vein is considered investigational. The failure of compression therapy removed from the policy statements on venous stasis and thrombophlebitis. References added. Policy updated with literature review through July 7, 2015. |
| 10/01/16 | Interim Update, approved September 13, 2016. Perforator vein criteria revised: Requirement of active ulcers changed to "healed or active ulcers" and "demonstrated perforator reflux" is more clearly defined with measurements of outward flow and vein diameter. |
| 12/01/16 | Policy moved to new format. Policy statements unchanged. Added Prior Authorization Requirements section. |
| 01/01/17 | Coding update, added CPT codes 36473 and 36474 effective 1/1/17. |



| Date | Comments |
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| 03/01/17 | Annual Review, approved February 14, 2017. No change to policy statement. Compression Therapy added to Definition of Terms. Reference 64 added. Removed CPT code 36469 from policy as it terminated as of 01/01/2015. |
| 11/02/17 | Minor formatting edits made. |
| 01/16/18 | Minor edit, added Documentation Requirements table to the Policy Coverage Criteria section. |
| 01/23/18 | Coding update, added CPT codes 36465, 36466, 36482, and 36483 (new codes effective 1/1/18). |
| 08/01/18 | Annual Review, approved July 25, 2018. Policy updated with literature review through March 2018; references 18, 21, 24-27, and 30-31 added; references 54 and 56 updated. Policy statements unchanged. |
| 11/01/18 | Interim Review, approved October 9, 2018. Reordered and clarified policy statement criteria by procedure type rather than vein type. Added criteria for number of treatment sessions of sclerotherapy allowed and criteria for requests for sclerotherapy after ablation of the saphenous veins for the treatment of residual or recurrent symptoms. |
| 01/01/19 | Interim Review, approved December 19, 2018. Added missing wording to statement: "Phlebectomy (stab avulsion, hook phlebectomy, or TIPP) or initial* sclerotherapy as a component of the treatment of <u>symptomatic varicose tributaries</u> when performed either at the same time or following prior treatment (surgical, radiofrequency, or laser) of the saphenous veins is considered medically necessary" to clarify the intent of the statement. Added new HCPCS code 0524T (new code effective 1/1/19). |
| 04/01/19 | Annual Review, approved March 19, 2019. Policy updated with literature review through November 2018; references 16, 19, 33-34 added. Minor edits to policy statements for clarity; otherwise intent of policy statements unchanged. |

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብሰብ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):

Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

Français (French):

Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnuv ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងរបស់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ដុល្លារចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).