Varicose Veins

MEDICAL POLICY NUMBER: 182

Effective Date: 1/1/2023

Last Review Date: 10/2022

Next Annual Review: 10/2023

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- Member benefits, which address coverage or non-coverage of specific services, may vary.
- Member benefit contract language takes precedent over medical policy.
- Drugs/Devices must be FDA-approved specifically for the procedure recommended to treat the condition.
- Duplex scanning must be performed by:
  - An accredited facility (e.g., Intersocietal Accreditation Commission [IAC]); or
  - A licensed vascular sonographer and read by a board-certified vascular/cardiothoracic surgeon or a board-certified physician who is accredited by APCA (Alliance for Physician Certification & Advancement) for RPVI (Registered Physician in Vascular Interpretation).
- See policy description section for the clinical, etiologic, anatomic, and pathophysiologic (CEAP) clinical findings classification (Table. 1), venous nomenclature (Table. 2), and associated terminology (Table. 3).

Ligation/Excision/Stripping

I. Ligation/excision/stripping of the great saphenous vein (GSV), small saphenous veins (SSV), or anterior accessory saphenous vein (AASV) for the treatment of symptomatic varicose veins may be considered **medically necessary** when **at least one** of the following criteria (A.-C.) are met:

   A. The patient is experiencing itching, discomfort, or heaviness in the leg(s) due to a varicosity confirmed by physical examination, and meets **all** of the following (1.-4.) criteria:

1. The patient's symptoms interfere with instrumental activities of daily living (e.g., bathing, feeding, household duties, and/or job activities); **and**
2. The patient's symptoms persist after conservative therapy for **at least** 6 weeks (e.g., exercise, leg elevation, and/or compressive therapy); **and**
3. Superficial venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
4. Endovenous intervention (e.g., ablation) is not feasible; **or**

B. The patient has been diagnosed with a superficial thrombophlebitis, and meets **both** of the following (1. **and** 2.) criteria:
1. The patient is continuing to experience thrombophlebitis after treatment with **at least one** of the following (a.-c.):
   a. NSAIDs or acetaminophen for **at least** 3 weeks; **or**
   b. Low molecular weight heparin (LMWH) for **at least** 6 weeks; **or**
   c. Fondaparinux for **at least** 6 weeks; **and**
2. Endovenous intervention (e.g., ablation) is not feasible; **or**

C. The patient is experiencing a significant hemorrhage or recurrent bleeding from a superficial varicosity and endovenous intervention (e.g., ablation) is not feasible.

II. Ligation/excision/stripping is considered **not medically necessary** when criterion I. above is not met.

Subfascial Endoscopic Perforating Vein Surgery (SEPS)

III. Subfascial Endoscopic Perforating Vein Surgery (SEPS) for the treatment of incompetent perforator veins may be considered **medically necessary** when **all** of the following (A.-C.) criteria are met:

A. Venous reflux ≥ 500 milliseconds; **and**
B. Vein diameter ≥ 3.5 millimeters; **and**
C. Located beneath an active or healed venous ulcer.

IV. Subfascial Endoscopic Perforator Vein Surgery (SEPS) is considered **not medically necessary** when criterion III. above is not met.

Ambulatory Phlebectomy

V. Ambulatory phlebectomy for the treatment of symptomatic varicose veins may be considered **medically necessary** when **at least one** of the following (A.-C.) criteria are met:

A. The patient is experiencing itching, discomfort, or heaviness in legs due to a varicosity confirmed by physical examination, and meets **all** of the following (1.-5.) criteria:
1. The patient's symptoms interfere with instrumental activities of daily living (e.g., bathing, feeding, household duties, and/or job activities); **and**
2. The patient's symptoms persist after conservative therapy for **at least** 6 weeks (e.g., exercise, leg elevation, and/or compressive therapy); **and**
3. Superficial venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
4. There is associated superficial venous incompetence of the greater saphenous vein, small saphenous vein, and/or anterior accessory saphenous vein; **and**

5. The ambulatory phlebectomy procedure is performed with saphenous vein ablation, either concurrently or at a later stage; **or**

B. The patient has been diagnosed with a superficial thrombophlebitis that is refractory to **at least one** of the following (1.-3.) treatments:
   1. NSAIDs or acetaminophen for **at least** 3 weeks; **or**
   2. Low molecular weight heparin (LMWH) for **at least** 6 weeks; **or**
   3. Fondaparinux for **at least** 6 weeks; **or**

C. The patient is experiencing a significant hemorrhage or recurrent bleeding from a superficial varicosity.

VI. Ambulatory phlebectomy is considered **not medically necessary** when criterion. V above is not met.

Endovenous Ablation (Laser or Radiofrequency)

VII. Endovenous ablation (laser or radiofrequency) of the great saphenous vein (GSV), small saphenous veins (SSV), or anterior accessory saphenous vein (AASV) for the treatment of chronic venous insufficiency may be considered **medically necessary** when **at least one** of the following (A.-E.) criteria are met:

A. The patient has an active venous ulcer and **both** of the following (1. and 2.) criteria are met:
   1. Venous reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
   2. The venous ulcer is refractory to **at least** 6 weeks of wound care with dressing and **at least** 6 weeks of compression hose (20 to 30 mmHg); **or**

B. The patient has a healed venous ulcer and venous reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**

C. The patient has been diagnosed with lipodermatosclerosis that is refractory to compression hose for **at least** 6 weeks and saphenous vein reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**

D. The patient has been diagnosed with lipodermatosclerosis and perforator vein reflux is ≥ 500 milliseconds as measured by duplex ultrasound and a saphenous reflux procedure is planned; **or**

E. The patient has lower limb edema or pigmentation or eczema and **both** of the following (1. **and** 2.) criteria are met:
   1. Superficial vein reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
   2. The symptoms are refractory to **all** of the following (a.-c.) treatments:
      a. Compression hose (20 to 30 mmHg) for **at least** six weeks; **and**
      b. Physical therapy or home exercise for **at least** 6 weeks; **and**
      c. Leg elevation for **at least** 6 weeks.

VIII. Endovenous ablation (laser or radiofrequency) of the great saphenous vein (GSV), small saphenous veins (SSV), or anterior accessory saphenous vein (AASV) for the treatment of symptomatic varicose veins may be considered **medically necessary** when **at least one** of the following (A.-C.) criteria are met:

A. The patient is experiencing itching, discomfort, or heaviness in legs due to a varicosity confirmed by physical examination, and meets **all** of the following (1.-3) criteria:

1. The patient's symptoms interfere with instrumental activities of daily living (e.g., bathing, feeding, household duties, and/or job activities); **and**
2. The patient's symptoms persist after conservative therapy for **at least** 6 weeks (e.g., exercise, leg elevation, and/or compressive therapy); **and**
3. Superficial venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**

B. The patient has been diagnosed with a superficial thrombophlebitis that is refractory to **at least one** of the following (1.-3.) treatments:
1. NSAIDs or acetaminophen for **at least** 3 weeks; **or**
2. Low molecular weight heparin (LMWH) for **at least** 6 weeks; **or**
3. Fondaparinux for **at least** 6 weeks; **or**

C. The patient is experiencing a significant hemorrhage or recurrent bleeding from a superficial varicosity.

IX. Endovenous ablation (laser or radiofrequency) for the treatment of recurrent or residual superficial venous reflux of the great saphenous vein (GSV) or small saphenous vein (SSV) may be considered **medically necessary** when criteria VII. or VIII. above is met.

X. Endovenous ablation (laser or radiofrequency) for the treatment of a known anatomical duplicate of the greater saphenous vein may be considered **medically necessary** when criterion VII. or VIII. above is met.

XI. Endovenous ablation (laser or radiofrequency) for the treatment of perforator vein incompetence is considered **medically necessary** when **all** of the following (A.-C.) criteria are met:

A. Venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
B. Vein size ≥ 3.5 millimeters; **and**
C. Located underneath an active or healed venous ulcer.

XII. Endovenous ablation (laser or radiofrequency) is considered **not medically necessary** when criteria V., VI, VII., VIII., IX., X., or XI. above is not met.

XIII. Repeat venous studies using duplex ultrasound following endovenous ablation may be considered **medically necessary** when performed **within one week** of the ablation procedure.

Sclerotherapy

XIV. Foam sclerotherapy (i.e., Varithena™) of the greater saphenous vein (GSV), small saphenous vein (SSV), or anterior accessory saphenous vein (AASV) for the treatment of chronic venous insufficiency may be considered **medically necessary** when **at least one** of the following (A.-E.) criteria are met:

A. The patient has an active venous ulcer and **both** of the following (1. **and** 2.) criteria are met:
1. Venous reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
2. The venous ulcer is refractory to **at least** 6 weeks of wound care with dressing and **at least** 6 weeks of compression hose; **or**

B. The patient has a healed venous ulcer and venous reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**
C. The patient has been diagnosed with lipodermatosclerosis and **both** of the following (1. **and** 2.) criteria are met:
    1. The symptoms are refractory to compression hose for at least 6 weeks; **and**
    2. Saphenous vein reflux is ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**
D. The patient has lower limb edema or pigmentation or eczema and **both** of the following (1. **and** 2.) criteria are met:
    1. Venous reflux ≥ 500 milliseconds as measured by duplex ultrasound; **and**
    2. The symptoms are refractory to **all** of the following (a.-c.) treatments:
        a. Compression hose for **at least** six weeks; and
        b. Physical therapy or home exercise for **at least** 6 weeks; and
        c. Leg elevation for **at least** 6 weeks.

XV. Foam sclerotherapy (i.e., Varithena™) of the greater saphenous vein (GSV), small saphenous vein (SSV), or anterior accessory saphenous vein (AASV) for the treatment of symptomatic varicose veins may be considered **medically necessary** when **at least one** of the following (A.-B.) criteria are met:

A. The patient is experiencing itching, discomfort, or heaviness in legs due to a varicosity confirmed by physical examination, and meets **all** of the following (1.-3) criteria:
    1. The patient's symptoms interfere with instrumental activities of daily living (e.g., bathing, feeding, household duties, and/or job activities); **and**
    2. The patient's symptoms persist after conservative therapy for **at least** 6 weeks (e.g., exercise, leg elevation, and/or compressive therapy); **and**
    3. Superficial venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **or**
B. The patient is experiencing a significant hemorrhage or recurrent bleeding from a superficial varicosity.

XVI. Foam sclerotherapy (i.e., Varithena™) for the treatment of recurrent or residual symptomatic chronic venous disease may be considered **medically necessary** when **both** of the following (A. **and** B.) criteria are met:
A. The patient has had a prior saphenous vein procedure; **and**
B. Criterion XIV. or XV. above are met.

XVII. Foam sclerotherapy (i.e., Varithena™) for the treatment of incompetent perforator veins is considered **medically necessary** when **all** of the following (A.-C.) criteria are met:

A. Venous reflux ≥ 500 milliseconds as measured by duplex ultrasound (US); **and**
B. Vein diameter of ≥ 3.5 millimeters; **and**
C. Located underneath an active or healed venous ulcer.

XVIII. Foam sclerotherapy (i.e., Varithena™) is considered **not medically necessary** when criteria XIV., XV., XVI., or XVII. above is not met.

Not Medically Necessary Treatments

XIX. Transilluminated powered phlebectomy is considered **not medically necessary** for any indication, including, but not limited to, chronic venous insufficiency or varicose veins.

XX. Endovascular embolization with a cyanoacrylate adhesive (e.g., VenaSeal™) has similar efficacy to but is more costly than standard treatments; therefore, it does not meet the definition of medical necessity and is considered **not medically necessary** for any indication (see Definition: Medical Necessity, criterion I.D.).

XXI. Repeat venous studies using duplex ultrasound (with the exception of criterion XIII.) within 6 months of the most recent treatment in the absence of new symptoms is considered **not medically necessary**.

Note: Repeat venous studies using duplex ultrasound **within one week following endovenous ablation** may be considered medically necessary. See criterion XIII. above.

XXII. Two procedures completed on the same vein at the same time is **not medically necessary**. This includes, but is not limited to, RFA on proximal GSV and Varithena on distal GSV.

Investigational Treatments

XXIII. Mechanochemical Endovenous Ablation (MOCA) (e.g., Clarivein) is considered **investigational** for any indication, including, but not limited to, chronic venous insufficiency or varicose veins.

XXIV. Cryoablation (i.e., cryostripping or cryofreezing) is considered **investigational** for any indication, including, but not limited to, chronic venous insufficiency or varicose veins.

Cosmetic Treatments

XXV. Any treatment of telangiectasias or reticular veins is considered **cosmetic**.

XXVI. Treatment of asymptomatic varicose veins is considered **cosmetic**.

XXVII. Liquid sclerotherapy (i.e., Asclera®) is considered **cosmetic**.

XXVIII. Photothermal sclerosis (i.e., intense pulsed light source)(e.g., PhotoDerm® Vasculight) is considered **cosmetic.**

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- Color photos (clear and interpretable quality) that demonstrate varicose vein(s)
- Complete duplex studies including vein names with measurements of seconds of reflux and average vein diameters. According to the Intersocietal Accreditation Commission, a complete venous study includes the following:
    - Deep veins: common femoral, mid-femoral, and popliteal
    - Long saphenous vein: SFJ, mid-thigh, knee, and mid-calf
    - Short saphenous vein: SPJ, and mid-calf
    - Perforators: site with seconds of reflux and diameters
    - Branch tributaries: site with seconds of reflux and diameters
    - Varicose veins (varices): diameters
- Complete medical history and physical examination, including the specific activities of daily living impaired, and how this affects daily and/or occupational function
- If required per medical necessity criteria, the conservative therapy treatment plan and the results of this therapy.
- The procedure requested, including:
    - Specific veins to be treated

Number of treatment sessions being requested

BACKGROUND

Chronic Venous Disease

According to UpToDate, "chronic venous disease is a common disorder that affects the veins of the legs…normal veins have a series of valves that open and close to direct blood flow from the surface of the legs to the deep leg veins, from which calf muscles pump blood back to the heart. If the valves within the veins fail to work properly, there is a blockage to normal flow, or the calf muscles cannot pump properly, blood can flow backwards in the veins and pool in the legs."[1] This pooling of blood can cause mild symptoms, such as itchiness, aching, heaviness in the legs, or dilated veins (e.g., varicose veins), to more severe symptoms, such as swelling of the legs, ankles, or feet, skin color changes, eczema, and chronic ulcers. Patients who develop these more severe symptoms are said to have chronic venous insufficiency.

Chronic venous disease is commonly caused by a blood clot that blocks blood flow, a leg injury or surgery, excess weight or weight gain, and/or standing or sitting for too long. A physical exam and duplex ultrasound is used to diagnose chronic venous disease. Disease management involves "reducing symptoms, such as swelling, treating skin problems, preventing and treating ulcers, and improving blood flow from the legs." Conservative therapies for chronic venous disease include, leg elevation, exercise, compression therapy, medications, and/or dressings to treat venous ulcers. Surgical therapy or ablation

is reserved for patients who do not respond to conservative therapies. The treatment of chronic venous disease is aimed at the prevention of venous ulceration and chronic wound problems.

Table 1. Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) Clinical Findings Classification of Chronic Venous Disease of the Lower Extremities:

Clinical Classification		
C0	No visible or palpable signs of venous disease.	
C1	• Telangiectasies (confluence of dilated intradermal venules <1 mm in diameter); or • Reticular veins (dilated bluish subdermal veins 1 to 3 mm in diameter).	
C2	Varicose veins (subcutaneous dilated veins 3 mm or greater in diameter).	
C3	Edema.	
C4	Skin changes ascribed to venous disease (e.g., pigmentation, venous eczema, lipodermatosclerosis)	
	C_{4a}	Pigmentation and eczema.
	C_{4b}	Lipodermatosclerosis and atrophie blanche.
C5	Healed venous ulcer.	
C6	Active venous ulcer.	
Etiologic Classification		
Ec	Congenital	
Ep	Primary	
Es	Secondary (post-thrombotic)	
En	No venous cause identified	
Anatomic Classification		
As	Superficial veins	
Ap	Perforator veins	
Ad	Deep veins	
An	No venous location identified	
Pathophysiologic Classification		
Pr	Reflux	
Po	Obstruction	
Pr,o	Reflux and obstruction	
Pn	No venous pathophysiology identifiable	

Table 2. Venous Nomenclatures

The following nomenclature was obtained from the Society for Vascular Surgery/American Venous Forum clinical practice guideline on the care of patients with varicose veins and associated chronic venous disease.[2]

Vein	Description
Greater saphenous vein (GSV)	Originates from the medial superficial veins of the dorsum of the foot and ascends in front of the medial malleolus along the medial border of the tibia, net to the saphenous nerve.

Small saphenous vein (SSV)	Originates from the lateral side of the foot and drains blood into the popliteal vein, joining it usually just proximal to the knee crease.
Anterior accessory saphenous veins (AASV)	Originates at the anterior distal to mid-thigh and courses toward the saphenofemoral junction over the anterior proximal thigh.
Perforator veins	Connect the superficial to the deep venous system. They pass through the deep fascia that separates the superficial compartment from the deep.

Table 3. Terminology

The following terminology was obtained from the American Venous Forum and the transatlantic interdisciplinary consensus document on the terminology of chronic venous disorders.[3]

Term	Definition
Chronic venous disease (CVD)	(Any) morphological and functional abnormalities of the venous system of long duration manifested either by symptoms and/or signs indicating the need for investigation and/or care.
Chronic venous insufficiency	CEAP C3-C6; A term reserved for advanced CVD, which is applied to functional abnormalities of the venous system producing edema, skin changes, or venous ulcers.
Venous symptoms	Complaints related to venous disease, which may include tingling, aching, burning, pain, muscle cramps, swelling, sensations of throbbing or heaviness, itching skin, restless legs, leg-tiredness and/or fatigue. Although not pathognomonic, these may be suggestive of chronic venous disease, particularly if they are exacerbated by heat or dependency in the day's course, and relieved with leg rest and/or elevation. Existing venous signs and/or (non-invasive) laboratory evidence are crucial in associating these symptoms with CVD.
Venous signs	Visible manifestations of venous disorders, which include dilated veins (telangiectasia, reticular veins, varicose veins), leg edema, skin changes, ulcers, as included in the CEAP classification.
Recurrent varices	Reappearance of varicose veins in an area previously treated successfully.
Residual varices	Varicose veins remaining after treatment.
Venous valvular incompetence	Venous valve dysfunction resulting in retrograde venous flow of abnormal duration.
Venous reflux	Retrograde venous flow of abnormal duration in any venous segment.
Primary	Caused by idiopathic venous valve dysfunction.
Secondary	Caused by thrombosis, trauma, or mechanical, thermal, or chemical etiologies.
Congenital	Caused by the absence or abnormal development of venous valves.

Ligation/Excision/Stripping

According to the Society of Vascular Surgery and the American Venous Forum, "open surgical treatment of varicose veins with ligation and stripping of the great saphenous vein (GSV) or small saphenous vein (SSV), combined with excision of large varicose veins, has been the standard of care of varicose vein treatment for more than a century."[2] Ligation involves the surgical tying off of the GSV. Ligation is also sometimes performed with stripping (also known as phlebectomy), which is the removal of this vein through incisions in the leg. If some of the valves in the GSV are still healthy just the weak portion of the vein can be ligated. If all the valves are weak, the vein is closed off by ligation and removed through stripping. This procedure is aimed at reducing the pressure of backward flow through the GSV; therefore, reducing the symptoms associated with chronic venous disease.

Subfascial Endoscopic Perforator Vein Surgery (SEPS)

SEPS is a minimally invasive alternative to open subfascial perforator vein surgery. "The procedure is used for patients with either healed or active ulcers (CEAP classifications 5 or 6), caused by chronic venous insufficiency, in whom incompetent calf perforating veins are thought to be an important contributing factor, particularly where conservative management (such as leg elevation, compression therapy and medication) has failed."[4] During the operation, the limb is elevated and two ports are placed in the subfascial space in the calf. A balloon is then introduced and inflated to improve access to the vein. The incompetent perforator veins are then clipped and removed.

Ambulatory Phlebectomy

Ambulatory phlebectomy involves the removal or avulsion of varicose veins through small stab wounds or puncture wounds.[2] A solution is injected under the skin to transilluminate the subcutaneous tissues under the varicose veins. Once the varicose veins are removed, compression bandage or compression stockings are applied to promote healing.

Endovenous Ablation (Laser, Thermal, or Radiofrequency)

According to the Society for Vascular Surgery and the American Venous Forum, "during the past decade, endovenous thermal ablation has largely replaced the classic ligation and stripping operation, and open surgery for saphenous incompetence is performed much less frequently in the United States."[2] Ablation of the saphenous veins is minimally invasive and has several advantages over standard open surgery. The procedure is done under local anesthesia and ultrasound guidance. Endovenous ablation includes laser and radiofrequency modalities. "Ablation is achieved by heat delivered into the vein through the percutaneously placed laser fiber or a radiofrequency catheter. Endovenous thermal ablation causes a direct thermal injury to the vein wall, resulting in destruction of the endothelium, collagen denaturation of the media, and fibrotic and thrombotic occlusions of the vein."

Sclerotherapy (Liquid, Foam, or Microfoam)

The Society for Vascular Surgery and the American Venous Forum define sclerotherapy as a "minimally invasive percutaneous technique using chemical irritants to close unwanted veins." [2] Ultrasound guided foam sclerotherapy has rapidly spread for the treatment of varicose veins, including the GSV, SSV, and perforator veins. "The mechanism of action of sclerosing solutions is the destruction of venous endothelial cells, exposure of subendothelial collagen fibers, and ultimately, the formation of a fibrotic obstruction." Sclerosing agents can be injected as a liquid or foam; however, the foam solution prolongs

the time of contact and amplifies the effect of the chemicals. Sclerotherapy can be performed in one outpatient session, and compression therapy is recommended for one week following treatment. Sclerotherapy is commonly performed with endovenous ablation using a staged treatment approach.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Several devices and drugs have been approved for the treatment of varicose veins by the U.S. FDA under the premarket approval (PMA) or 510(k) premarket notification process. This list is not all inclusive. See the FDA PMA or 510(k) databases for further information.

Table 4: Devices

Device & Manufacturer	Indications for Use
ClariVein® Infusion Catheter by Vascular Insights[5]	The ClariVein® IC is indicated for infusion of physician specified agents in peripheral vasculature.
ERBECRYO 2 Cryosurgical Unit by ERBE USA, Inc.[6]	The ERBECRYO 2 Cryosurgical Unit and Accessories are intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion. Including, but not limited to, varicose veins of the lower limbs (cryo stripping).
Diomed Surgical Laser and Endovenous Laser Therapy (EVLT) Procedure Kit by Diomed, Ltd.[7]	The Diomed Delta 15 and Diomed Delta 30 Lasers are intended for use in delivering up to 15 or up to 30 Watts, respectively, of continuous wave or pulsed radiation to a flexible optical fiber or spot handpiece for use in ablation, incision, excision, coagulation and vaporisation of soft tissues in open and endoscopic surgical procedures, including EndoVenous Laser Treatment (EVLT).
VNUS Radiofrequency Generator by VNUS Medical Technologies, Inc.[8]	The VNUS Radiofrequency Generator is intended for use with VNUS radiofrequency devices intended for vessel and tissue coagulation. The specified predicate devices are indicated for "coagulation of blood vessels in patients with superficial vein reflux" (VNUS Closure System), and "vessel and tissue coagulation" (VNUS Vessel and Tissue Coagulation System).
TriVex System™ by LeMaitre Vascular (formerly Smith & Nephew)[9]	The TriVex System™ is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins.

Table 5: Drugs

Product & Manufacturer	Indications for Use	Contraindications for Use

Varithena™ by Biocompatabilities Inc. (formerly Varisolve™)[10]	Varithena™ (polidocanol injectable foam) is a sclerosing agent indicated 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. Varithena™ improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.	• Known allergy to polidocanol • Acute thromboembolic disease
Asclera™ by Merz North America, Inc.[11]	Asclera™ (polidocanol) is a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. It has not been studied in larger varicose veins > 3 mm in diameter.	• Known allergy to polidocanol • Acute thromboembolic disease
VenaSeal Closure System by Covidien LLC.[12]	The VenaSeal Closure System (VenaSeal system is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).	• Separate use of the individual components of the VenaSeal Closure System is contraindicated. These components must be used as a system. • The use of the VenaSeal system is contraindicated when any of the following conditions exist: ○ Previous hypersensitivity reactions to the VenaSeal adhesive or cyanoacrylates; ○ Acute superficial thrombophlebitis; ○ Thrombophlebitis migrans; ○ Acute sepsis exists.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of ligation, subfascial endoscopic perforator vein surgery, ambulatory phlebectomy, endovenous ablation, and sclerotherapy as a treatment for varicose veins and chronic venous insufficiency due to chronic venous disease. Below is a summary of the available evidence identified through September, 2022.

Medically Necessary Treatments

- In 2017 (last review 2020), Hayes conducted a review of reviews comparing the effectiveness of endovenous radiofrequency ablation (EVRFA) compared to conventional surgery for the treatment of symptomatic varicose veins.[13] Systematically searching the literature through October 2017, investigators assessed 4 systematic reviews and 4 primary studies (2 RCTs and 2 observational studies). Sample sizes in the RCTs ranged from 8 to 250; the 2 observational studies had sample sizes of 4366 and 131,887 patients. Outcomes of interest included failure of the procedure, technical recurrence, symptomatic recurrence, reintervention, changes in symptom scores measured by validated scales, quality of life and adverse events. Follow-up varied up to 5 years. Results from a "low-quality body of evidence" suggested that EVRFA is at least as effective for many outcomes compared to surgery, and is associated with less postoperative pain and faster recovery than conventional surgery. Evidence was mixed for patient-centered outcomes and quality of life. Limitations of the evidence included the small number of studies reporting some outcomes, lack of reporting of statistical test results, and methodological limitations of individual studies. Hayes ultimately assigned a "C" rating (potential but unproven benefit) for use of EVRFA as an alternative to conventional surgery for treating symptomatic varicose veins in adults without contraindications. Hayes concluded that questions remained regarding EVRFA's long-term safety and durability.

- In 2017, the Washington State Health Care Authority published a review of reviews evaluating the safety and efficacy of various treatments for varicose veins.[14] Searching the literature through March 2017, 23 publications were included for review (8 systematic reviews and 15 publications of primary data not already included in 1 or more of the systematic reviews.) Interventions of interest included EVLA, endovascular RFA, sclerotherapy (i.e., liquid or foam chemical ablation), ambulatory phlebectomy (i.e. stab phlebectomy or microphlebectomy.) Outcomes of interest included failure of the procedure, second or additional procedures after failure of initial procedure, technical recurrence, symptomatic recurrence, quality of life and adverse events. Each systematic review was assessed to be of "good quality." Overall, evidence suggested that EVLA was at least as effective as conventional surgery in the treatment of varicose veins for many clinical and patient-centered outcomes. Evidence also suggested that EVLA, EVRFA and sclerotherapy were relatively safe compared with surgery. No studies comparing ambulatory phlebectomy to surgery met inclusion criteria, although phlebectomy may have been an adjunctive treatment in studies of the other interventions. Limitations included not providing a list of excluded studies and missing details about the quality of individual and/or the body of evidence. Individual studies were limited in quality and quantity and the limited availability of appropriate data to pool for analyses. In its "final findings and decisions" document,[15] investigators stated that EVLA, EVRFA and ambulatory phlebectomy should be conditionally covered benefits. Indications (required to be present) demonstrated reflux in the affected vein, with a minimum of 3 months of symptoms of pain and/or swelling, and for tributary varicose veins and a diameter of more than 3 mm.
- In 2017, He and colleagues conducted a systematic review and meta-analysis to investigate and compare the relative efficacy, recurrence, and complications of endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) for the treatment of varicose veins.[16] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The primary outcome of interest was pain and quality of life (QOL). The secondary outcome of interest was complications, including vein occlusion, thrombophlebitis, hematoma, and recanalization.

Following systematic review, the authors identified 12 studies (10 randomized controlled trials and 2 cohort studies) as eligible for inclusion; thus producing a total sample size of 1,577 patients. Meta-analysis indicated no statistically significant differences between EVLA and RFA for 3 day pain scores, 10 day pain scores, 1 month QOL, and 1 year QOL. "RFA was associated with the lower overall complication (OR: 3.49, 95%CI:1.36 to 8.96) in patients with varicose veins compared to the EVLA treatment."[16]

Strengths of this systematic review include the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers, large sample size, and assessment of heterogeneity. Limitations were identified in the poor quality of included studies, potential for biases, and significant heterogeneity between studies. "EVLA and RFA seem to be the same safe and effective on clinical efficacy (vein ablated length, 3 days and 10 days pain scores, 1 month and 1 year quality of life, occlusion, thrombophlebitis, haematoma and recanalization)."[16]

- In 2017 (last review 2021), Hayes published an evidence review of systematic reviews to evaluate the effectiveness of endovenous laser therapy versus conventional surgery for symptomatic varicose veins.[17] The primary outcome measures were failure of the procedure, technical recurrence, symptomatic recurrence, reintervention, changes in symptom scores measured by validated scales (e.g., Venous Clinical Severity Score [VCSS]); patient satisfaction; quality of life; time to return to work or normal activity; postoperative pain; adverse events. A total of 21 unique studies from the systematic reviews were identified, representing a sample of 136,930 patients (patients and/or limbs enrolled, not necessarily number of patients analyzed). Studies included adults aged 37.6 to 54 years with symptomatic, unilateral or bilateral, superficial, primary great saphenous vein (GSV) and/or small saphenous vein (SSV) insufficiency with saphenofemoral incompetence assessed as CEAP clinical class C_2 or higher.

  The authors reported the following conclusions:

  - There is moderate-quality evidence that technical failure is similar or reduced with EVLA compared with conventional surgical techniques.
  - There is moderate-quality evidence that EVLA is similar to conventional surgical techniques with respect to technical recurrence.
  - There is moderate-quality evidence of no difference in symptomatic recurrence between EVLA and conventional surgery.
  - The evidence suggests no difference in disease severity measures between EVLA and conventional surgery.
  - There is very low quality and inconsistent evidence on the outcomes of postoperative pain and time to return to work or normal activity.
  - Evidence of moderate quality suggests no difference between EVLA and conventional surgical techniques for treating varicose veins with respect to QOL scores.
  - There is low-quality evidence of no difference between EVLA and conventional surgery with respect to proportion of patients requiring reintervention either because of technical failure or because of recurrence after successful initial treatment.
  - Complication rates were generally low and few statistically significant differences were reported for EVLA compared with surgery.

Hayes gave a B rating for EVLA as an alternative to conventional surgery for treating symptomatic varicose veins in adult patients. This rating is based on "moderate-quality evidence suggests that EVLA is at least comparable with conventional surgery in the treatment of varicose veins for some clinical, patient-centered, and safety outcomes."

- In 2020, ECRI published a clinical evidence assessment on Varithena injectable foam (Boston Scientific Corp.) for treating varicose veins.[18] The review included 4 randomized controlled studies and one retrospective single-centered case series. Three of the RCTs compared Varithena with placebo and one compared Varithena with surgery or other sclerotherapy. RCTs found better symptom improvement compared to placebo or other sclerotherapy, but symptom relief was better improved by high-ligation surgery at 3-month and 12-month follow up. Limitations of these studies included open-label RCT in one study, single-arm studies, small sample sizes, short-term follow up in 4 studies, retrospective design of one study, and an unclear reporting in one RCT. ECRI concluded that evidence is somewhat favorable for Varithena Injectable Foam for treating varicose veins.

- In 2019 (reviewed 2021), Hayes updated a health technology assessment (originally published in 2015) evaluating the safety and efficacy of polidocanol endovenous Microfoam (PEM) (i.e. Varithena) 1% for treatment of varicose veins.[19] Six unique clinical studies that evaluated the efficacy or safety of PEM 1% in treating varicose veins were considered (n = 7 to 399). Two fair-quality randomized controlled trials, 3 poor-quality RCTs, and 1 very-poor-quality retrospective case series comprised the evidence base. The authors concluded that PEM 1% is a minimally invasive, nonsurgical treatment alternative for varicose veins that may provide relief of symptoms, though well-designed, non-manufacturer funded RCTs are needed to better understand durability and benefits, as well as optimal patient selection criteria. The updated Hayes report concluded use of polidocanol endovenous microfoam (PEM) 1% for treating incompetent great saphenous veins, accessory saphenous veins, and visible varicosities above and below the knee in adults to have a C-rating.

- In 2016, Boersma et al. conducted a systematic review and meta-analysis to evaluate treatment modalities for small saphenous vein (SSV) incompetence.[20] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The primary outcome of interest was anatomical success, defined as closure of the treated vein on follow-up duplex ultrasound imaging. Secondary outcomes of interest were technical success and major complications (paresthesia and deep vein thrombosis [DVT]).

  The authors identified 53 studies evaluating surgery (n=9), endovenous laser ablation (EVLA) (n=28), radiofrequency ablation (RFA) (n=9), ultrasound guided foam sclerotherapy (UGFS) (n=6), and other therapies (n=1) as eligible for inclusion. Following meta-analysis, the pooled anatomical success rate was 58.0%. Technical success was reported as 89.4% for surgery, 99.7% for EVLA, 100% for RFA, 100% for UGFS, and 100% for other therapies. "Neurologic complications were most frequently reported after surgery (mean 19.6%) and thermal ablation (EVLA: mean 4.8%; RFA: mean 9.7%). Deep venous thrombosis was a rare complication (0% to 1.2%)."

  Strengths of this systematic review include the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers and inclusion of a large number of studies. Limitations are present in the poor quality of selected studies (5 randomized controlled trials and 44 cohort studies) and the heterogeneity present between studies due to various outcome measures.

Ultimately, the authors concluded "endovenous thermal ablation (EVLA/RFA) should be preferred to surgery and foam sclerotherapy in the treatment of SSV incompetence."

- In 2014, Nesbitt and colleagues conducted a Cochrane systematic review to determine whether endovenous ablation (radiofrequency [RFA] and laser [EVLA]) and ultrasound guided foam sclerotherapy [UGFS] have any advantages or disadvantages in comparison with open surgical saphenofemoral ligation and stripping of great saphenous vein (GSV) varices.[21] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The primary outcomes of interest were recurrent varicosities, recanalization, neovascularization, technical procedure failure, patient quality of life (QOL) scores, and associated complications.

  Following systematic review, the authors identified 13 studies (n=3,081 randomized patients) as eligible for inclusion. "Three studies compared UGFS with surgery, eight compared EVLT with surgery and five compared RFA with surgery (two studies had two or more comparisons with surgery)." The overall quality of evidence was determined to be moderate. For the studies comparing UGFS to surgery, the results indicated no difference in the rate of recurrences and rate of technical failure. For EVLT versus surgery, the results indicated no statistically significant difference between groups for recurrences and recanalization. EVLT showed statistically reduced rates for neovascularization. In comparing RFA versus surgery, there were no statistically significant differences for recurrence, recanalization, neovascularization, or technical failure. Due to heterogeneity between studies, meta-analysis was not possible for the outcomes of QOL, operative complications, and pain; however, QOL generally increased similarly in all treatment groups, complications were generally low, and pain was similar between the treatment groups.

  This Cochrane systematic review was of very good quality and had several strengths, including:

  1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
  2. contacting authors of selected studies for additional information or data
  3. assessment of heterogeneity and publication bias
  4. meta-analyses only being conducted when studies were determined to be homogeneous with respect to population, treatment, and outcome measures
  5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

  Limitations of this systematic review are seen in the inclusion of studies with a high risk of bias and the potential for publication bias. The authors concluded "currently available clinical trial evidence suggests that UGFS, EVLT and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins."

Investigational Treatments

<u>Endovenous Mechanochemical Ablation (MOCA)</u>

- In 2022 Hayes conducted a health technology assessment to evaluate endovenous mechanochemical ablation (MOCA) (ClariVein® Infusion Catheter) for the treatment of varicose veins.[22] The literature search identified 7 studies (n=118-395 patients/limbs) published in 9 articles that evaluated MOCA using the ClariVein catheter for the treatment of varicose veins. Studies included 4 randomized controlled studies (RCTs) reported in 6 articles, 2 retrospective comparative studies, and 1 single-arm pretest-posttest study. The studies presented an overall low-quality body of evidence, but suggested that MOCA for the treatment of systematic varicose veins appears safe and effective. The outcomes of interest included pain, clinical severity, quality of life (QOL), safety, and rate of venous occlusion. Hayes gave a C rating for use of mechanochemical endovenous ablation (MOCA) (ClariVein Infusion Catheter) for treatment of symptomatic varicose veins. This Rating reflects a low-quality body of consistent evidence suggesting that MOCA for treatment of symptomatic varicose veins appears to be safe and efficacious in the short term. However, substantial uncertainty remains regarding the appropriate patient population, treatment parameters, and long-term durability of the procedure. Hayes urged for additional well-designed trials with larger sample sizes that directly compare MOCA using ClariVein catheter with clinical alternatives over an ext4ended period are needed.

- In 2021, Alozai and colleagues published a systematic review and meta-analysis of mechanochemical endovenous ablation using Flebogrif for varicose veins.[23] Five articles were included in the analysis, totalling 348 procedures in 392 patients. One study was an RCT, one study was a prospective comparative study, and 3 were prospective case-series. Four studies reported the 3-month anatomic success, and 3 studies reported the 12-month anatomic success. The pooled 3-month anatomic success rate was 95.6% (95% CI, 93.2%-98.0%). The 12-month anatomic success rate was 93.2% (95% CI, 90.3%-96.1%). The only major complication reported within 3 months was deep vein thrombosis, which developed in 0.3% of the patients. The minor complications of thrombophlebitis and hyperpigmentation had occurred in 13.3% to 14.5% and 3.3% to 10.0% of patients, respectively, within 3 months.

  Limitations of this review include the following:
  - Clinical success, pain reduction, and QOL were not assessed
  - Four of 5 studies were not randomized or blinded, high risk of bias
  - Three studies had no comparator groups
  - Small sample sizes
  - Short term follow up

  The authors concluded that MOCA using the Flebogrif device is safe and well-tolerated for saphenous vein insufficiency, but well-designed studies of sufficient sample size and follow-up are needed to compare effectiveness against other standard treatments.

<u>Cryoablation</u>

Randomized Controlled Trials (RCTs)

In 2008 through 2011, Disselhoff et al. conducted an RCT to compare endovenous laser ablation with cryostripping for great saphenous varicose veins.[24,25] A total of 120 patients with great saphenous varicose veins were randomized 1:1 to endovenous laser ablation or cryostripping. “Principal outcomes measures were: freedom from recurrent varicose veins on duplex imaging, and improvement in Venous

Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Severity Score (AVVSS) 6, 12 and 24 months after treatment."[24]

At 5-year follow-up, the results indicated no statistically significant difference between EVLA and cryostripping for freedom from recurrent varicose veins. Neovascularization was more common after cyrostripping; however, incompetent tributaries were more common after EVLA. Both treatment groups showed significant improvement in VCSS and AVVSS throughout 5 years; however, the improvements were not statistically significant.

Methodological strengths of this study include the randomized, controlled design using a comparator group with an extended follow-up period. However, significant limitations are present in the small sample size, high attrition (31% of patients lost to follow-up at 5-years), and lack of intention to treat analysis. Although the authors concluded there is no significant differences between EVLA and cryostripping, further studies of good methodological quality are required to support the efficacy, safety, and medical necessity of this treatment for varicose veins.

Nonrandomized Studies

The evidence review identified three nonrandomized studies evaluating cryoablation for the treatment of varicose veins.[26-28] Although these studies suggest cryoablation may be efficacious for the treatment of varicose veins, the validity of these conclusions is significantly limited due to the poor study quality. All studies have very small sample sizes short follow-up periods. Further studies of good methodological quality are required to support the efficacy, safety, or medical necessity of cryoablation to treat varicose veins.

<u>Cyanoacrylate Adhesive</u>

Systematic Reviews

- In 2019 (updated 2022), Hayes published a new health technology assessment regarding the use of cyanoacrylate embolization with the VenaSeal Closure System for the treatment of varicose veins in patients with symptomatic venous reflux disease.[29] In a comprehensive review of the literature, the authors included 9 studies (across 13 publications) in their review. They rated the overall body of evidence as low-quality, comprised of 1 good and 2 fair-quality RCTs, and 6 retrospective comparative studies that rated very poor quality. Patients included adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound. Collectively, the studies suggested that he VenaSeal Closure System may result in reduced symptom severity, improved QOL, and high venous occlusion rates. Given the current paucity of data, well-designed trials comparing the VenaSeal System with other endovenous techniques are needed. Hayes gave this technology a C rating.

- In 2015, updated in 2021, ECRI published a clinical evidence assessment on VenaSeal Closure System (Medtronic) for embolizing varicose veins.[30] The review included one systematic review of 20 randomized controlled trials (n=4570) comparing VenaSeal with EVLA, RFA, MOCA, sclerotherapy, and surgery. The review also included one RCT (n=222) comparing VenaSeal to RFA, and 3 retrospective observational studies. The systematic review and 2 retrospective studies reported successful embolization compared to other treatments or before-procedure results. The RCT found

no difference between VenaSeal and RFA at 36-month follow up. Both the systematic review and one retrospective study reported less intraoperative pain with VenaSeal than RFA or other procedures. The systematic review found lower adverse events with VenaSeal than any other treatment, and the RCT found few events than RFA. Among the retrospective studies, one found fewer events than RFA, while the other found no significant differences in adverse events. Limitations of this review include:

- The systematic review had short follow up of 6 months
- Only 108 participants in the systematic review were treated with VenaSeal
- The RCT did not blind, high risk of bias
- Retrospective, single-center observational study design for 3 studies
- One retrospective study had no comparator group

ECRI concluded that the evidence is somewhat favorable for the VenaSure closure system for embolizing varicose veins.

- In 2017, Vos and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of mechanochemical endovenous ablation (MOCA) and cyanoacrylate vein ablation (CAVA) for treatment of great saphenous vein (GSV) incompetence.[31] Independent investigators systematically searched the literature for prospective studies through December 2016, identified eligible studies, assessed study quality, extracted data and pooled results. The primary outcome of interest was anatomic success. Secondary outcomes of interest were initial technical success, Venous Clinical Severity Score (VCSS), Aberdeen Varicose Vein Questionnaire Score (AVVQS), and complications. In total, 15 studies were included for review. Pooled anatomic success for MOCA and CAVA were calculated at 94.1% and 89.0% respectively, at 1-year follow-up. VCSS and AVVQS scores improved significantly for both groups' patients compared to baseline, with no significant difference between groups. Limitations included the limited quantity and quality of studies included for review, manufacturer-funding, lack of long-term follow-up, and heterogeneity of patient populations, and outcome measures. Investigators concluded that both MOCA and CAVA appeared effective, but that additional high-quality RCTs were needed to better determine their potential role in clinical practice.

Randomized Controlled Trials (RCTs)

- In 2018, Gibson and colleagues published results at 2-year follow-up from an RCT comparing the safety and efficacy of cyanoacrylate embolization (CAE) to radiofrequency ablation (RFA) for the treatment of incompetent great saphenous veins.[32] In total, 222 patients were randomly assigned to receive either CAE (n=108) or RFA (n=114). Outcomes of interest included treatment success, VCSS, AVVQS and patient-reported quality of life. At 24-month follow-up, the complete closure rate was 95.3% in the CAE group and 94% in the RFA group. Symptoms and quality of life improved similarly in both groups. No clinically significant device- or procedure-related late adverse events were reported. Investigators conclude that both treatments produced statistically and clinically significant improvements in VCSS and quality of life measurements. Limitations include the study's small sample size, lack of long-term follow up, substantial loss to follow-up among both groups (26% in the RFA group and 19% in the CAE group), potential for confounding from patients' adjunctive treatment regimens, and author's conflicts of interest with VenaSeal's manufacturer.

- In 2015, Morrison et al. conducted a RCT to compare cyanoacrylate embolization (CAE) and radiofrequency ablation (RFA) for incompetent great saphenous veins (GSV).[33] A total of 222 subjects with symptomatic GSV incompetence were randomly assigned to receive CAE (n=108) or RFA (n=114). The primary outcome of interest was closure of the target vein at 3 months' follow-up.

Secondary outcomes of interest included pain during vein treatment, extent of ecchymosis (bruising) at 3 days' follow-up, general and disease specific quality of life (QOL), and adverse events.

At 3 months' follow-up, the reported vein closure rates were 99% for CAE and 96% for RFA (no statistically significant difference). No statistically significant differences between groups were identified for the outcome of pain during vein treatment. Patients who underwent treatment with CAE had statistically significantly less ecchymosis in the treated region compared with RFA. Both groups reported similar rates for all other adverse events.

Strengths of this study included the randomized, controlled design using a comparator group. However, significant methodological limitations are present in the small sample size and short follow-up period. The authors concluded that CAE is non-inferior to RFA for the treatment of incompetent GSVs at 3 months follow-up; therefore, further studies of good methodological quality are required in order to establish the safety, effectiveness, and medical necessity of this treatment for varicose veins.

Nonrandomized Studies

The evidence review identified an additional study by Bozkurt and colleagues (2016) that evaluated cyanoacrylate glue for the treatment of venous insufficiency.[34] The results of this study indicate cyanoacrylate adhesion may be a safe and effective endovenous ablation technique for varicose insufficiency. However, significant methodological limitations are present in the lack of randomization, small sample size, and short follow-up period. Therefore, further studies of good methodological quality are required to establish the efficacy, safety, and medical necessity of cyanoacrylate adhesives for treating varicose veins.

Transilluminated Powered Phlebectomy (TIPP)

Randomized Controlled Trials

In 2017, Yin and colleagues conducted an RCT comparing the efficacy of ultrasound-guided foam sclerotherapy plus great saphenous vein (GSV) high ligation (n =73) to stripping plus multi-stab avulsion or transilluminated powered phlebectomy (TIPP) of the great saphenous vein (n=90).[35] Follow-up was 12 months. Primary outcomes of interest included venous filling index, Venous Clinical Severity Score, and Aberdeen Varicose Vein Questionnaire Score, reflux recurrence rates and complication rates. Patients improved across all outcomes compared to baseline, and did not significantly differ between groups. Patient satisfaction, operating times and hospital costs were more favorable among patients receiving ultrasound guided foam sclerotherapy. Limitations included small sample size, lack of long-term follow-up, and loss to follow-up in the phlebectomy group (18%, n=74/90). While investigators concluded that ultrasound-guided foam sclerotherapy with GSV high ligation was a safe and effective treatment for severe lower extremity varicosis, authors also stated that larger RCTs with long-term follow-up were needed to validate results.

Nonrandomized Studies

Two recent retrospective studies evaluating the safety and efficacy of TIPP.[36] One study assessed 979 limbs and conducted multivariable logistic regression to evaluate the relationship between procedure type and complications, controlling for patient characteristics, severity of disease, pre-operative

anticoagulation and post-operative compression.[36] Investigators found that Venous Clinical Severity Scores improved more with radiofrequency ablation (RFA) plus TIPP when compared to RFA alone (3.8 ± 3.4 vs. 3.2 ± 3.1, $p = 0.018$). No significant difference was reported between RFA plus TIPP versus RFA alone for deep venous thrombosis, asymptomatic endovenous heat-induced thrombosis or infection. Another study, assessing 1,034 patients at 12-year follow-up reported that all TUPP procedures were technically successful, with zero patients requiring conversion to hook stab phlebectomy, and few adverse events.[37] Limitations included the studies' retrospective design, the lack of data from more than one center, the lack of randomization, heterogenous patient populations, and the lack of a control group, all of which preclude a full determination of TIPP's true efficacy. Investigators from both studies concluded that TIPP appears to be a safe and effective procedure, either when used as an adjunct to RFA or alone.

CLINICAL PRACTICE GUIDELINES

American Venous Forum, Society for Vascular Surgery, American College of Phlebology, Society for Vascular Medicine, and International Union of Phlebology

The Guidelines Committee of the American Venous Forum (AVF) tasked a multi-organizational group with a joint review of the available evidence and requested guidelines recommendations regarding compression therapy after invasive treatment of superficial veins. In 2019, guidelines were published after a review and evaluation of the evidence base using GRADE methodology.[38]

Summary

Guideline 1.1: Compression after thermal ablation or stripping of the saphenous veins.

When possible, we suggest compression (elastic stockings or wraps) should be used after surgical or thermal procedures to eliminate varicose veins. [GRADE - 2; LEVEL OF EVIDENCE - C]

Guideline 1.2: Dose of compression after thermal ablation or stripping of the varicose veins.

If compression dressings are to be used postprocedurally in patients undergoing ablation or surgical procedures on the saphenous veins, those providing pressures >20 mm Hg together with eccentric pads placed directly over the vein ablated or operated on provide the greatest reduction in postoperative pain. [GRADE - 2; LEVEL OF EVIDENCE - B]

Guideline 2.1: Duration of compression therapy after thermal ablation or stripping of the saphenous veins.

In the absence of convincing evidence, we recommend best clinical judgment to determine the duration of compression therapy after treatment. [BEST PRACTICE]

Guideline 3.1: Compression therapy after sclerotherapy.

We suggest compression therapy immediately after treatment of superficial veins with sclerotherapy to improve outcomes of sclerotherapy. [GRADE - 2; LEVEL OF EVIDENCE - C]

Guideline 3.2: Duration of compression therapy after sclerotherapy.

In the absence of convincing evidence, we recommend best clinical judgment to determine the duration of compression therapy after sclerotherapy. [BEST PRACTICE]

Guideline 4.1: Compression after superficial vein treatment in patients with a venous leg ulcer.

In a patient with a venous leg ulcer, we recommend compression therapy over no compression therapy to increase venous leg ulcer healing rate and to decrease the risk of ulcer recurrence. [GRADE - 1; LEVEL OF EVIDENCE - B]

Guideline 4.2: Compression after superficial vein treatment in patients with a mixed arterial and venous leg ulcer.

In a patient with a venous leg ulcer and underlying arterial disease, we suggest limiting the use of compression to patients with ankle-brachial index exceeding 0.5 or if absolute ankle pressure is >60 mm Hg. [GRADE - 2; LEVEL OF EVIDENCE - C]

Intersocietal Accreditation Commission (IAC)

In 2021, the Intersocietal Accreditation Commission (IAC) published the following standards and guidelines on vascular testing for accreditation.[39]

4.7.2B Lower Extremity Venous Duplex for Reflux

4.7.2.1B Transverse grayscale images without and with transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum:

i. common femoral vein;
ii. saphenofemoral junction;
iii. proximal femoral vein
iv. mid femoral vein;
v. distal femoral vein
vi. great saphenous vein;
vii. popliteal vein;
viii. small saphenous vein;
ix. additional images to document areas of suspected reflux and as required by the protocol.

4.7.2.2B Spectral Doppler waveforms with the extremity(s) in a dependent position, demonstrating baseline flow and response to distal augmentation. If present, reflux duration of retrograde flow must be measured with calipers and documented as required by the protocol and must include at a minimum:

i. common femoral vein;
ii. saphenofemoral junction;
iii. great saphenous vein at proximal thigh;

iv. great saphenous vein at knee
v. femoral vein mid-thigh
vi. popliteal vein;
vii. anterior accessory saphenous vein (when identified);
viii. small saphenous vein at saphenopopliteal junction if visualized. If not visualized there, the small saphenous vein at the proximal calf must be documented;
ix. Perforator vein waveforms in the setting of active or healed venous ulcers, as required by the protocol;
x. Additional waveforms as required by the protocol.

4.7.2.3B Transverse grayscale images of diameter measurement must be documented as with the extremity(s) in a dependent position and must include at a minimum:

i. saphenofemoral junction;
ii. great saphenous vein at proximal thigh;
iii. great saphenous vein at knee;
iv. anterior accessory saphenous vein (when identified);
v. small saphenous vein at the saphenopopliteal junction if visualized. If not visualized there, the small saphenous vein at the proximal calf must be documented.

Society for Vascular Surgery/American Venous Forum (SVS/AVF)

The 2011 SVS/AVF evidence-based clinical practice guideline for the care of patients with varicose veins and associated venous disease gave the following recommendations:[2]

- Patients with varicose veins or more severe chronic venous diseases (CVDs), a complete history and detailed physical examination are complemented by duplex ultrasound scanning of the deep and superficial veins (GRADE 1A)
- Suggest compression therapy for patients with symptomatic varicose veins (GRADE 2C) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B)
- Recommend compression therapy as the primary treatment to aid healing of venous ulceration (GRADE 1B)
- To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A)
- For treatment of the incompetent great saphenous vein, we recommend endovenous thermal ablation (RFA or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B)
- We recommend phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C)
- We recommend against selective treatment of perforating vein incompetence in patients with simple varicose veins (CEAP class C_2; GRADE 1B), but we suggest treatment of pathologic perforating veins (outward flow duration ≥500 ms, vein diameter ≥3.5 mm) located underneath healed or active ulcers (CEAP class C_5-C_6; GRADE 2B).

National Institute for Health and Care Excellence (NICE)

- The 2013 evidence-based NICE guideline for the diagnosis and management of varicose veins gave the following recommendations:[40]
    - Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.
    - For people with confirmed varicose veins and truncal reflux:
        - Offer endothermal ablation
        - If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy
        - If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery
        - If incompetent varicose tributaries are to be treated, consider treating them at the same time
        - Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable
        - Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances
        - Consider compression hosiery for symptom relief of leg swelling associated with varicose veins during pregnancy.

- In 2020, NICE published guidelines on cyanoacrylate glue occlusion for varicose veins. They gave the following recommendations:[41]

    - "Evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
    - The procedure should only be done by clinicians with appropriate training in this procedure and experience in the use of venous ultrasound."

American College of Radiology (ACR)

The 2009 (revised 2012) ACR evidence-based appropriateness criteria for the radiologic management of lower-extremity venous insufficiency gave the following recommendations:[42]

- Endoluminal laser or radiofrequency ablation or compression stocking therapy only for left small saphenous venous insufficiency resulting in intermittent pain and swelling without skin discoloration or ulceration
- Endoluminal laser or radiofrequency ablation for left great saphenous insufficiency with associated lower leg skin ulceration
- Compression stocking therapy only for symptomatic bilateral great saphenous venous insufficiency and large visible varicose veins during pregnancy
- Compression stocking therapy only for chronic left femoral venous thrombosis with left great saphenous venous insufficiency and lower-extremity swelling
- Compression stocking therapy only, endoluminal laser ablation, or endoluminal radiofrequency therapy for symptomatic bilateral great saphenous venous insufficiency with remote history of deep venous thrombosis with no residual thrombus present
- Endoluminal laser or radiofrequency therapy for right great saphenous venous insufficiency status post vein stripping 1 year ago with persistent lower-extremity swelling and reflux is noted in the below-knee greater saphenous vein measuring up to 5 mm.

EVIDENCE SUMMARY

There is sufficient evidence to support the treatment of certain symptomatic varicose veins and chronic venous insufficiency using ligation, phlebectomy, ablation (laser or radiofrequency), and sclerotherapy. The evidence also supports that these treatments improve a patient's function and instrumental activities of daily living. Endovascular embolization with a cyanoacrylate adhesive has similar efficacy to but is more costly than standard treatment and therefore is considered not medically necessary for treating chronic venous insufficiency or varicose veins.

There is insufficient evidence to support the use of mechanochemical endovenous ablation or cryoablation to treat varicose veins. Further studies of good methodological quality are required to establish the safety, efficacy, and superiority of these treatments over standard therapies such as ligation, ablation, and sclerotherapy. Therefore, mechanochemical endovenous ablation, cryoablation, or endovascular embolization with a cyanoacrylate adhesive to treat varicose veins is considered investigational.

BILLING GUIDELINES AND CODING

- There is no specific CPT code to report foam sclerotherapy; therefore, this procedure might be billed with codes for sclerotherapy (36470, 36471, S2202) or the unlisted vascular procedure code (37799).
- There is no specific CPT code to report stab phlebectomy of varicose veins, one extremity; less than 10 incisions. Therefore, this procedure might be billed with the unlisted vascular procedure code (37799).

Duplex Scanning

- The CPT codes for duplex scanning (93970 or 93971) may be billed in conjunction with varicose vein treatment codes.
- Duplex scanning must be performed by an accredited vascular lab (e.g., Intersocietal Accreditation Commission [IAC] or American College of Radiology [ACR]).

Session Limits

- Phlebectomy (CPT Codes: 37765, 37766, or 37799) following an ablation procedure is limited to 1 billable procedure per leg ≤ 6 months from the initial ablation procedure.
- Sclerotherapy (CPT Codes: 36470, 36471, S2202, or 37799) following an ablation procedure is limited to 1 billable procedure per leg ≤ 6 months from the initial ablation procedure.

CODES*		
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
	36299	Unlisted procedure, vascular injection

	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)
	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
	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 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; subsequent vein(s) 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; subsequent vein(s) 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 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
	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
	37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
	37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
	37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
	37799	Unlisted procedure, vascular surgery (*Note:* May be used to bill for foam sclerotherapy or stab phlebectomy; <10 incisions. See Billing Guidelines for more information.
HCPCS	J3490	Unclassified drugs
	S2202	Echosclerotherapy

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.