Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

---

***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Echosclerotherapy for the Treatment of Varicose Veins

Description/Background

Varicose veins are caused by a defect in either the vein wall or valve leaflets. The defect results in reflux from the deep to the superficial veins through incompetent perforator veins, in other critical venous junctions and along the superficial venous network. Varicose veins tend to be both chronic and recurrent and can be categorized as primary or secondary. When valve incompetence and reverse blood flow are present in the superficial venous system, they are referred to as primary varicose veins. Varicosities arising after deep vein thrombosis and post phlebitis syndrome are called secondary varicose veins.

The size of varicosities does not always correlate with symptom severity. Small varicosities may cause discomfort, a burning sensation, nocturnal cramps and restlessness of the legs. Some patients with large varicosities may have no symptoms. Symptoms associated with large varicosities include heaviness in the legs at the end of the day, tension, aching, a swollen sensation, and restless legs, cramps, itching and tingling. Symptoms increase with age and are more common in women than men when varicosities are present.

Treatment options for varicose veins focus first on identifying and correcting the site of reflux and second, to redirecting venous flow through veins with intact valves. Surgical treatment of varicosities is based on the following principles:

- Control of the most proximal point of reflux typically at the saphenofemoral junction, as identified by preoperative Doppler ultrasonography. Surgical ligation is the common form of treatment of the site of reflux.
- Isolation of the refluxing greater saphenous from the circulation. The most typical strategy for isolation is vein stripping, which is always preceded by ligation.
- Removal of the varicose tributaries.

Treatment goals usually include:

- Alleviating or reducing pain and other symptoms.
- Preventing thrombotic or cutaneous complications.

While sclerotherapy is an accepted and effective treatment of telangiectactic vessels, it has also been used in the treatment of varicose tributaries without prior ligation with or without vein stripping. This application of sclerotherapy creates issues regarding its effectiveness in the absence of the control of the point of reflux and isolation of the refluxing saphenous vein. In addition, when the sclerosant is injected into the greater or lesser saphenous vein, sclerotherapy has been investigated as a minimally invasive alternative to vein stripping, either with or without ligation. Since the saphenous vein is not visible with the naked eye, injection is typically guided by ultrasonography, and the combined procedure may be referred to as "echosclerotherapy." Since the greater saphenous vein is larger and deeper than telangiectatic dermal veins, sclerotherapy of this vein raises issues regarding appropriate volume and concentration of the sclerosant, and the ability to provide adequate post-procedure compression. Moreover, the use of sclerotherapy, as opposed to the physical removal of the vein with stripping, raises the issue of recurrence due to recanalization.

Echosclerotherapy (ultrasound-guided sclerotherapy) is a procedure by which the greater or lesser saphenous vein, other varicose veins, the saphenofemoral junction or perforating veins are injected under direct duplex ultrasound visualization to treat varices. Since the saphenous vein is not visible with the naked eye, injection is typically guided by ultrasonography. Care must be taken to ensure that the appropriate volume and concentration of the sclerosant is injected and that there is an ability to provide adequate post-procedure compression. Ultrasound may be used for diagnosis, during the injection with sclerosing solution and during follow-up studies. Ultrasound guided sclerotherapy (echosclerotherapy) is primarily used to treat large veins beneath the surface of the skin.

During echosclerotherapy, duplex ultrasound is said to enhance the precision of the therapy. Echosclerotherapy is also called aimed sclerotherapy, duplex sclerotherapy, or sonographic sclerotherapy.

One protocol for sclerotherapy, as the sole treatment of saphenofemoral incompetence, has been referred to as the COMPASS procedure, an acronym for comprehensive objective mapping, precise image-guided injection, antireflux positioning and sequential sclerotherapy. The preoperative use of Doppler ultrasonography is to identify the point of origin or reflux and other contributing refluxing sources, followed by image-guided injection of the sclerosant into the greater saphenous vein. Anti-reflux positioning refers to the positioning of the patient with the legs elevated to eliminate reflux and venous hypertension. Finally, sequential sclerotherapy refers to the use two or three sessions of sclerotherapy until the varicosities resolve.

Regulatory Status:

N/A

Medical Policy Statement

The safety and effectiveness of echosclerotherapy for the treatment of the saphenous vein varicosities is established. It may be considered a useful therapeutic option in individuals for whom traditional sclerotherapy of saphenous vein varicosities would be indicated.

Inclusionary and Exclusionary Guidelines

Inclusions:
Ultrasound guidance to the saphenous vein in individuals having sclerotherapy would be considered established.

Ultrasound guidance to symptomatic varicose tributaries in individuals having sclerotherapy would be considered established.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

S2202 36465 36466 37799 36470 36471
76942

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

A 2006 randomized controlled trial (RTC) of 60 patients compared ultrasound-guided sclerotherapy with sapheno-femoral ligation under local anesthesia to sapheno-femoral ligation, stripping and multiple avulsions under general anesthesia. At three-month post procedure, both groups saw improvements in the venous clinical severity score and the Aberdeen vein questionnaire, although recanalized veins occurred in four sclerotherapy patients (13%). Quicker recovery and shorter treatment time was reported in the sclerotherapy with sapheno-femoral ligation group, but a longer follow-up study is needed.[2]

In another study of 163 legs, ultrasound-guided foam sclerotherapy (UGFS) achieved early complete occlusion safely in over 90% of the legs with varicose veins. Improvements in sclerotherapy have included the routine use of Doppler ultrasonography to target refluxing vessels and more effective foam/sclerosant injectate. It has been suggested that these improvements may be associated with a reduction in recurrence rates associated with sclerotherapy. Data in more recent reports from controlled trials are inadequate to permit scientific conclusions regarding the equivalence or superiority of sclerotherapy as an alternative to either ligation or ligation and stripping. [3]

A 3-year follow-up was reported from a prospective observational study of sclerotherapy in 489 patients with refluxing saphenous veins and related tributaries. Out of 807 veins treated, 56% were associated with the great saphenous vein and 22% with the small saphenous vein; 22% were tributaries alone. Ultrasound at 3 – 5 days after each treatments showed successful occlusion in an average of 1.5 sessions for the group as a whole (65% in one session and 26%

in two sessions). The analysis showed 3-year survival rates of 83% for tributaries, 53% for great saphenous veins and 36% for small saphenous veins. These results do not support the use of sclerotherapy for refluxing saphenous veins, and evidence remains insufficient to evaluate the long-term efficacy of sclerotherapy for varicose tributaries. [4]

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. In these situations, the use of ultrasound guidance would be considered medically necessary in the small subset of patients for whom the sclerotherapy would be considered medically indicated. Ultrasound guidance of the varicose tributaries is considered not medically necessary or incidental to the injection procedure.

The use of duplex-guided ultrasound for sclerotherapy of varicose veins of the lower extremities has not been shown to definitively increase the effectiveness or safety of this procedure. Although there is very little published medical literature on the use of echosclerotherapy, and no large long-term outcomes have been reported, echosclerotherapy has become the preferred method of many physicians for sclerosing varicosities of the saphenous veins.

An article by Chwala et al in 2015 states that sclerotherapy was previously used mostly in the treatment of spider veins, telangiectasia, and reticular veins.[8] Discouragement concerning treatment of varicose veins resulted from common recurrence of the problem, mainly caused by leaving untreated saphenous vein trunks (great or small). Foam sclerotherapy with ultrasound guidance, also referred to as echosclerotherapy, enabled closing trunks as large as 10 mm in diameter. Its effectiveness is comparable to surgical methods and is slightly worse than thermal treatment. It has become a viable tool in the surgeon's armamentarium for the treatment of symptomatic varicose veins of the lower extremities.

Government Regulations

National:

No NCD on this topic.

Local:

WPS Local Coverage Determination (LCD) for Treatment of Varicose Veins of the Lower Extremities (L34536); For services performed on or after 9/30/2021.

Coverage Indications, Limitations, and/or Medical Necessity

Historically, varicose veins have been treated by conservative measures such as exercise, periodic leg elevation, weight loss, compressive therapy and avoidance of prolonged immobility. When conservative measures are unsuccessful, and symptoms persist, the next step has been sclerotherapy or surgical ligation with or without stripping. Sclerotherapy involves the injection of a sclerosing solution into the varicose vein(s).

More recently, endoluminal radiofrequency ablation (ERFA) and endoluminal laser ablation have been developed as alternatives to sclerotherapy and surgical intervention. These procedures are designed to damage the intimal wall of the vein resulting in fibrosis and subsequent ablation of the lumen of a segment of the vessel. Both procedures utilize specially designed catheters inserted through a small incision in the distal thigh and advanced, often under ultrasound guidance, nearly to the saphenofemoral junction. The catheter is then slowly

withdrawn while controlled radiofrequency or laser energy is applied. This is followed by external compression of the treated segment.

Doppler ultrasound or duplex studies are often used to map the anatomy of the venous system prior to the procedure. There is adequate evidence that pre-procedural ultrasound is helpful, and Medicare will cover one ultrasound or duplex scan prior to the procedure to determine the extent and configuration of the varicosities when it is medically necessary.

Evidence and clinical experience supports the use of ultrasound guidance during the procedure and shows that the outcomes may be improved and complication rates may be minimized when ultrasound guidance is used. The CPT codes for radiofrequency and laser include the intra-operative ultrasound service in the valuation and ultrasound may not be billed separately with these procedures.

A duplex ultrasound examination is considered medically necessary and will be allowed when performed within 1 week (preferably within 72 hours) of EFRA to check for any evidence of thrombus extension from the saphenofemoral junction into the deep system.

A. Indications for surgical treatment and sclerotherapy:
1. A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed; AND
2. The patient is symptomatic and has one or more of the following:
    a. pain, aching, cramping, burning, itching and/or swelling during activity or after prolonged standing severe enough to impair mobility
    b. Recurrent episodes of superficial phlebitis
    c. Non-healing skin ulcerations
    d. Bleeding from a varicosity
    e. Stasis dermatitis
    f. Refractory dependent edema
3. The treatment of spider veins/telangiectasis will be considered medically necessary only if there is associated hemorrhage.

B. Indications for ERFA or laser ablation:
In addition to the above (see A), the patient's anatomy and clinical condition are amenable to the proposed treatment including ALL of the following:
1. Absence of aneurysm in the target segment
2. Maximum vein diameter of 20 mm for ERFA or 30 mm for laser ablation.
3. Absence of thrombosis or vein tortuosity, which would impair catheter advancement
4. The absence of significant peripheral arterial disease

C. Limitations for ERFA and laser ablation:
1. ERFA and laser ablation are covered only for the treatment of symptomatic varicosities of the lesser or greater saphenous veins and their tributaries which have failed 3 months of conservative therapy
2. Intra-operative ultrasound guidance is not separately payable with ERFA, laser ablation
3. The treatment of asymptomatic varicose veins, or symptomatic varicose veins without a 3-month trial of conservative measures, by any technique, will be considered cosmetic and therefore not covered

4. The treatment of spider veins or superficial telangiectasis by any technique is also considered cosmetic, and therefore not covered unless there is associated bleeding
5. Coverage is only for devices specifically FDA-approved for these procedures
6. One pre-operative Doppler ultrasound study or duplex scan will be covered
7. Post-procedure Doppler ultrasound studies will be allowed if medically necessary

The stab phlebectomy of the same vein performed on the same day as endovenous radiofrequency or laser ablation may be covered if the criteria for reasonable and necessary as described in this LCD are met.

If sclerotherapy is used with endovenous ablation, it may be covered if the criteria for reasonable and necessary as described in this LCD are met.

The treatment of asymptomatic veins with endoluminal ablation or sclerotherapy is not considered medically reasonable and necessary. If it is determined on review that the varicose veins were asymptomatic, the claim will be denied as a noncovered (cosmetic) procedure.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cosmetic and Reconstructive Surgery
- Endovenous Ablation for the Treatment of Varicose Veins (e.g., ClariVein®, VenaSeal™ Closure System)

References

1. Blue Cross Blue Shield Association, “Sclerotherapy as a Treatment of Varicose Veins,” Medical Policy Reference Manual, Policy #7.01.55 last reviewed December 2007.
2. Bountouroglou, D. G, et al., “Ultrasound-guided Foam Sclerotherapy Combined with Sapheno-femoral Ligation Compared to Surgical Treatment of Varicose veins: Early Results of a Randomized Controlled Trial,” European Journal of Vascular Endovascular Surgery, Vol. 31, 2006, pp. 93-100.
3. Darke, S. G. and S. J. A. Baker, “Ultrasound-guided Foam Sclerotherapy for Treatment of Varicose Veins,” British Journal of Surgery, Vol. 93, 2006, pp. 969-974.
4. Myers, K. A., et al., “Outcome of Ultrasound-guided sclerotherapy for varicose Veins: medium-term Results assessed by Ultrasound Surveillance,” European Journal of Vascular Endoscopic Surgery, Vol. 33, 2007, pp. 116-121.
5. Teruya, Theodore H., MD and Jeffrey L. Ballard, MD, “New Approaches for the Treatment of Varicose Veins,” Surgical Clinics of North America, Vol. 84, Issue 5, October 2004, pp. 1397-1417.
6. Wisconsin Physicians Service (WPS), “The Treatment of Varicose Veins of the Lower Extremities,” #CSURG-041 V6, original Michigan effective date 2/16/05, most recent Michigan revision date 9/30/21. Accessed January 2022.

7. HAYES Brief. Ultrasound-Guided Foam Sclerotherapy (UGFS) for Varicose Veins. Lansdale, PA: HAYES, Inc. November 4, 2011, updated December 9, 2013, archived December 4, 2014.
8. Chwala M, Wojciech S, et al. Varicose Veins of Lower Extremities, Hemodynamics and Treatment Methods. Adv Clin Exp Med. 2015; 24(1):5-14.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/21/03	7/21/03	7/7/03	Joint policy established
1/7/05	1/7/05	12/22/05	Routine maintenance
9/1/06	7/11/06	5/24/06	Routine maintenance
11/1/07	8/21/07	10/30/07	Routine maintenance
3/1/09	12/1/09	12/14/08	• Recommendation to approve the policy as written and then retire the policy. • The code S2202 is to be payable (pay like sclerotherapy) • Medical policy statement and recommendation changed to state that echosclerotherapy is safe and effective treatment for the saphenous vein when sclerotherapy is indicated, and is excluded for the varicose tributaries.
1/1/13	10/16/12	11/12/12	Updated references; no changes to policy status.
5/1/16	2/16/16	2/16/16	Updated references and rationale, no changes to policy status.
5/1/17	2/21/17	2/21/17	Routine policy maintenance.
5/1/18	2/20/18	2/20/18	Routine policy maintenance. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance.
5/1/20	2/18/20		Routine policy maintenance. Added codes 36465 and 36466 to policy as established. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.
5/1/23			• MPS changed to echosclerotherapy on vein tributaries are now established

			• Codes 36470, 36471 and 76942 are added to the policy as established (ds)
7/1/23	4/18/23		Policy replaced with Treatment of Varicose Veins/Venous Insufficiency. (ds)

Next review date: Replaced by JUMP policy, *Treatment of Varicose Veins/Venous Insufficiency*

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ECHOSCLEROTHERAPY FOR THE TREATMENT OF VARICOSE VEINS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.