Treatment of Superficial Venous Disease of the Lower Leg

Background

The diagnosis and treatment of venous disease has advanced more in the last 10 years than in the previous 2 centuries combined. Ultrasound, endovenous ablation devices, foam sclerotherapy and tumescent anesthesia have greatly improved patient care and have moved treatment from the operating room to the office or radiology suite. This has created challenges for insurers. Medical necessity policy for the treatment of chronic venous disease (CVD) has become fragmented and inconsistent across the U.S. among private insurers and Medicare. As with any medical specialty, those who are most committed to that specialty generally provide the best care. Commitment includes some form of training, a practice focused in that area and continuing education through attendance at meetings and other CME. The American College of Phlebology (ACP) the American Venous Forum (AVF), the Society of Interventional Radiology (SIR) and other organizations have been at the forefront of advancing education, research and appropriate treatment of venous disease.

In 2011, the Society for Vascular Surgery and the American Venous Forum undertook a comprehensive summary of all the available venous research and graded it by relevance and quality of data. Their goal was to analyze all the available evidence-based medicine and create rational guidelines for treatment of venous disease of the lower limbs and pelvis. This review, by Gloviczki et al, was well received by the medical community across specialties treating venous disease, as it built consensus over a variety of topics.

The American College of Phlebology has prepared this white paper with the goal of creating a summation document that reflects the evidence-based recommendations in the Gloviczki paper as well as many other current studies. Other recommendations are based on American College of Phlebology's consensus of experts where the evidence-based research is sparse, yet the therapy is considered standard of care.

We acknowledge that all carriers are free to determine coverage guidelines, etc., based upon their own independent review of the literature and resources like Cochrane and others. However, we suggest that evidence based medical necessity should not vary greatly based on geography or insurer. We would like to introduce the concept of "medically significant venous insufficiency" or "evidence-based medical significance." This eliminates confusion around terms like "cosmetic" or "not medically necessary." The medical evidence should determine the definition of medically significant venous insufficiency using a combination of CEAP and VCSS classifications (discussed below). We would propose that payers retain the evidence-based definition of medical significance, but choose at what level it becomes either a "covered benefit" or a "non-covered benefit." Insurers could establish different benefit levels for their various premium options. In this way, the evidence-based medical criteria would still be consistent across the industry. In the following pages are medical necessity guidelines in a summary format.

These recommendations have been determined by the method suggested by the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) working group. (www.gradeworkinggroup.org)

For each guideline, the letter A, B or C marks the quality of current evidence as high, medium or low quality. The grade of recommendation of a guideline can be strong (1) or weak (2), depending on the risk and burden of a particular diagnostic test or a therapeutic procedure to the patient vs. the expected benefit. The words, "we recommend," are used for GRADE 1–strong recommendations–if the benefits clearly outweigh risks and burdens, or vice versa; the words, "we suggest," are used for GRADE 2–weak recommendations–when the benefits are closely balanced with risks and burdens. Where current evidence is weak or lacking, the degree of consensus of the committee reflects the grade with the quality of the recommendation adjusted accordingly.

Table I. Grading Recommendations According to Evidence

Grade of Recommendation/ Description	Benefit vs Risk and Burdens	Methodologic Quality of Supporting Evidence	Implications
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation
1C. Strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values
2C. Weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Summary of Guidelines for Treatment of Venous Disease

Indications for Treatment

Compression therapy is an effective method for the management of symptoms related to superficial disease but it does not correct the source of reflux. When patients have a correctable source of reflux definitive treatment should also be offered unless it is contraindicated or unwanted. GRADE 1A (1,8,9,10,11)

We recommend against compression therapy as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate. GRADE 1A (1,8,9,10,11)

After interventional treatment, we recommend the use of a compression garment in the postoperative period. There is extra benefit to the patient in the form of reduced pain after use of compression. The compression dosage and duration is at the discretion and clinical judgment of the treating physician. GRADE 2B

Superficial venous insufficiency is a chronic disease and as such we recommend that patients with this disease be counseled to wear a compression garment even after definite treatment has been provided. The compression dosage is at the discretion and clinical judgment of the treating physician GRADE 2C

We suggest the treatment of some CEAP C2 patients with isolated varices, by medical compression hose alone may be an acceptable form of treatment. A short 1-2 week trial of compression hose may be appropriate where an alternative etiology of symptoms is considered, e.g. musculoskeletal pain or neuropathy (spinal stenosis, sciatica, hip or knee arthritis, diabetic neuropathy etc). GRADE 2C (2,8,9,10,11)

Indications for treatment include pain or other discomfort (ie, aching, heaviness, fatigue, soreness, burning), edema, varix hemorrhage, recurrent superficial phlebitis, stasis dermatitis or ulceration. We recommend patients should be evaluated using the CEAP classification and the Venous Clinical Severity Score (VCSS). We would define medically necessary as a CEAP classification of C2 or higher. GRADE 1A (1)

In addition

We recommend all patients being considered for treatment must have a duplex ultrasound of the superficial venous system and, at a minimum, evaluation of the common femoral vein and popliteal vein for patency and competence. The exam should ideally be done in the standing position. GRADE 1A (1,3,4,5,6)

We suggest all noninvasive vascular diagnostic studies be per formed by a qualified physician or by a qualified technologist under the general supervision of a qualified physician. GRADE 1C (2)

We recommend that named veins (Great Saphenous Vein (GSV), Small Saphenous Vein (SSV), Anterior Accessory of the Great Saphenous Vein (AAGSV), Posterior Accessory of the Great Saphenous Vein (PAGSV), Intersaphenous Vein (Vein of Giacomini)) must have a reflux time > 500 msec, regardless of the reported vein diameter. GRADE 1A (1,7,6)

Treatment of Named Saphenous Veins

We recommend endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence. GRADE 1B (1,15)

We suggest Mechanical/chemical ablation (Clarivein Device) may also be used to treat truncal venous reflux. GRADE 2B (2)

We recommend open surgery is appropriate in veins not amenable to endovenous procedures but otherwise is not recommended because of increased pain, convalescent time, and morbidity. GRADE 1B (1)

We suggest when open surgery of the great saphenous vein is performed it should include high ligation and invagination stripping to the level of the knee. GRADE 2B (1)

We recommend when open surgery of the small saphenous vein is performed it include high ligation and selective invagination of the proximal portion. GRADE 1B (1)

Treatment of Circumflex Veins and Other Non-Truncal Veins

The treatment of other non-truncal, tributary varicose vein reflux (circumflex veins anterior and posterior thigh) is more complex. The medical record should reflect that these veins are incompetent and note their size, presence or absence of tortuosity, and depth relationship to the skin, i.e. accessible or not accessible by phlebectomy.

We recommend varicose (visible) symptomatic tributary veins can be treated by stab phlebectomy, liquid sclerotherapy or foam chemical ablation. GRADE 1B (1, 2, 13)

We recommend (non visible) symptomatic tributary veins be treated by ultrasound-guided liquid sclerotherapy or foam chemical ablation. GRADE 1B (1, 2, 12,14)

Treatment of Perforator Veins

We suggest treatment of incompetent perforating veins located beneath a healed or open venous ulcer. They should have outward flow of 500 ms, with a diameter of 3.5 mm. GRADE 2B (1)

We suggest, in patients with perforator reflux as the primary or only source of disease, treatment of the perforator with endovenous thermal ablation, ligation or ultrasound guided sclerotherapy. Subsequent or simultaneous treatment of symptomatic varicosities arising from the incompetent perforator is also considered best practice. GRADE 2B (2)

CPT/HCPCS Codes

36011	SELECTIVE CATHETER PLACEMENT, VENOUS SYSTEM, FIRST ORDER BRANCH
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
36475	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; FIRST VEIN TREATED
36476	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; SECOND AND SUBSEQUENT VEINS TREATED IN A SINGLE EXTREMITY, EACH THROUGH SEPARATE ACCESS SITES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
36478	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; FIRST VEIN TREATED
36479	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; SECOND AND SUBSEQUENT VEINS TREATED IN A SINGLE EXTREMITY, EACH THROUGH SEPARATE ACCESS SITES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
37241	VASCULAR EMBOLIZATION OR OCCLUSION, INCLUSIVE OF ALL RADIOLOGICAL SUPERVISION AND INTERPRETATION, INTRAPROCEDURAL ROADMAPPING, AND IMAGING GUIDANCE NECESSARY TO COMPLETE THE INTERVENTION; VENOUS, OTHER THAN HEMORRHAGE (EG, CONGENITAL OR ACQUIRED VENOUS MALFORMATIONS, VENOUS AND CAPILLARY HEMANGIOMAS, VARICES, VARICOCELES)
37244	VASCULAR EMBOLIZATION OR OCCLUSION, INCLUSIVE OF ALL RADIOLOGICAL SUPERVISION AND INTERPRETATION, INTRAPROCEDURAL ROADMAPPING, AND IMAGING GUIDANCE NECESSARY TO COMPLETE THE INTERVENTION; FOR ATRIAL OR VENOUS HEMORRHAGE OR LYMPHATIC EXTRAVASATION
37500	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

CPT/HCPCS Codes (cont.)

37735	LIGATION AND DIVISION AND COMPLETE STRIPPING OF LONG OR SHORT SAPHENOUS VEINS WITH RADICAL EXCISION OF ULCER AND SKIN GRAFT AND/OR INTERRUPTION OF COMMUNICATING VEINS OF LOWER LEG, WITH EXCISION OF DEEP FASCIA
37760	LIGATION OF PERFORATOR VEINS, SUBFASCIAL, RADICAL (LINTON TYPE), WITH OR WITHOUT SKIN GRAFT, OPEN
37765	STAB PHLEBECTOMY OF VARICOSE VEINS, ONE EXTREMITY; 10-20 STAB INCISIONS
37766	STAB PHLEBECTOMY OF VARICOSE VEINS, ONE EXTREMITY; MORE THAN 20 INCISIONS
37780	LIGATION AND DIVISION OF SHORT SAPHENOUS VEIN AT SAPHENOPOPLITEAL JUNCTION (SEPARATE PROCEDURE)
37785	LIGATION, DIVISION, AND/OR EXCISION OF VARICOSE VEIN CLUSTER(S), ONE LEG. FOR BOTH LEGS, REPORT WITH A MODIFIER 50.
37799	UNLISTED PROCEDURE, VASCULAR SURGERY
75894	TRANSCATHETER THERAPY, EMBOLIZATION, ANY METHOD RADIOLOGICAL SUPERVISION AND INTERPRETATION
76942	ULTRASONIC GUIDANCE FOR NEEDLE PLACEMENT (EG, BIOPSY, ASPIRATION, INJECTION, LOCALIZATION DEVICE), IMAGING SUPERVISION AND INTERPRETATION
93770	DETERMINATION OF VENOUS PRESSURE
93965	NONINVASIVE PHYSIOLOGIC STUDIES OF EXTREMITY VEINS, COMPLETE BILATERAL STUDY (EG, DOPPLER WAVEFORM ANALYSIS WITH RESPONSES TO COMPRESSION AND OTHER MANEUVERS, PHLEBORHEOGRAPHY, IMPEDANCE PLETHYSMOGRAPHY)
93970	LOWER EXTREMITY VENOUS DUPLEX ULTRASOUND - BILATERAL
93971	DUPLEX SCAN OF EXTREMITY VEINS INCLUDING RESPONSES TO COMPRESSION AND OTHER MANEUVERS; UNILATERAL OR LIMITED STUDY

ICD-9 Codes

448.1	NEVUS, NON-NEOPLASTIC (SPIDER VEINS)
448.9	TELANGIECTASIA, TELANGIECTASIS
451.0	PHLEBITIS AND THROMBOPHLEBITIS OF SUPERFICIAL VESSELS OF LOWER EXTREMITIES
451.2	PHLEBITIS AND THROMBOPHLEBITIS OF LOWER EXTREMITIES UNSPECIFIED
454.0	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
454.1	VARICOSE VEINS OF LOWER EXTREMITIES WITH INFLAMMATION
454.2	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION
454.8	VARICOSE VEINS OF LOWER EXTREMITIES WITH OTHER COMPLICATIONS
456.6	VULVAR VARICOSITIES OF PIRENIUM (SPECIFICALLY)
459.10	POSTPHLEBETIC SYNDROME WITHOUT COMPLICATIONS
459.11	POSTPHLEBETIC SYNDROME WITH ULCER
459.12	POSTPHLEBETIC SYNDROME WITH INFLAMMATION
459.13	POSTPHLEBETIC SYNDROME WITH ULCER AND INFLAMMATION
459.19	POSTPHLEBETIC SYNDROME WITH OTHER COMPLICATION
459.31	CHRONIC VENOUS HYPERTENSION WITH ULCER
459.32	CHRONIC VENOUS HYPERTENSION WITH INFLAMMATION
459.33	CHRONIC VENOUS HYPERTENSION WITH ULCER AND INFLAMMATION
459.81	VENOUS(PERIPHERAL) INSUFFICIENCY, NSPECIFIED
459.89	OTHER SPECIFIED DISORDERS OF CIRCULATORY SYSTEM (PHLEBOSCLEROSIS, VENOFIBROSIS, COLLATERAL CIRCULATION[VENOUS], ANY SITE)

References

The American College of Phlebology guidelines are based on consensus documents and research. These consensus documents, as well as other materials reviewed in forming the ACP guidelines included but were not limited to:

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Disclaimer

Adherence to these guidelines will not ensure successful performance. Furthermore these guidelines should not be deemed inclusive of all proper methods of treatment or exclusive of other protocols reasonably directed to obtain the same results. The physician and patient must make the ultimate judgment regarding the propriety of any performance and interpretation of studies in light of all the circumstances presented by the individual patient.

These guidelines reflect the best available data at the time it was prepared; the results of future research or technology may require alteration of the minimum standards and reporting as set forth in this guideline.