Editors' Choice

From the American Venous Forum

The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology

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ABSTRACT

Background: Stimulated by published reports of potentially inappropriate application of venous procedures, the American Venous Forum and its Ethics Task Force in collaboration with multiple other professional societies including the Society for Vascular Surgery (SVS), American Vein and Lymphatic Society (AVLS), and the Society of Interventional Radiology (SIR) developed the appropriate use criteria (AUC) for chronic lower extremity venous disease to provide clarity to the application of venous procedures, duplex ultrasound imaging, timing, and reimbursements.

Methods: The AUC were developed using the RAND/UCLA Appropriateness Method, a validated method of developing appropriateness criteria in health care. By conducting a modified Delphi exercise and incorporating best available evidence and expert opinion, AUC were developed and scored.

Results: There were 119 scenarios rated on a scale of 1 to 9 by an expert panel, with 1 being never appropriate and 9 being appropriate. The majority of scenarios consisted of symptomatic indications were deemed appropriate for venous intervention. For scenarios with anatomically short segments of reflux and/or no symptoms, the indications were rated less appropriate. For the indication of edema, a wide dispersion of ratings was observed especially for short segments of saphenous reflux or stenting for iliac/inferior vena cava disease, noting that there are multifactorial causes of edema, some of which could coexist with venous disease and possibly impact effectiveness of treatment. Several scenarios were considered never appropriate, including treatment of saphenous veins with no reflux, iliac vein or inferior vena cava stenting for iliac vein compression as an incidental finding by imaging with minimal or no symptoms or signs, and incentivizing sonographers to find reflux.

Conclusions: The AUC statements are intended to serve as a guide to patient care, particularly in areas where highquality evidence is lacking to aid clinicians in making day-to-day decisions for common venous interventions. This may also prove useful when applied on a population level, such as practice patterns, and not necessarily to dictate decision making for individual cases. As a product of a collaborative effort, it is hoped that this could be utilized by physicians and multiple stakeholders committed toward improving patient care and to identify and stimulate future research priorities. (J Vasc Surg: Venous and Lym Dis 2020;8:505-25.)

Keywords: Vein ablation; Vein care; Appropriate use criteria; RAND/UCLA

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Author conflict of interest: none.

Presented at the Thirty-first Annual Meeting of the American Venous Forum, Rancho Mirage, Calif, February 19-22, 2019.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

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https://doi.org/10.1016/j.jvsv.2020.02.001



Journal of Vascular Surgery: Venous and Lymphatic Disorders July 2020

SUMMARY OF APPROPRIATE USE CRITERIA

Refer to Appendices 1 and 2 (online only) for assumptions and definitions.

1-2. Appropriateness criteria for saphenous vein ablation

No.	Procedure	Appropriateness category
1.1	Ablation of the CSV in a symptomatic patient with varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6), when the CSV demonstrates axial reflux <i>with or without</i> SFJ reflux	Appropriate
1.2	Ablation of the below-knee GSV in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6), when there is segmental GSV reflux below the knee directed to the affected area	Appropriate (see Section 1 discussion)
1.3	Ablation of the below-knee GSV in a symptomatic patient with <i>edema</i> due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 1 discussion)
1.4	Ablation of the SSV in a symptomatic patient with varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6), when the SSV demonstrates reflux directed to affected area	Appropriate
1.5	Ablation of the SSV with reflux that communicates with the CSV or thigh veins by intersaphenous vein, in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6), when the SSV demonstrates reflux directed to affected area	Appropriate
1.6	Ablation of the AAGSV in a symptomatic patient with varicose veins, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2, 4-6), when the AAGSV demonstrates axial reflux directed to affected area	Appropriate
1.7	Ablation of the AAGSV in a symptomatic patient with <i>edema</i> due to venous disease (CEAP	May be appropriate

Continued.

No.	Procedure	Appropriateness category		
	class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	(see Section 1-2 discussion)		
1.8	Ablation of the AAGSV with no reflux, but GSV with reflux (CEAP classes 2-6)	Rarely appropriate		
1.9	Therapeutic ablation for <i>asymptomatic</i> disease and visible veins (CEAP classes 1-2) ^a	Rarely appropriate		
2.0	Ablation for a vein with no reflux	Never appropriate		
AACSV, Anterior accessory great saphenous vein; CEAP, Clinical, Etiol- ogy, Anatomy, and Pathophysiology; CSV, great saphenous vein; SFJ, saphenofemoral junction; SSV, small saphenous vein. ^a Excludes cosmetic indications and cannot be extrapolated to such indications				

3. Appropriateness criteria for treatment of nontruncal varicose veins with or without telangiectasia

No.	Procedure	Appropriateness category			
3.1	Treatment of nontruncal varicose veins with or without telangiectasia by sclerotherapy, ambulatory phlebectomy, or powered phlebectomy in a symptomatic patient with varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6)	Appropriate			
CEAP, Clinical, Etiology, Anatomy, and Pathophysiology.					

4. Appropriateness criteria for management decisions for diseased tributaries associated with saphenous ablation

No.	Management decisions	Category
4.1	Providing care for the diseased tributaries of an ablated saphenous vein either concomitantly or as a staged procedure	Appropriate
4.2	Referral of patient to another health care provider for care of diseased tributaries of an ablated vein	May be appropriate
4.3	Making no provisions for care of diseased tributaries	Rarely appropriate

(Continued)

5. Appropriateness criteria for perforator veins

No.	Procedure	Appropriateness category		
5.1	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6)	Appropriate (see Section 5 discussion)		
5.2	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with <i>edema</i> due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 5 discussion)		
5.3	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with telangiectasia or varicose veins (CEAP classes 1-2)	Rarely appropriate		
5.4	Perforator vein treatment in an asymptomatic patient with visible telangiectasia or varicose veins (CEAP classes 1-2)	Never appropriate		
CEAP, Clinical, Etiology, Anatomy, and Pathophysiology.				

7. Appropriateness criteria for duplex ultrasound for chronic venous disease

No.	Procedure	Appropriateness category
7.1	Duplex ultrasound scanning for chronic venous disease in the upright position if technically feasible and safe, eliciting reflux by distal compression and release, and documenting duration of reflux	Appropriate
7.2	Examining the patient in the steep reverse Trendelenburg position, particularly if testing in the standing position is not technically feasible or safe	May be appropriate
7.3	Eliciting reflux using the Valsalva maneuver, particularly for interrogation of the common femoral vein or saphenofemoral junction	May be appropriate
7.4	The technique of creating nonphysiologic "flash" reflux with proximal compression during duplex ultrasound scanning	Rarely appropriate
7.5	Incentivize sonographers based on test results	Never appropriate

6. Appropriateness criteria for iliac vein or inferior vena cava (*IVC*) stenting as first-line treatment

No.	Procedure	Appropriateness category		
6.1	Iliac vein or IVC stenting for obstructive disease <i>without</i> superficial truncal reflux as first-line treatment in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6)	Appropriate (see Sector 6 discussion)		
6.2	Iliac vein or IVC stenting for obstructive disease with or without superficial truncal reflux as first-line therapy in a symptomatic patient with edema due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 6 discussion)		
6.3	Iliac vein or IVC stenting for obstructive disease in an asymptomatic patient for iliac vein compression, such as May-Thurner compression, for incidental finding by imaging or telangiectasia (CEAP class 1)	Never appropriate		
CEAP, Clinical, Etiology, Anatomy, and Pathophysiology.				

8. Appropriateness criteria for timing and reimbursement decisions

No.	Timing and reimbursements	Appropriateness category
8.1	Scheduling the ablation of different veins on different days for clinical reasons including patient preference and safety is appropriate, whereas scheduling treatment on different days for reasons other than clinical reasons including patient preference and safety is not considered generally acceptable.	Appropriate
8.2	Submitting separate charges for a single saphenous ablation requiring multiple access sites	Rarely appropriate
8.3	Submitting two or more separate charges for ablation of two continuous saphenous segments accessed with a single access point or multiple access points (eg. the above- knee GSV and below-knee posterior accessory saphenous vein)	Rarely appropriate

INTRODUCTION

Revolutionary changes have occurred in the management of chronic venous disease in the 21st century with the expanded use of noninvasive percutaneous techniques for eliminating saphenous reflux (thermal and nonthermal), treatment of varicose vein disease by chemical or mechanical methods, and catheterdirected venous recanalization and stenting. These technical advances provide a simpler, safer treatment option compared with open surgical procedures and can be used to address venous diseases that for decades have been under-recognized and undertreated. Unfortunately, simplifying the technology and training required has resulted in unprecedented use of venous interventions across the United States,¹ with a sudden increase well beyond 480% of previous rates of utilization² just within a short time. With this noticeable magnitude of growth, the opportunity for inappropriate use has been reported and in some cases documented.³⁻⁸ The scope of the overuse is estimated to be relatively large, with the exact prevalence being unknown.

Purpose. The aim was to develop a multisociety position document to provide clarity for the appropriate management of commonly encountered scenarios for treatment of venous pathologic conditions. Several societies participated in the project or endorsed the position statement (Table I).

The appropriate use criteria (AUC) consisted of scenarios addressing treatment of superficial and perforator venous disease and did not include deep venous disease with the exception of iliac vein and inferior vena cava (IVC) obstruction. Cases include venous ablation (thermal and nonthermal) of saphenous veins, management of nontruncal varicose veins and telangiectasia, timing of managing tributaries with saphenous ablation procedures, treatment of perforators, stenting of iliac vein and IVC, duplex ultrasound for chronic venous assessment, and reimbursement practices.

Ultimately, the goal of developing the AUC is to provide clinicians the tool to help them deliver high-quality care for patients with venous disease by reducing abuse and overuse of venous interventions without sacrificing appropriate care of those who legitimately benefit from venous interventions. In addition, this document may serve as an educational tool for early venous practitioners and as a guide to identify areas of venous treatment that require more investigation. The hope of the writers and endorsers

Table I. Participating professional societies

American Venous Forum
Society for Vascular Surgery
American Vein and Lymphatic Society
Society of Interventional Radiology

it that this may provide guidance for physicians and patients by providing a vetted standard that may be used in decision-making and may drive practices within a given population of patients toward a more standardized treatment paradigm, as seen with other specialties.^{9,10}

These AUC do not consider the cosmetic aspects of venous interventions, and therefore the recommendations should not be extrapolated to such patients.

METHODS

The AUC process. The AUC were developed in accordance with the RAND/UCLA Appropriateness Method (RAM).¹¹ Originally constructed as a tool to measure overuse and underuse of medical and surgical procedures, the RAM has been clinically validated and is a means of determining appropriateness in health care when it is not feasible to conduct a randomized controlled trial (RCT) for every clinical situation in question.

Based on this methodology, the venous AUC combine best available evidence with expert opinion and engage a panel of experts in the field through a modified Delphi exercise. Although panelists are given an opportunity for discussion before the final round and are allowed to share their ratings, no effort is made to reach a consensus in accordance with the RAM process. Results are allowed to be anonymous, and ratings are not dependent on a group decision. This structured, quantitative technique has been applied to numerous procedures and practices including coronary revascularization,^{9,12} peripheral artery intervention,¹³ carotid endarterectomy,¹⁰ dialysis access procedures,¹⁴ bariatric surgery,¹⁵ radiologic imaging,^{16,17} and others.¹⁸

Although the AUC incorporate evidence when it is available, it is important to point out how they may differ from guidelines. Guidelines are based on evidence that addresses broad and specific cases and provide strength of recommendations based on quality or strength of evidence. The AUC process provides for recommendations that address scenarios in which high-quality evidence is lacking or RCTs are not available and in some cases are not feasible. The AUC document provides recommendations to clinicians for managing clinical situations that fill the gap where scientific literature and guidelines lack specificity and detail for daily clinical decision-making.

In this AUC document, guideline recommendations were used to establish the basis for evidence-based practice but by nature extend beyond the guidelines to provide "best practice" grading. Some considerations in medical practice extend into appropriate indications for treatment. The need for us to address and clearly point out unacceptable practice as well as acceptable practice has been expressed by government authorities, and some of these practices were deemed important to the authors of this document.

These statements are intended to serve as recommendations for whether an intervention is appropriate on a

population level, which may include practice patterns. The appropriateness statements are not intended to determine the standard of care for individual patients. Ultimately, case-specific factors must be taken into consideration in determining the most appropriate management modality for an individual patient.

Panel selection and multisociety (multidisciplinary) participation. The AUC were initiated by the American Venous Forum (AVF). An AVF Ethics Task Force was specifically created to find ways to address the reports of inappropriate use of venous technology. The Task Force elected to create a multisociety (multidisciplinary) project that included participation by the AVF, the Society for Vascular Surgery (SVS), the American Vein and Lymphatic Society, and the Society of Interventional Radiology. All were invited to review and vet the final document, which led to its endorsement (Table I). Multiple specialties that included vascular surgery, phlebology, and interventional radiology were represented.

Once the decision was made to undergo multisociety AUC, the selection of panelists consisted of two steps. The AVF Task Force suggested names of active members from the AVF who were experts in the field. The other societies were invited to participate and to nominate members of their society and were asked to consider those suggested by the AVF. As a result, 16 were invited, and all agreed to participate as panelists.

All 16 panelists (Table II) completed the activities described here and signed confidentiality agreements and self-reported conflict of interest disclosures (Appendix 3, online only). These disclosures were reviewed by the AVF Ethics Task Force, and no objections were raised.

Scenario creation. After 18 months of deliberations, the AVF Ethics Task Force's Clinical Practice subgroup along with the AUC technical panel constructed definitions, assumptions, and clinical scenarios to be used in the ratings process. Definitions were consistent with existing standards when available (Appendix 2, online only). The clinical scenarios for venous procedures were formulated on the basis of the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification clinical class^{19,20} C1 to C6, the presence or absence of symptoms, and in some scenarios anatomic extent of disease. These scenarios were created by the AVF Ethics Task Force to address areas in treatment of superficial venous disease and venous stenting that they thought would benefit from clarification and result in standardization. Care was taken to develop scenarios that were broad enough to capture most of the clinical experience without being overly specific as to limit their general applicability. A set of underlying assumptions were applied to all scenarios (Appendix 1, online only). This includes the assumption that all diagnostic testing is accurate in the clinical scenarios, including the method of determining the presence of superficial reflux, perforator reflux, or iliac vein or IVC obstruction. The scenarios exclude cosmetic indications.

Literature review and definitions. A thorough literature review was conducted by the technical panel to summarize the current state of knowledge regarding vein care. The MEDLINE database was searched using the PubMed search engine. Key search words were vein therapy, venous ablation, perforator ablation, sclerotherapy, iliac vein stenting, duplex ultrasound scanning of chronic venous disease, staged procedure for ablation, and

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Lowell S. Kabnick, MD	Vascular surgery	New York University Langone	New York, NY
Neil M. Khilnani, MD	Interventional radiology	Cornell University	New York, NY
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Joanne M. Lohr, MD	Vascular surgery	Lohr Surgical Specialists	Cincinnati, Ohio
Margaret W. Mann, MD	Dermatology	Case Western Reserve University	Cleveland, Ohio
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Marc A. Passman, MD	Vascular surgery	University of Alabama, Birmingham	Birmingham, Ala
Suresh Vedantham, MD	Interventional radiology	Washington University School of Medicine	St. Louis, Mo
Thomas W. Wakefield, MD	Vascular surgery	University of Michigan	Ann Arbor, Mich

Table II. Expert panelists

Table	III.	Ap	bro	priat	eness	rating	scale
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Rating	Explanation
7, 8, 9	Appropriate Treatment is a generally acceptable and reasonable approach for the indication. <i>and</i> Treatment is likely to improve the patient's health outcomes or survival.
4, 5, 6	May be appropriate Treatment may be an acceptable or reasonable approach for the indication. <i>or</i> Treatment may improve the patient's health outcomes or survival. <i>or</i> More research or patient information is necessary to classify the appropriateness of the indication.
2, 3	Rarely appropriate Treatment is not a generally acceptable or reasonable approach for the indication. and Treatment lacks clear benefit/risk advantage. and Treatment is rarely effective for the indication.
1	Never appropriate

venous tributaries, among others. The time period for the search was 1980 to 2018. A comprehensive summary of the literature results was prepared and is pending publication.

Panelist round 1 ratings. In accordance with the RAM, the scenarios were rated in two rounds. In round 1, the evidence summary, definitions, assumptions, and scenarios were distributed to all panelists. The panelists independently rated the appropriateness of each clinical scenario using a scale of 1 to 9 (Table III) and returned their ratings to the technical group. Panelist scores were kept confidential from all other panelists and the investigators with the exception of the appointed data collector in the technical group (J.V.). Panelists were not obligated to disclose their individual ratings, although they were free to do so. This rating scale differs from the standard RAM in that a rating of 1 is defined as "never appropriate." All other ratings are the same as defined in the RAM. Before proceeding to the second round of voting, the panelists were provided with the results from the first round, which included their own ratings as well as descriptive statistics of the ratings of the entire panel. Panelists were then supplied a new ratings sheet to be completed for the second round of ratings.

Panelist discussion and round 2 ratings. Round 2 rating was conducted over a webinar conference call. Of the 16 panelists, 14 attended and participated in the meeting. The remaining two panelists were supplied with a recording of the webinar. Before the second round of rating, each panelist was supplied with a Journal of Vascular Surgery: Venous and Lymphatic Disorders July 2020

unique rating sheet that included a notation of the individual's rating from round 1, the distribution of round 1 scores from all panelists, and the median score for each scenario. During the webinar, the panelists were given the opportunity to discuss and to clarify the definitions, assumptions, and scenarios. No effort was made to reach a panel consensus in accordance with the RAM process. Panelists were not obligated to disclose their individual ratings, although they were free to do so.

After the discussion was completed, the panelists were asked to re-rate the appropriateness of each scenario. The round 2 ratings were analyzed in the same fashion as the round 1 ratings. The results of the second round of rating were used to determine the final AUC.

Agreement/disagreement calculation. The round 2 ratings served as the basis for the results of this study. Agreement/disagreement was calculated for each scenario using the inter-percentile range adjusted for asymmetry required for disagreement (IPRAS) method as described in the RAM, as follows:

$$IPR = IPR_{UL} - IPR_{LL}$$

$$IPRAS = IPR_R + (AI \times CFA)$$

where

 IPR_{UL} = inter-percentile range upper limit = 70th percentile rating

 IPR_{LL} = inter-percentile range lower limit = 30th percentile rating

 $IPR_r =$ inter-percentile range required for disagreement when perfect symmetry exists = 2.35

AI = asymmetry index = Abs (5 - Avg (IPR_{LL}, IPR_{UL}))

CFA = correction factor for asymmetry = 1.5

If IPR < IPRAS, then agreement

If IPR \geq IPRAS, then disagreement

Level of appropriateness determination. Level of appropriateness was then determined for each scenario on the basis of the median rating and the agreement/ disagreement as prescribed by RAM (Table IV). An agreement/disagreement value was calculated for each item as defined in the RAM. Agreement was defined as an inter-percentile range (30%-70%) that is less than the threshold value for disagreement calculated by the IPRAS method. This agreement/disagreement value was then used in conjunction with the median rating to calculate an overall level of appropriateness for each item.

Unique to this project, a level of appropriateness of "never appropriate" was developed. Never appropriate was defined as a scenario with a unanimous rating of 1.

Creation of appropriate use summary statements. The tested scenarios and their calculated levels of appropriateness are reported under Results, which include the

Table IV. Level of appropriateness determina	tion
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	Panelist rating				
Agreement/disagreement	Unanimous rating of 1	Median 1-3	Median 3.5-6.5	Median 7-9	
Agreement	Never appropriate	Rarely appropriate	May be appropriate	Appropriate	
Disagreement	Not possible	May be appropriate	May be appropriate	May be appropriate	

two-dimensional color tiled tables with summary table for each. The calculated level of appropriateness with median scores for individual scenarios was used as the basis for developing AUC summary statements. This was accomplished by consensus from the AUC writing group.

Statistics and calculations. No inferential statistics were performed. All calculations were performed using Microsoft Excel version 16.0 (Microsoft Corp, Redmond, Wash).

RESULTS

Section 1-2. Saphenous ablation

Great saphenous vein (GSV) ablation for symptomatic axial reflux. The panelists rated ablation for *axial* reflux of the GSV, with or without saphenofemoral junction (SFJ) reflux, in symptomatic patients with CEAP classes 2 to 6 as appropriate (Table V). This appropriateness rating is supported by current evidence indicating the benefit of eliminating saphenous reflux for symptomatic clinical C2 to C6 disease^{21,22} and is supported by multiple published guidelines.²³⁻²⁹ Several RCTs have shown treatment of symptomatic saphenous reflux to be safe, effective, and beneficial over compression therapy.³⁰⁻³⁴

The panelists' ratings indicate that for symptomatic states with longer anatomic extent such as axial GSV reflux, ablation is more likely appropriate as opposed to segmental reflux (Table V). The terms used were based on the definition agreed on and published by the VEIN-TERM multisocietal, international consensus statement.³⁵ Axial reflux is defined as uninterrupted reflux from the groin to the calf. Segmental reflux is defined as localized retrograde flow that can involve any of three venous systems—superficial, deep, or perforating or combinations thereof—in thigh or calf but not in continuity from groin to calf.

The importance of distinguishing axial from shorter segments of reflux is supported by studies that show axial reflux is associated with more advanced symptoms of chronic venous insufficiency than with lesser extent of reflux³⁶⁻³⁸ (see GSV ablation for segmental reflux). The term *axial reflux* used in the AUC refers to continuous reflux by way of the GSV or other superficial reflux that extends from above to below the knee with or without perforator vein or deep vein involvement. Others³⁶ have shown that isolated saphenous vein

incompetence can lead to clinical deterioration associated with *longer extent of reflux*, such as above and below the knee, and also superficial reflux confined to below the knee albeit to a lesser degree. Reflux confined to the below-knee segment was associated with more signs and symptoms than the above-knee segment.

When GSV reflux is accompanied by proximal or SFJ reflux, the findings indicate it appropriate to ablate the GSV for symptomatic C2 to C6 disease. The panelists cited the evidence from an RCT³⁹ showing that elimination of incompetent saphenous veins with proximal SFJ and in some cases axial reflux treated by stripping resulted in a lower failure rate at 6 years of follow-up compared with simple branch sclerotherapy.

Axial reflux could refer to a GSV with or without SFJ reflux. When it is accompanied by no SFJ reflux (ie, the junction is either assumed or proven to be competent or previously interrupted and communicates with the GSV through incompetent thigh perforators or other sources of collateral flow), the remaining refluxing GSV may be the source of recurrent symptoms. In an RCT by Winterborn et al,⁴⁰ recurrence was found to be higher when the SFJ is ligated and the refluxing GSV is left untreated compared with stripping of the entire affected GSV. Thus, for axial GSV reflux, ablating the GSV will likely lead to decreased recurrence even if the SFJ shows no reflux.

GSV ablation for segmental reflux^a. Treatment outcomes of segmental reflux for the GSV have not been specifically studied or differentiated within studies.³⁶ This lack of evidence likely contributes to the rating of may be appropriate for segmental GSV reflux in the thigh without SFJ reflux for classes C3 to C6 (Table V).

For symptomatic C2 disease, the panelists rated treatment rarely appropriate for ablation of GSV reflux isolated to the thigh without SFJ reflux. Although the scenario received a rarely appropriate score, some panelists suggested this may be appropriate if extent of superficial disease is leading to significant symptomatic varicosities associated with the thigh GSV reflux. SFJ without reflux may refer to cases in which the SFJ had been interrupted by ablation or ligation and the

^aSegmental reflux is defined as localized retrograde flow that can involve any of three venous systems—superficial, deep, or perforating or combinations thereof—in thigh or calf but not in continuity from groin to calf.³⁵

Table V. Appropriateness criteria of great saphenous vein (USV) ablat	aphenous vein (USV) ablation
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	Asymptomatic			Symptomatic		
	C ₁	C ₂	Cı	C ₂	C ₃	C ₄₋₆
GSV ablation (above knee only unless indicated)						
1. GSV axial reflux with SFJ reflux	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	Appropriate Median: 7	Appropriate Median: 8	Appropriate Median: 9
2. GSV axial reflux without SFJ reflux (ie, reflux below a competent or previously interrupted SFJ that communicates with an incompetent thigh perforator)	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	Appropriate Median: 7	Appropriate Median: 7	Appropriate Median: 9
3. Below-knee GSV reflux only and ablate the GSV below the knee	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	May be appropriate Median: 4	May be appropriate Median: 4	Appropriate Median: 7
4. Segmental GSV reflux without SFJ reflux	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 3	May Be appropriate Median: 4.5	May be appropriate Median: 6
5. Nonphysiologic reflux or "flash" reflux	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1
6. No reflux	Never appropriate Median: 1	Never appropriate Median: 1				

Summary

	Procedure	Appropriateness category
1.1	Ablation of the GSV in a symptomatic patient with varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6), when the GSV demonstrates axial reflux <i>with or without</i> SFJ reflux	Appropriate
1.2	Ablation of the below-knee GSV in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6), when there is segmental GSV reflux below the knee directed to the affected area	Appropriate (see Section 1 discussion)
1.3	Ablation of the below-knee GSV in a symptomatic patient with <i>edema</i> due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 1 discussion)
CEAD Clir	aical Etiology Anatomy and Pathonhysiology, SEI sanhanofemoral junction	

remaining GSV is supplied by an incompetent thigh perforator or incompetent anterior accessory GSV (AAGSV).

For reflux isolated to the below-knee GSV, panelists gave a higher rating of appropriateness for higher clinical classes C4 to C6. In general, grouping C4a, C4b, C5, and C6 in one category produced discussion about how the ratings may have been different if each category was separated. For example, some thought C4a and C4b with skin discoloration may have had a lower rating than C5 and C6 if rated separately. Others suggested that C5 may have had a lower rating than C6 because it depended on the time of ulcer healing, giving a higher rating of appropriateness to a more recent ulcer event. Despite the appropriate rating for below-knee GSV reflux for C4 to C6, the panelists acknowledged that most ablation studies do not consider extent of disease or distinguish between cases of axial and segmental reflux and that future studies will benefit from making such distinction.

Although the indication of treating a refluxing belowknee GSV for edema received a rating of may be appropriate, the panelists acknowledged that there were no data to suggest treating the below-knee segment would improve venous causes of edema. This is an area in which more research is needed to predict benefit.

	Asymptomatic		Symptomatic			
	C ₁	C ₂	C ₁	C ₂	C ₃	C ₄₋₆
SSV ablation						
7. SSV reflux	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	Appropriate Median: 7	Appropriate Median: 7	Appropriate Median: 9
8. SSV reflux that communicates with the GSV or thigh veins by intersaphenous vein	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	May be appropriate Median: 5.5	May be appropriate Median: 5.5	Appropriate Median: 7.5
9. No reflux	Never appropriate Median: 1	Never appropriate Median: 1	Never appropriate Median: 1	Never appropriate Median: 1	Never appropriate Median: 1	Never appropriate Median: 1

Table VI. A	Appropriateness	criteria of	small saphenous	vein (SSV) ablation
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Summary

No.	Procedure	Appropriateness category
1.4	Ablation of the SSV in a symptomatic patient with varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6), when the SSV demonstrates reflux directed to affected area	Appropriate
1.5	Ablation of the SSV with reflux that communicates with the GSV or thigh veins by intersaphenous vein, in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6), when the SSV demonstrates reflux directed to affected area	Appropriate
CEAP, Clinica	al, Etiology, Anatomy, and Pathophysiology; <i>GSV</i> , great saphenous vein.	

Segmental reflux is suggested to be associated with less clinical severity than axial reflux.^{36,41} However, when studied by segments,³⁶ the one exception seemed to be the below-knee GSV. Aching, swelling, and skin changes have been found to be common in the presence of below-knee *segmental GSV* reflux.³⁶ In a single-center practice of vascular disease, distal reflux below the knee was found to be present in the majority of patients with signs and symptoms of chronic venous disease.⁴²

For segmental reflux associated with clinical classes Cl and C2, several panelists suggested simple branch ablation without ablating the entire saphenous vein as an alternative treatment. Two methods that aim to preserve the saphenous vein in select cases are well described in the literature: the ambulatory selective varices ablation under local anesthesia^{43,44} and the ambulatory conservative hemodynamic treatment of varicose veins.⁴⁵⁻⁴⁷

GSV ablation for edema CEAP class C3. The group indicated for segmental reflux and symptomatic edema C3 due to venous disease may be appropriate for ablation of the GSV (see C3, edema).

GSV ablation with no reflux. The panelists scored ablation by thermal or nonthermal methods for patients with no reflux as never appropriate. The group recognizes that there may be instances when the method of conservative hemodynamic treatment of varicose veins may include resection of a short segment of GSV regardless of competency, and there is some evidence to support this method. This was not one of the scenarios of the AUC, and therefore the criteria are not to be extrapolated to these situations.

SSV ablation. Treatment of SSV reflux was deemed similar to GSV reflux in that it is appropriate to treat if reflux is directed to an affected area in symptomatic cases (Table VI), which is supported by multiple guidelines.^{23,25-28} A systematic review and meta-analysis⁴⁸ of 5 RCTs and 44 cohort studies for treatment of SSV demonstrated that endovenous treatment of SSV reflux resulted in better outcomes with endovenous laser ablation or radiofrequency ablation compared with surgery or foam sclerotherapy. Given the increasing evidence of the effectiveness of nonthermal methods, they suggested that the potential of reduced sural nerve injury with nonthermal techniques below the knee should be considered. The assumption in this case was that SSV ablation may have value if its source of reflux is from the saphenous popliteal junction and it is not a short segment. However, the authors acknowledge that a specific length of reflux for treatment of the SSV has not yet been studied.

AACSV ablation. Treatment of the AACSV has been widely accepted, which is most likely due to its similarities to the GSV in location and length.⁴⁹ The pertinent literature consists of reports demonstrating the safety of AACSV ablation,⁵⁰ improvement of patient severity scores^{51,52} and low recurrence rates at 1 year.⁵² Despite limited data, multiple guidelines for ablating truncal veins including AACSV^{27,28,53} recommend treatment as an acceptable standard and align with the panelists' ratings (Table VII), acknowledging that some payers do not consider treatment of AACSV a valid indication.

AACSV reflux is reported as a frequent cause of recurrence after GSV ablation⁵⁴⁻⁵⁶ although its overall clinical significance remains unclear. Despite new AAGSV reflux after GSV ablation, the lack of evidence to predict in which patient it will become clinically significant may explain why the panelists rated ablating the AAGSV with no reflux rarely or never appropriate even if it is accompanied by an incompetent GSV. In a longitudinal single-center cohort study of prevalence and risk of accessory saphenous vein reflux after GSV ablation, Proebstle and Möhler⁵⁴ found 2% presenting with reflux at baseline. After 4 years, 32% of all legs showed reflux of the AAGSV. The Recurrent Veins After Thermal Ablation (REVATA) study by Bush et al⁵⁵ consisting of 7 centers in a retrospective cohort study of 2380 patients demonstrated recurrence in 164 patients after a median of 3 years, and new AAGSV reflux was identified in 29% of all recurrences. They concluded that the AAGSV is an important source of proximal reflux and recurrence after initial treatment of the GSV. In a systematic review of RCTs evaluating recurrence of varicose veins after GSV endovenous ablation by O'Donnell et al,56 incompetence of the AAGSV was identified in 19% of the 125 limbs with recurrence, second only to recanalization of the treated GSV.

GSV, SSV, or AAGSV ablation for asymptomatic disease. When presented with *asymptomatic* scenarios, the panelists rated *therapeutic* GSV, SSV, or AAGSV ablation rarely or never appropriate (Tables V-VIII). During the round 2 discussion, the panelists generally expressed that the current data do not support widespread treatment of the asymptomatic state. However, they noted that those with large varices with reflux and at risk for superficial phlebitis, bleeding, or complications may warrant consideration in low-risk intervention cases. Likewise, the Medicare Evidence Development and Coverage Advisory Committee and the SVS/AVF coalition have expressed no confidence or a low level of confidence that treatment of asymptomatic venous disease has any measurable benefit.⁵⁷

In designing the AUC scenarios, the technical team acknowledged that higher clinical classes (eg, C4-C6) presenting with clinical signs are highly unlikely to be asymptomatic and did not include this situation in this study. If encountered, cases of asymptomatic C4 to C6 disease would require a thorough appraisal of symptoms, and treatment should be based on severity of signs including assessment of time of day (earlier may be less symptomatic) and alterations in lifestyle, such as prolonged leg elevation, that may spuriously result in reports of fewer symptoms. Edema due to venous disease may be more likely to be asymptomatic, and indications for treatment are less likely to provide benefit. If patients report no symptoms, decision for treatment should consider the severity of accompanying signs.

Primary venous disease is a progressive condition that is incompletely understood, but ultrasound and histologic studies suggest that the pathophysiologic process in part stems from an abnormal composition of the vein wall resulting in venous functional changes.^{58,59} From population studies, progression from C2 to higher C classes can be expected in one-third of patients during 6 years⁵⁷ to 13 years of observation.⁶⁰ The rate of disease progression is estimated to be 4.3% per year, and almost one-third of those with varicose veins develop skin changes during 13 years of follow-up.^{60,61} In one clinical report, clinical and anatomic deterioration can be expected in one-third of symptomatic chronic venous disease cases after 6 months.⁶² Whereas the evidence confirms that progression of disease is a possibility even in the asymptomatic state, to propose prophylactic intervention before development of symptoms or skin changes, criteria for identifying those who are at risk for clinical deterioration are required. To date, these parameters remain undefined.

Section 3. Treatment of symptomatic nontruncal varicose veins and telangiectasia

The panelists thought that treatment of symptomatic nontruncal varicose veins with or without telangiectasia is appropriate in association with symptomatic varicose veins, edema, skin or subcutaneous changes, and healed or active ulcers (CEAP C2-C6; Table IX). Despite limited data, several guidelines support treatment for the clinical indications stated^{23,25,27,57,63,64} and recommend treatment as an acceptable standard. The panelists' ratings align with published guidelines, recognizing that some payers do not consider treatment of nontruncal varicose veins a valid indication.

Nontruncal varicose veins and telangiectasia are common manifestations of chronic venous disease; treatment is important because of their high frequency and association with saphenous disease, which can lead to the full spectrum of clinical states. When tributaries are associated with saphenous reflux, they may or may not routinely require treatment in conjunction with saphenous ablation (see management decisions for diseased tributaries associated with saphenous ablation). However, nontruncal tributaries may require primary treatment to address symptoms, such as bleeding and superficial thrombophlebitis, without needing to treat the truncal veins, such as in the case of competent superficial truncal veins.



	Asymp	Asymptomatic		Asymptomatic Symptomatic		tomatic		
	C ₁	C ₂	C ₁	C ₂	C ₃	C ₄₋₆		
AAGSV ablation								
10. AACSV axial reflux leading to affected area	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	Appropriate Median: 7	May be appropriate Median: 6.5	Appropriate Median: 9		
11. AAGSV no reflux, but GSV reflux present	Rarely appropriate Median: 1	Never appropriate Median: 1	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1		
12. No reflux	Never appropriate Median: 1	Never appropriate Median: 1						

Summary

No.	Procedure	Appropriateness category
1.6	Ablation of the AAGSV in a symptomatic patient with varicose veins, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2, 4-6), when the AAGSV demonstrates axial reflux directed to affected area	Appropriate
1.7	Ablation of the AAGSV in a symptomatic patient with <i>edema</i> due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 1-2 discussion)
1.8	Ablation of AAGSV with no reflux, but GSV with reflux (CEAP classes 2-6)	Rarely appropriate
CEAP. Clin	ical. Etiology, Anatomy, and Pathophysiology, CSV, great saphenous vein.	

Section 4. Management decisions for diseased tributaries associated with saphenous ablation

The panelists indicated that providing care for diseased tributaries of an ablated saphenous vein concomitantly or in a staged procedure for clinical reasons is appropriate (Table X). Findings of the AUC are consistent with guidelines supporting either approach as a reasonable option.^{23,27}

Several studies have shown that saphenous ablation is associated with regression of remaining tributaries, resulting in the lack of need to directly remove or treat the remaining varicosities in 30% to 60% of cases.⁶⁵⁻⁶⁷ As a result, there are two acceptable approaches to managing tributaries: treatment as a simultaneous procedure

Table VIII. Appropriateness criteria for asymptomaticdisease or no reflux

No.	Procedure	Appropriateness category
1.9	Therapeutic ablation for asymptomatic disease and visible veins	Rarely appropriate
2.0	Ablation for a vein with no reflux	Never appropriate

at the time of ablation⁶⁸⁻⁷³ and as a staged procedure, reserving treatment for tributaries that did not completely regress or only partially improved.^{65,66,68}

A review of eight studies⁷⁴ that examined the results of saphenous vein ablation and phlebectomy as combined vs staged procedures suggests that a treatment approach based on the patient's or physician's preference will result in the best patient-reported outcomes. Combined treatment of saphenous incompetence and symptomatic varicosities resulted in better short-term and better or equivalent long-term patient outcomes. The authors concluded that the patient-centered approach would support acceptance of both strategies, depending on the patient's preference and safety, including drug dosing. For venous ulceration, one study showed that concurrent treatment may reduce ulcer recurrence rates.⁷⁵

Providing care of diseased tributaries with ablation (staged or concomitant) was deemed an important aspect of overall treatment, and the lack of providing care was considered rarely appropriate. This section was meant to address a specific scenario encountered in common venous practice and does not assume or imply that clinicians must be prepared to provide total care for all aspects of venous disease, such as the case of concomitant pelvic with infrainguinal disease.

Table IX. Appropriateness criteria of nontrunc	I varicose veins with or without telangiectasias
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	Asympt	omatic	Symptomatic			
	C ₁ C ₂		C1	C ₂	C ₃	C ₄₋₆
Nontruncal varicose vein or telangiectasia treatment (sclero			therapy, phlebectomy, p	powered phleber	ctomy)	
13. Reflux	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2.5	Appropriate Median: 7	Appropriate Median: 7	Appropriate Median: 8

Summary

No.	Procedure	Appropriateness category			
3.1	Treatment of nontruncal varicose veins with or without telangiectasia by sclerotherapy, ambulatory phlebectomy, or powered phlebectomy in a patient with symptomatic varicose veins, edema due to venous disease, skin or subcutaneous changes, healed or active ulcers (CEAP classes 2-6)	Appropriate			
CEAP, Clir	CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; CSV, great saphenous vein.				

Section 5. Perforator treatment

AUC scores reflect the published guidelines for managing perforators (Table XI). The SVS/AVF guidelines recommend against selective perforator interruption for mild chronic venous disease or C2 disease.^{23,57} For more advanced stages, SVS/AVF 2014 guidelines suggest treatment of pathologic perforators for classes C5 and C6.²⁴ For those who may benefit from treatment, SVS/AVF guidelines²⁴ recommend ablation by percutaneous techniques such as ultrasound-guided sclerotherapy or endovenous thermal techniques over open perforator interruption.

Incompetent perforator veins have been cited as important contributors to the pathophysiologic process of chronic venous disease and more advanced stages including skin changes and ulceration. "Pathologic" perforator veins have been defined in the SVS/AVF joint guidelines²³ as a perforator vein with an outward flow duration of \geq 500 milliseconds, with a diameter \geq 3.5 mm, located beneath a healed or active venous ulcer. The Task Force and technical group acknowledged the value of the previously published definition but for the purposes of these AUC expressed a need to be more general by referring to a perforator as a "large-diameter vein with high outward flow directed toward the affected areas" that connects the deep to the superficial system; the term pathologic is avoided so as not to exclude large perforators that may not reach the criteria of 3.5 mm yet may be clinically important.

Evidence for treating perforator disease is conflicting, and treatment for many classes is not clearly beneficial as reflected by the panelists' scores. Although some evidence exists to support perforator treatment for advanced chronic venous insufficiency such as C5 and C6, evidence to treat C4a and C4b is minimal. Like segmental belowknee GSV reflux, grouping C4a, C4b, C5, and C6 into one category resulted in discussion about how the ratings may have been different if each category was separated. Appropriateness was considered strongest for C6 and C5 and less so for C4b and C4a. Some suggested that if C4a was rated separately, the scenario may not have reached an appropriate score and likely would have had a lower rating than C4b, C5, and C6. Others considered C4b cases at risk for venous ulcer and suggested they were similar to C5 and C6. For edema due to venous disease, significant swelling is rarely due to incompetent perforator veins alone, and treatment will rarely help edema as expressed by the panelists. The Ethics Task Force and design group acknowledged these findings as a limitation of these AUC.

Section 6. Treatment of iliac vein or IVC obstructive disease as first-line treatment

For iliac vein or IVC obstructive disease, defined as \geq 50% area reduction by intravascular ultrasound or occlusion and *no superficial truncal reflux*, the panelists rated stenting as first-line treatment appropriate for symptomatic patients with CEAP classes 4 to 6 (Table XII). Although most of the evidence consists of case series, guidelines and summaries suggest that stenting for symptomatic venous obstructions for advanced stages (C4b-C6) is beneficial.^{24,76} The threshold of 50% area reduction has not been proven by robust data to be the optimal level of treatment, but the Task Force and design team chose this level, given the current evidence and general application, acknowledging that such a threshold may change with future studies.

Indications for iliac vein stenting as first line treatment are likely to be stronger for more advanced clinical severity (C3-6) as seen by ratings. Grouping C4a, C4b, C5, and C6 into one category raised discussion about how the ratings may have been different if each category was separated. In general, the group noted that more symptomatic cases are more likely to benefit from iliac stenting as recommended by several guidelines.^{24,27,57,77,78} Some suggested that if C4a skin discoloration was separated, this would likely not have reached an appropriateness rating for iliac stenting as would have C4b, C5, and C6.

The panelists suggested that the results of treating edema seemed less predictable with stenting (see C3, edema), which accounts in part for the rating by the Table X. Appropriateness criteria for management decisions for diseased tributaries associated with saphenous ablation

Management decisions for diseased tributaries				
Provide care for the diseased tributaries of an ablated vein				
14. at the time of the vein ablation procedure	Appropriate Median: 8			
15. in a staged fashion (at a follow-up procedure) for clinical reasons	Appropriate Median: 7			
16. Refer patient to another health care provider for care of diseased tributaries of an ablated vein	May be appropriate Median: 5			
17. Make no provisions for the care of the diseased tributaries of an ablated vein	Rarely appropriate Median: 1			

Summary

No.	Procedure	Appropriateness category
4.1	Provide care for the diseased tributaries of an ablated saphenous vein either concomitantly or as a staged procedure	Appropriate
4.2	Refer patient to another health care provider for care of diseased tributaries of an ablated vein	May be appropriate
4.3	Make no provisions for the care of diseased tributaries	Rarely appropriate

panelists of may be appropriate with or without coexisting superficial truncal reflux. The panelists indicated that edema can range from ankle to entire leg and if unilateral would more likely be due to a venous cause. The level of edema below or above the knee is not specified in reports, and its significance in iliocaval disease and how it affects outcomes need further research.

Treatment of asymptomatic iliac vein compression, such as May-Thurner disease, as an incidental finding by imaging or for CEAP CI disease was deemed never appropriate. For symptomatic C2 disease *with or without superficial truncal disease*, the panelists indicated that stenting as first-line therapy was rarely appropriate because there are other modalities that can address infrainguinal varicosities. For advanced post-thrombotic syndrome and iliac vein obstruction, panelists expressed that there may be rare cases of symptomatic C2 disease and post-thrombotic syndrome that could warrant initial iliac vein treatment.

Endovascular treatment of chronic iliac vein and IVC obstructive disease is increasingly used to manage non-thrombotic iliac vein lesions and post-thrombotic causes of iliac and caval obstruction. Although application of the technology appears to be on the rise, the panelists concurred that research and evidence in this area are lacking. They also expressed the need to identify cases in which iliac vein stenting should not be considered.

Systematic reviews and meta-analyses suggest that iliac vein and IVC stenting is safe,⁷⁹⁻⁸¹ results in a high technical success rate,^{80,82,83} and is associated with long-term stent patency.^{81,84} Studies consist primarily of C3 to C6 cases, and the findings suggest clinical improvement in such cases.^{79,81-83} However, owing in part to the lack of control groups to distinguish between natural progression of

chronic venous disease and the beneficial effects of intervention, the quality of evidence has a low rating by systematic review,⁷⁹ and it is considered weak evidence by American and European guidelines and a consortium of venous societies with presentation to the Medicare Evidence Development and Coverage Advisory Committee.^{24,76,78} The paucity of evidence has contributed to the challenges of predicting when stenting will be effective. In general, symptoms associated with venous obstruction are more likely to be associated with heaviness and achiness and relieved or improved with leg elevation. Venous claudication is another clinical manifestation of venous obstruction. Factors that need to be considered to determine when stenting may be helpful include the severity of symptoms and bilaterality of symptoms, especially because symptoms such as swelling and pain may have other nonvenous causes.

The concurrent presence of both superficial axial reflux and iliocaval obstruction is a confounding factor. In several studies^{82,83,85,86} in which stenting was the primary treatment for iliac disease that involved a limited number of superficial interventions, the positive effect in these reports is likely to be the result of stenting of the deeper system. In the presence of coexisting superficial truncal reflux, the panelists rated that it may be appropriate to treat the iliac vein and IVC as first-line therapy for advanced chronic venous insufficiency (C4-C6). They commented that it remains unclear as to whether stenting should be done first or used subsequently or concomitantly with treatment of superficial disease. The strategy of treating the superficial system first may be preferred because of fewer procedural risks. The panelists stressed the need for further research to understand the benefit of treating the obstruction alone,

Table XI. Appropriateness criteria for managing perforators

	Asymptomatic			Symptomatic			
	C ₁	C ₂	C ₃	C ₁	C ₂	C ₃	C ₄₋₆
Perforator vein ablation	or interruption	with high out	vard flow and la	arge diameter c	lirected toward	affected area	
18. Calf perforator vein	Never appropriate Median: 1	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2.5	May be appropriate Median: 4	Appropriate Median: 7
19. Thigh perforator communicating with incompetent CSV below a competent or interrupted SFJ	Never appropriate Median: 1	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 3	May be appropriate Median: 4.5	Appropriate Median: 7

Summary

No	Procedure	Appropriateness category
	Flocedule	
5.1	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6)	Appropriate (see Section 5 discussion)
5.2	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with edema due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 5 discussion)
5.3	Perforator vein treatment of veins with high outward flow and large diameter directed toward affected area in a symptomatic patient with telangiectasia or varicose veins (CEAP classes 1-2)	Rarely appropriate
5.4	Perforator vein treatment in an <i>asymptomatic</i> patient with visible telangiectasia or varicose veins (CEAP classes 1-2)	Never appropriate
CEAP, Clinica	, Etiology, Anatomy, and Pathophysiology; CSV, great saphenous vein; SFJ, saphenofemoral junction	

ablation of the superficial truncal vein alone, or optimal timing of treatment when both are considered necessary.

C3, Edema

The panelists rated interventions for treatment of leg edema due to venous disease (CEAP class 3) as may be appropriate for several scenarios in considering saphenous vein ablations and perforator, iliac, and IVC treatments. Panelists indicated that swelling may be multifactorial and can be associated with numerous coexisting nonvenous causes that would not be expected to benefit from venous interventions. They thought that the presentation of no varicose veins with reflux and edema would be uncommon if venous disease was the underlying cause and swelling may or may not improve with treatment. In contrast, when a patient presents with varicose veins, reflux, and edema, the group thought intervention more likely to be of benefit with improved reduction of swelling, in which case the indication for treating venous reflux would be stronger. Unilateral limb swelling was also noted by panelists to be a potential predictor of a favorable response. Again, the response of edema C3 to either ablation for isolated below-knee GSV reflux or segmental vein reflux is not supported by data and led to a rating of may be appropriate. More research is needed to determine its usefulness for these indications.

In general, for several C3 indications, a wide dispersion of ratings was observed, which may at least in part have been due to differences in how C3 was perceived. Several panelists viewed the CEAP classification as a continuum, whereas others viewed C3 disease to be a separate and distinct entity with swelling as the most compelling presentation. Those who considered edema to be a continuum and representative of a more serious sign of venous insufficiency than classes C1 and C2 considered it more likely to deserve treatment. Others believed that edema due to venous disease may have other coexisting nonvenous causes that can be difficult to distinguish from true venous causes. Treatment in this setting may result in improvement; however, in some cases, partial or no improvement may be realized because of coexisting nonvenous conditions.

Section 7. Duplex ultrasound diagnostic techniques for chronic venous disease

The panelists considered standardization of diagnostic testing for proper diagnosis and treatment of chronic venous disease important, as shown by the Investigating

	Asymptomatic			Symptomatic			
	C ₁	C ₂	C ₃	C ₁	C ₂	C ₃	C ₄₋₆
Iliac vein or IVC	stenting as the	first-line therapy	for vessels with	known stenosis	or obstruction	_	
20. Untreated superficial truncal reflux	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	May be appropriate Median: 4	May be appropriate Median: 6
21. No superficial truncal reflux or previously eliminated superficial truncal reflux	Never appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 1	Rarely appropriate Median: 2	May be appropriate Median: 6	Appropriate Median: 8

No.	Procedure	Appropriateness category			
6.1	Iliac vein or IVC stenting for obstructive disease <i>without</i> superficial truncal reflux as first-line treatment in a symptomatic patient with skin or subcutaneous changes, healed or active ulcers (CEAP classes 4-6)	Appropriate (see Section 6 discussion)			
6.2	Iliac vein or IVC stenting for obstructive disease <i>with or without</i> superficial truncal reflux as first-line therapy in a symptomatic patient with <i>edema</i> due to venous disease (CEAP class 3), provided careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema	May be appropriate (see Section 6 discussion)			
6.3	Iliac vein or IVC stenting for obstructive disease in an asymptomatic patient for iliac vein compression, such as May-Thurner compression, for incidental finding by imaging or telangiectasia (CEAP class 1)	Never appropriate			
CEAP, Clinical, Etiology, Anatomy, and Pathophysiology.					

Venous Disease Evaluation and Standardization of Testing (INVEST) study.⁸⁷ They believed that the upright position is the preferred position if the patient is not restrained by physical factors as supported by guidelines and studies^{23,88-91} (Table XIII). In addition, the panelists thought that examination in the steep reverse Trendelenburg position may be appropriate in those who cannot safely stand. The INVEST study⁸⁷ showed that even a difference between horizontal and standing positions is of significantly lesser magnitude compared with a difference between two ultrasound scans performed at different times of day (morning vs afternoon). Because it is impractical to perform all ultrasound scans at the same time of the day, performing scans in a steep reverse Trendelenburg position instead of standing in some patients is unlikely to increase the rate of false-negative and false-positive results in a routine clinical practice.

Reflux through an incompetent valve in the standing position is reported to correlate with a reflux time of

>0.5 second in saphenous veins and >1.0 second in the femoral and popliteal veins.^{90,91} Reflux duration is best documented by spectral Doppler waveforms indicating the reflux duration time. A "still image" of color alone does not represent the confirmation of reflux >0.5 second and should not be deemed sufficient ultrasound data of reflux duration time.⁹²

The Valsalva maneuver as a means for eliciting reflux was rated may be appropriate; it may be the preferred technique to demonstrate common femoral vein or saphenofemoral incompetence,^{23,89} particularly if the result of distal compression and release is normal or the test is not feasible. For distal assessment below the groin level, such as the distal saphenous, popliteal, or calf veins, Valsalva maneuver may be less reliable, especially if valves in the proximal thigh are competent or the patient is unable to perform an adequate Valsalva maneuver, in which case distal compression and release would provide a more accurate assessment of

Table XIII. Appropriateness criteria of duplex ultrasound diagnostic techniques for chronic venous disease

Diagnostic techniques	
Duplex ultrasound of the lower extremities for evaluation of reflux	
22. in the supine position	Rarely appropriate Median: 2.5
23. in steep reverse Trendelenburg position	May be appropriate Median: 6
24. in the upright position (assuming the patient can safely stand)	Appropriate Median: 9
Documentation of reflux using	
25. a still image (without documentation of duration)	Rarely appropriate Median: 1
26. spectral analysis (or other method to document duration)	Appropriate Median: 9
Elicitation of reflux of CFV or SFJ using	
27. distal compression and release	Appropriate Median: 8
28. Valsalva maneuver	May be appropriate Median: 6
29. Elicitation of reflux distal to the SFJ or SPJ with distal compression and release	Appropriate Median: 8
30. Elicitation of reflux by compression proximal to the area of interrogation (nonphysiologic or flash reflux)	Rarely appropriate Median: 1
31. Provide incentives for ultrasound technicians based on test results	Never appropriate Median: 1

Summary

No.	Procedure	Appropriateness category
7.1	Duplex ultrasound scanning for chronic venous disease in the upright position if technically feasible and safe, eliciting reflux by distal compression and release and documenting duration of reflux	Appropriate
7.2	Examining the patient in the steep reverse Trendelenburg position, particularly if testing in the standing position is not technically feasible or safe	May be appropriate
7.3	Eliciting reflux using the Valsalva maneuver, particularly for interrogation of the CFV or SFJ	May be appropriate
7.4	The technique of creating nonphysiologic flash reflux with proximal compression during duplex ultrasound scanning	Rarely appropriate
7.5	Incentivize sonographers based on test results	Never appropriate
CFV, Commo	n femoral vein; SFJ, saphenofemoral junction; SPJ, saphenopopliteal junction.	

competency. For the saphenofemoral junction, International Union of Phlebology consensus⁸⁹ considers Valsalva maneuver an acceptable standard to test for valvular competency. The standard technique to elicit reflux, particularly at and below the knee, is by distal compression and release, which was rated appropriate.

"Flash" reflux. Retrograde flow duration of >0.5 second is the cutoff value for reflux in the saphenous vein and distinguishes normal from abnormal.^{90,91} Because most RCTs and guidelines accept the duplex ultrasound value of reflux >0.5 second as the primary criterion for treatment, it is not surprising that reports of creating flash reflux or nonphysiologic reflux have surfaced that meet

the >0.5-second criterion. Flash reflux is produced by proximal compression of a normal saphenous vein, creating nonphysiologic retrograde flow in the truncal vein between two competent valves or reflux between two competent valves with reflux out incompetent branches. Reports of creating and treating flash reflux were discussed during AVF and American Vein and Lymphatic Society annual meetings and during round-table discussions reported in venous publications,³⁻⁵ which concluded that this method is inappropriate.

The AUC ratings indicated that it is not acceptable to employ techniques to generate flash reflux. Flash reflux is defined in the AUC as a short duration of Table XIV. Appropriateness criteria for timing and reimbursement decisions

Timing and reimbursement decisions			
32. Submission of charges for vein ablation procedures that are reflective of the actual services provided	Appropriate Median: 9		
33. Submission of separate charges for a single saphenous vein ablation requiring multiple access sites	Rarely appropriate Median: 1		
34. Submission of two or more separate charges for the ablation of two continuous saphenous vein segments accessed with a single access point (eg, the above-knee GSV and the below-knee posterior accessory saphenous vein)	Rarely appropriate Median: 1		
35. Submission of two or more separate charges for the ablation of two continuous saphenous vein segments accessed with multiple access point (eg, the above-knee GSV and the below-knee posterior accessory saphenous vein)	Rarely appropriate Median: 1		
36. Schedule the ablation of different veins (same or opposite leg) on different days for clinical reasons, such as patient preference or patient safety	Appropriate Median: 7		
37. Schedule the ablation of different veins (same or opposite leg) on different days for maximization of reimbursement	Rarely appropriate Median: 1		

Summary

No.	Procedure	Appropriateness category	
8.1	Scheduling the ablation of different veins on different days for clinical reasons including patient preference and safety is appropriate, whereas scheduling treatment on different days for reasons other than clinical reasons including patient preference and safety is not considered generally acceptable.	Appropriate	
8.2	Submitting separate charges for a single saphenous ablation requiring multiple access sites	Rarely appropriate	
8.3	Submitting two or more separate charges for ablation of two continuous saphenous segments accessed with a single access point or multiple access points (eg, the above-knee CSV and below-knee posterior accessory saphenous vein).	Rarely appropriate	

GSV, Great saphenous vein.

nonphysiologic reflux that may be >0.5 second, produced by proximal compression during duplex ultrasound imaging of an otherwise competent saphenous vein. In fact, of the 16 panelists, all rated it never appropriate with the exception of one panelist, who rated it rarely appropriate; so by AUC design, the rating was rarely.

Overall, duplex ultrasound criteria ratings were consistent with multiple published duplex ultrasound-related guidelines.^{23,25,27,88,89,93}

Section 8. Appropriateness criteria for timing and reimbursement decisions

The panelists agreed that ablation of different veins (same or opposite leg) on different days for clinical reasons such as patient safety and patient preference should be considered appropriate (Table XIV). For example, multiple sessions may be needed to accommodate local anesthetic dose limitations or ability of the patient to endure the procedure in a conscious state for the duration of treatment. However, scheduling treatment on different days for reasons other than a patient's clinical reasons is not considered generally acceptable. Submitting separate charges for a single saphenous vein ablation requiring multiple access sites or submitting two or more charges for ablation of two continuous saphenous vein trunks, specifically the GSV in the thigh and posterior accessory GSV in the calf, with either a single access point or multiple access points, is rarely appropriate (ie, not generally acceptable).

Each vein ablated should be associated with appropriate symptoms or signs of venous disease with intrinsic reflux. When individuals are reporting ablation of multiple (ie, three or more) truncal veins per leg as frequent practice, particularly for C2 disease, there is reason to suspect that normal or relatively normal veins are being ablated. Current publications indicate that the mean number of saphenous vein ablations per person ranges from 1.3 to 1.9.^{7,8,94,95} The mean number provides a guide; however, this number should not be used to determine reimbursement for individual cases because there are many factors that should be considered for each case. Multiple truncal veins, such as GSV, AAGSV, and SSV, may be severely incompetent with reflux directed to symptomatic varicose veins, in which case most patients and providers would prefer treatment at the same time. As a consequence, there may be occasional patients who

require three or more ablations in a limb. Such a pattern may be encountered more commonly in treating advanced venous insufficiency, such as in a practice with a large volume of C5 or C6 disease, when multiple saphenous veins may be associated with reflux.

Although multiple access attempts may be needed for challenging cases in which the vein diameter, tortuosity, previous phlebitis, or prior surgery may interfere with cannulation, treatment of each truncal vein is generally considered a single procedure even if the access for ablation needs to be interrupted for technical reasons. However, rare exceptions due to unique patient circumstances need to be taken into consideration. In the case in which practice patterns of a population repeatedly deviate from the norm, the question of inappropriate care should be raised.

Limitations and future directions. To determine the best treatment for patients, a careful assessment is needed to distinguish venous causes of symptoms and signs from other nonvenous causes. The AUC recommendations can be applied as a guide to management but do not replace the need for careful individual assessment.

Limitations of the study were discussed under the specified categories and include a finite number of clinical scenarios evaluated. This document is not meant to be a guide that addresses all possible clinical situations. Our goal in this first round was to consider frequently encountered practical scenarios and to address some of the urgent concerns of inappropriateness that up to now have not been addressed by appropriate use methods. If this is found to be a useful tool, then further areas may need to be addressed beyond the focus of this project, which was primary varicose vein disease. Additional situations could be considered in future AUC projects, such as management of infrainguinal secondary venous insufficiency, multilevel disease combining above and below the inguinal ligament, acute venous thrombotic disease, recurrent disease, pelvic venous insufficiency, and assessment of different techniques and modalities of treatment.

CEAP C class is a descriptive classification, and although it was designed to represent an ascending spectrum of severity, it does not provide a qualitative or quantitative measure of severity of symptoms or signs. The determination of whether a patient may benefit from treatment of veins will rely on many factors, including clinical severity. In the future, the AUC may benefit from incorporating a measure of clinical severity, such as the Venous Clinical Severity Score,⁹⁶ which may provide guidance in appropriate use. The literature review submitted to the panelists was based on a comprehensive collection of published scientific studies and a thorough appraisal of the available systematic reviews, meta-analyses, and guidelines. A new systematic review was not conducted. Also, in lieu of a webinar, an in-person meeting would have been optimal. Where evidence was weak or not available, expert opinions were used to recommend appropriate use.

CONCLUSIONS

The advancement of endovascular technology for the treatment of venous disease has been accompanied by staggering rates of utilization and warrants clinical standards as the field evolves. These AUC for venous care provide the first appropriate use document for venous procedures and may serve to fill in the gap where high-quality scientific evidence is lacking to aid clinicians in making the day-to-day decisions for patient care. As a product of a collaborative effort with multiple professional societies, it serves as an expansion of existing guidelines based on an appropriate use process while identifying areas in which research is needed to provide further support for evidence-based decisions.

These recommendations should not be used to determine insurance coverage for individual patients. It is recognized that the individual case may have many distinctive characteristics that need to be considered for treatment choices. As such, the ultimate decision for appropriate treatment of an individual patient must be determined "at the bedside" by the clinician, who incorporates evidence, experience, clinical factors, socioeconomic factors, treatment setting, and patient preference in conjunction with appropriateness principles in pursuit of providing the best care for our patients.

We would like to thank Joseph Zygmunt, RVT, for providing us with references for the section on duplex ultrasound criteria.

AUTHOR CONTRIBUTIONS

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- Statistical analysis: Not applicable
- Obtained funding: Not applicable
- Overall responsibility: EM

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Submitted Nov 19, 2019; accepted Feb 2, 2020.

Additional material for this article may be found online at www.jvsvenous.org.

APPENDIX 1 (online only).

Assumptions

- Diagnostic information is accurate.
- Ablation refers to treatment by thermal, chemical, or mechanical techniques.
- For each scenario, aside from the stated disease described, the remaining venous system is normal.
- The vein in question is continuous (ie, "GSV axial reflux above and below the knee" refers to reflux occurring along a continuous vessel).
- The existing published literature regarding vein ablation is accurate.
- The patient in question has no contraindication to the proposed intervention.
- There are no patient-generated mitigating factors, such as noncompliance or DNR status.
- The physician performing the intervention possesses adequate skill to perform the procedure.
- It is not a recurrent vein (ie, recurrent GSV unless otherwise specified).
- Indication for treatment is not cosmetic.
- All scenarios refer to chronic venous disease (not acute DVT).
- Deep system is normal except for iliac and IVC scenarios, in which case disease is isolated to the iliac or caval system.
- All scenarios refer to primary venous insufficiency except for iliac and IVC cases, which may be primary (nonthrombotic iliac vein lesions) or secondary due to post-thrombotic disease.
- The section on nontruncal varicose veins or telangiectasia refers to treatment of isolated indexed veins in the presence of concomitant superficial reflux, unspecified.
- CEAP C3 refers to edema due to venous disease.

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; DNR, do not resuscitate; DVT, deep venous thrombosis; CSV, great saphenous vein; IVC, inferior vena cava.

APPENDIX 2 (online only).

Definitions

- Anatomy
 - Superficial vein: otherwise known as saphenous veins, veins of the lower extremity that lie between the dermis and muscle fascia
 - Great saphenous vein
 - Small saphenous vein
 - Anterior accessory great saphenous vein
 - Intersaphenous vein: superficial vein of the lower extremity that communicates between the great and small saphenous veins
 - Deep vein: veins of the lower extremity located deep to the muscle fascia
 - Crural veins: anterior tibial vein, posterior tibial vein, peroneal vein
 - Muscular veins: gastrocnemial vein, soleal vein

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- Popliteal vein
- Femoral vein (formerly known as the superficial femoral vein)
- Deep femoral vein
- Common femoral vein
- External iliac vein
- Internal iliac vein
- Common iliac vein
- Inferior vena cava
- Perforator vein: veins of the lower extremity that drain from the superficial veins to the deep veins
- Truncal vein: named longitudinal saphenous or deep veins
- Nontruncal vein: un-named or nonlongitudinal saphenous or deep vein
- Saphenofemoral junction
- Segment: one of 18 named venous segments as defined by advanced Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification
- Symptoms
 - Complaints related to venous disease
 - May include tingling, aching, burning, pain, muscle cramps, swelling, sensations of throbbing or heaviness, itching skin, restless legs, leg tiredness, fatigue, or bleeding
 - May be exacerbated by heat or dependency throughout the day's course
 - May be relieved by leg rest or elevation
 - $\circ\,$ Asymptomatic: no symptoms or symptoms that are not related to venous disease
- Signs
 - Visible manifestations of venous disorders according to CEAP clinical class (based on revised CEAP classification²⁰)

 C_0 no visible or palpable signs of venous disease C_1 telangiectasias or reticular veins

 C_2 varicose veins: distinguished from reticular veins by a diameter of \geq 3 mm

- C₃ edema
- C_{4a} pigmentation or eczema
- $C_{\rm 4b}$ lipodermatosclerosis or atrophie blanche C_5 healed venous ulcer
- C_6 active venous ulcer
- Flow findings
 - Reflux: retrograde venous flow of abnormal duration of ≥0.5 second for all except the femoral and popliteal veins, in which reflux is defined as ≥1.0 second
 - Axial reflux: uninterrupted retrograde venous flow from the groin to the calf (leading to affected area)
 - Segmental reflux: localized retrograde flow in venous segments of any of the three venous systems (superficial, deep, perforating) in any combination in the thigh or calf, but not in continuity from the groin to calf
 - Flash reflux: a short duration of nonphysiologic reflux, which may be >0.5 second, produced by proximal compression during duplex ultrasound imaging of an otherwise competent saphenous vein
 - \circ Perforator vein reflux: outward flow of abnormal duration ${>}0.5$ second

- Miscellaneous
 - Venous ablation: rendering a vein no longer patent or destruction of a vein by mechanical, thermal, or chemical means
 - $\circ\,$ Diseased tributaries: varicose veins or telangiectasias associated with the vein in question
 - Iliac vein or inferior vena cava occlusion: total blockage to venous flow
- \circ Iliac vein or inferior vena cava stenosis: partial blockage to venous flow of ≥50% area reduction
- Iliac vein or inferior vena cava obstruction can refer to occlusion or stenosis
- \circ Cosmetic request: the patient is concerned about the appearance or has explicitly requested a cosmetic (nontherapeutic) procedure in the setting of no symptoms and minimal (C_{0-2}) signs

APPENDIX 3 (online only).

Disclosures

Panelists

Last name	Financial, professional, or personal	Entity/person	Nature of conflict
Almeida	Professional	American Venous Forum	Board of directors
Almeida	Professional	Society for Vascular Surgery	Executive committee member
Dalsing	None	_	_
Elias	Financial	Medtronic Inc	Scientific advisory board
Elias	Financial	Vascular Insights LLC	Consultant
Elias	Financial	LeMaitre Inc	Consultant
Elias	Financial	Hancock Jaffe Laboratories	Consultant
Elias	Financial	Lifeline Vascular	Consultant
Gibson	Financial/research	Medtronic Inc	Research support, scientific advisory board, speakers bureau
Gibson	Financial/research	Bristol-Myers Squibb	Research support, speakers bureau
Gibson	Research	Bayer	Research support
Gibson	Financial/research	Vascular Insights LLC	Research support/consultant
Gibson	Research	AngioDynamics	Research support
Gibson	Professional	American Vein and Lymphatic Society	Serves on board and multiple committees
Gibson	Professional	American Board of Venous and Lymphatic Medicine	Serves on board
Gibson	Financial	Vesper Medical	Scientific advisory board
Gloviczki	None	-	-
Kabnick	Professional and financial	Bard, Boston Scientific, and AngioDynamic Tre-Sheath	
Khilnani	Professional	American Vein and Lymphatic Society	Board of directors
Khilnani	Professional	Intersocietal Accreditation Commission Vein Center	Board of directors
Khilnani	Financial	Medtronic Inc	Honorarium
Khilnani	Research	Society of Interventional Radiology	Research support
Khilnani	Financial	International Vein Congress	Honorarium
Khilnani	Financial	Venous Symposium	Honorarium
Lawrence	None	_	-
Lohr	None	-	-
Mann	Financial	Wiley-Blackwell	Book royalties
Mann	Research	Sciton	Research support
Mann	Financial	Merz/Asclera	Consultant
Mann	Professional	American Vein and Lymphatic Society	Board of directors
Mann	Professional	Intersocietal Accreditation Commission Vein Center	Board of directors
Mann	Professional	American Board of Venous and Lymphatic Medicine	Multiple committees
Meissner	Professional	International Union of Phlebology	Executive committee member
Meissner	Professional	Intersocietal Accreditation Commission Vein Center	Executive committee member
Meissner	Professional	American Vein and Lymphatic Society	Board of directors

Continued.

Last name	Financial, professional,	Entity/porson	Nature of conflict
		Entry/person	
Morrison	Financial/Research	Medtronic Inc	Research support, speaker's bureau
Morrison	Financial	Medi	Education grant
Morrison	Financial	BTG	Speakers bureau
Morrison	Financial	Merz/AngioDynamics	Speakers bureau
O'Donnell	Financial	Tactile Medical	Consultant
Passman	None	-	-
Vedantham	Research	Cook Medical	Research support
Vedantham	Professional	Society of Interventional Radiology	Board of directors
Wakefield	Professional	Jobst Institute	Board of directors
Wakefield	Professional	University of Toledo Foundation	Member
Wakefield	Financial	Moore/SVS Review Course 2017	Honorarium
Wakefield	Financial	Veith Meeting 2017	Honorarium
Wakefield	Financial	Bergan Lecture, Northwestern Chicago 2018	Honorarium
Wakefield	Financial	American Heart Association 2017	Honorarium
Wakefield	Financial	Vascular Cures 2018	Honorarium
Wakefield	Professional	Visiting Professor, Wichita Kansas	Honorarium
Wakefield	Research	National Institutes of Health	Research support

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Monahan	None		
Ozsvath	Financial	Medtronic Inc	Consultant
Vossler	None		
Woo	None		