#### **APPROPRIATE USE CRITERIA**

# ACCF/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part II: Testing for Venous Disease and Evaluation of Hemodialysis Access

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force

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# Abstract

The American College of Cardiology Foundation (ACCF), in partnership with key specialty and subspecialty societies, conducted a review of common clinical scenarios where noninvasive vascular testing (venous ultrasound and physiological testing) is frequently considered. The indications (clinical scenarios) were derived from common applications or anticipated uses, as well as from current clinical practice guidelines and results of studies examining the implementation of the original appropriate use criteria (AUC). The 116 indications in this document were developed by a diverse writing group and scored by a separate independent technical panel on a scale of 1 to 9, to designate appropriate use (A) (median 7 to 9), maybe appropriate use (M) (median 4 to 6), and rarely appropriate use (R) (median 1 to 3).

## **Preface**

In an effort to respond to the need for the rational use of imaging services in the delivery of high-quality care, the American College of Cardiology Foundation (ACCF) has undertaken a process to determine the appropriate use of cardiovascular imaging for selected patient indications. Appropriate use criteria (AUC) publications reflect an ongoing effort by the ACCF to critically and systematically create, review, and categorize clinical situations where diagnostic tests and procedures are utilized by physicians caring for patients with cardiovascular diseases. The process is based on current understanding of the technical capabilities of the imaging modalities examined. Although impossible to be entirely comprehensive given the wide diversity of clinical disease, the indications are meant to identify common scenarios encompassing the majority of situations encountered in contemporary practice. Given the breadth of information they convey, the indications do not directly correspond to the Ninth Revision of the International Classification of Diseases (ICD-9) system, as these codes do not include clinical information, such as symptom status.

The ACCF believes that careful blending of a broad range of clinical experiences and available evidence-based information will help guide a more efficient and equitable allocation of healthcare resources in cardiovascular imaging. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner, but it is not intended to ignore ambiguity and nuance intrinsic to clinical decision making. AUC thus should not be considered substitutes for sound clinical judgment and practice experience.

We are grateful to the technical panel, a professional group with a wide range of skills and insights, for their thoughtful and thorough deliberation of the merits of peripheral vascular ultrasound for various indications. We would also like to thank the individuals who provided a careful review of the draft of indications, the parent AUC Task Force, and the ACC staff, Z. Jenissa Haidari and Joseph Allen, for their exceptionally skilled support in the generation of this document.

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# **1. Introduction**

Improvements in cardiovascular imaging technology and their application, coupled with increasing therapeutic options for cardiovascular disease, have led to an increase in cardiovascular imaging. Diagnostic imaging services reimbursed under Medicare's physician fee schedule grew more rapidly than any other type of physician service from 1999 to 2003, although more recently, the rate of imaging volume growth in Medicare has been slowing. Still, the armamentarium of noninvasive diagnostic tools has expanded greatly, offering a variety of new and more sophisticated imaging techniques. As imaging technology and clinical applications continue to advance, the healthcare community needs to understand how to best incorporate these technologies into daily clinical care and how to choose between new and long-standing established imaging technologies. In an effort to respond to this need and to ensure the effective use of advanced diagnostic imaging tools, the Appropriate Use Criteria (AUC) project was initiated. This document serves as the second in a 2-part series evaluating noninvasive testing for peripheral vascular disorders with ultrasound and physiological testing. The focus of this document is clinical indications associated with evaluation of the venous system as well as preparation for and evaluation of dialysis access (e.g., arteriovenous fistulas). Appropriate use criteria for evaluation of peripheral arterial disorders (carotid, lower and upper extremities, abdominal aorta, visceral artery) have been previously published (1). The indications and findings from this AUC process are meant to help inform and ensure the highest quality and most efficient use of vascular laboratory testing (vascular ultrasound and physiological testing) in the evaluation of the venous system.

# 2. Methods

The indications included in this publication cover a wide array of cardiovascular signs and symptoms as well as clinical judgments as to the likelihood of cardiovascular findings. Within each main disease category, a standardized approach was used to capture the majority of clinical scenarios without making the list of indications excessive. During the development of this document, the AUC Task Force revised the terminology and definitions to better clarify the appropriateness categories to avoid misinterpretation and misuse of appropriate use criteria documents (2).

The indications were constructed by experts in peripheral vascular disease and in other fields and were modified on the basis of discussions among the task force and feedback from independent reviewers and the technical panel. Wherever possible, indications were mapped to relevant clinical guidelines and key publications/references where available in the medical literature (Online Appendix).

#### **Indication Development**

The indications were constructed by a writing group with expertise in both the science and clinical practice of vascular ultrasound and physiological testing, vascular medicine and vascular surgery, and vascular imaging and intervention. The writing group was tasked with developing a list of clinical scenarios covering the majority of patients that clinicians might consider referring for noninvasive ultrasound and physiological testing. The term "indication" is used interchangeably with "clinical scenario" in the document for brevity and does not imply that a procedure should necessarily be performed. Indication modifications were made through discussions with the American College of Cardiology Foundation (ACCF) AUC Task Force and feedback from reviewers that include additional experts in the areas noted in the previous text. The current document includes indications related to noninvasive vascular testing for venous disease and for hemodialysis access. Appropriate use criteria for the evaluation of arterial disorders have been previously published (1).

#### **Rating Process and Scoring**

The technical panel first rated the indications independently. The technical panel then convened for a face-toface meeting to discuss each indication. At this meeting, panelists were provided with their scores and a blinded summary of their peers' scores. After the meeting, panelists once again independently rated each indication according to the originally published classification terms to indicate their final scores. The technical panel then completed an additional third rating process to address a few areas that required further clarification and to incorporate the revised indication classification terminology (2). During this final rating, the technical panel was asked to reexamine the indications using the new terms and expanded definitions, realizing that the use of new terms could result in some reclassification of the clinical scenarios.

When rating each clinical scenario, the technical panel was asked to assess whether ultrasound and/or physiological testing was appropriate, maybe appropriate, or rarely appropriate, according to the following definition of appropriate use:

An appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequence\* by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.

The technical panel scored each indication as follows:

## Median Score 7 to 9: Appropriate Care

An appropriate option for management of this patient population due to **benefits generally outweighing risks**; effective option for individual care plans, although not always necessary depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

#### Median Score 4 to 6: Maybe Appropriate Care

At times an appropriate option for management of this patient population due to variable evidence or agreement regarding the benefits/risks ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).

#### Median Score 1 to 3: Rarely Appropriate Care

**Rarely an appropriate option** for management of this patient population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

The division of these scores into 3 levels of appropriateness is somewhat arbitrary, and the numeric designations should be viewed as a continuum. Further, there is diversity in clinical opinion for particular clinical scenarios, such that scores in the intermediate level of appropriate use should be labeled "maybe appropriate," because critical patient or research data may be lacking or discordant. This

<sup>\*</sup>Negative consequences include the risks of the procedure (i.e., radiation or contrast exposure) and the downstream impact of poor test performance such as delay in diagnosis (false negatives) or inappropriate diagnosis (false positives).

designation should be a prompt to the field to carry out definitive research investigations whenever possible. It is anticipated that the AUC reports will continue to be revised as further data are generated and information from the implementation of the criteria is accumulated.

To prevent bias in the scoring process, the technical panel was deliberately composed of a minority of specialists in vascular noninvasive testing. In addition, care was taken in providing objective, nonbiased information, including guidelines and key references, to the technical panel.

The level of agreement among panelists as defined by RAND (3) was analyzed based on the BIOMED rule for a panel of 14 to 16 members. As such, agreement was defined as an indication where 4 or fewer panelists' ratings fell outside the 3-point region containing the median score.

Disagreement was defined as where at least 5 panelists' ratings fell in both the appropriate and the rare appropriate categories. Any indication having disagreement was categorized as maybe appropriate regardless of the final median score. Indications that met neither definition for agreement or disagreement are in a third, unlabeled category.

# **3. Assumptions**

To prevent any inconsistencies in interpretation, specific assumptions are provided that were considered by the technical panel in rating the relevant clinical indications for the appropriate use of peripheral vascular ultrasound and physiological testing:

- 1. Clinical indications assume that a history and physical examination has been performed by a qualified healthcare provider before performance of the vascular ultrasound or physiological testing examination.
- 2. A peripheral vascular ultrasound and physiological testing examination and report will include performance of the vascular ultrasound or physiological testing examination using a standardized scanning protocol and standardized documentation of gray scale (B-mode), color flow, and spectral Doppler wave form images as required for the specific test type. Scanning protocols may be developed by the laboratory based upon laboratory-specific considerations and techniques as well as recommended technical elements per appropriate organizations (e.g., American Institute of Ultrasound in Medicine, Society for Vascular Ultrasound) or laboratory accrediting organizations (Intersocietal Accreditation Commission [IAC]) (4).
- 3. Interpretation of the vascular ultrasound or physiological testing examination by a physician

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interpreter using **standard, laboratory-specific diagnostic criteria** that have been developed by the laboratory or adapted from the ultrasound literature and are validated internally for accuracy as part of ongoing quality assurance programs. It is implicit that diagnostic criteria will vary across laboratories, but adherence to pre-defined criteria within a laboratory is required. Laboratory-specific protocols should be compiled in written policy and procedure manuals that are made available to medical and technical staff for review and discussion.

- 4. Appropriate equipment is used for each specific type of testing, including appropriate frequency ultrasound transducers and properly sized cuffs and others sensors for physiological testing.
- 5. Documentation that the vascular sonographer used optimal angle correction techniques to ensure accurate angle of insonation for reporting of Doppler velocity measurements. In general, an angle of insonation of  $60^{\circ}$  or less is used with appropriate sample volume placement.
- 6. All standard vascular ultrasound and physiological testing techniques have a sensitivity and specificity similar to those found in the published literature for the specific examination type.
- 7. Testing should be performed by a credentialed technologist (registered vascular technologist [RVT] or registered vascular sonographer [RVS]) and interpreted by a credentialed physician (registered physician in vascular interpretation [RPVI]). Finally, the testing should be done in a facility accredited in vascular testing (e.g., IAC-Vascular Testing).
- 8. If prior testing is of poor technical quality, repeat imaging may sometimes be appropriate in a different facility or after the conditions that restricted the prior testing are no longer present (e.g., bowel gas, open wounds) prior to the specified timeframes.
- 9. The appropriate use of testing is assumed to have the potential to impact clinical decision making and to direct therapeutic interventions.
- 10. The range of potential indications for vascular ultrasound and physiological testing is quite large, particularly in comparison with other cardiovascular imaging tests. Thus, the indications are, at times, purposefully broad to cover an array of vascular signs and symptoms as well as the ordering physician's best judgment as to the presence of vascular abnormalities. Additionally, there are likely clinical scenarios that are not covered by the current indications in this document.
- 11. Venous duplex examinations that are performed to assess for suspected venous thrombosis in the limbs

require performance of gray scale (B-mode) compression maneuvers in addition to color flow and spectral Doppler examination.

- 12. Complete vascular examinations (ultrasound and physiological testing) require bilateral studies in the majority of clinical cases, though specific clinical indications may warrant a unilateral or limited study, (e.g., unilateral leg pain and swelling and suspected lower extremity deep vein thrombosis). The decision to perform a complete bilateral or unilateral examination should be determined by the study indications and the standardized laboratory scanning protocol.
- 13. When a unilateral venous examination is performed, a spectral Doppler waveform from a contralateral proximal deep vein (e.g., subclavian or internal jugular vein for the upper extremities or common femoral vein for the lower extremities) should be recorded to allow for comparative assessment of flow patterns in the limbs.
- 14. For the clinical scenarios presented in the section on Hemodialysis Vascular Access Duplex Ultrasound (Table 8) it is acknowledged that the appropriate vascular laboratory assessment might include more than duplex ultrasound of the extremity veins. Depending on the scenario, additional testing could include arterial duplex scanning and physiological tests such as segmental limb pressures and digit pressure measurements.
- 15. To optimize patient care and minimize need for unnecessary repeat studies, it is generally recommended that repeat or serial scans (e.g., for surveillance of calf vein thrombosis with contraindication to anticoagulation) be performed in the same facility.
- 16. Raters were instructed to consider cost implicitly when making the appropriate use determination.
- 17. Raters were instructed to consider patient safety implicitly in the appropriate use determination.
- 18. If the reason for a test can be assigned to more than 1 clinical indication, it should be matched to the indication with the highest appropriate use score.
- 19. For each indication, the rating should reflect whether the test is reasonable for the patient according to the appropriate use definition, not whether the test is better or worse than another modality.
- 20. The category of "maybe appropriate" should be used when insufficient clinical data are available for a definitive categorization or there is disagreement as defined in the methods. The designation of "maybe appropriate" is assumed to not provide grounds for denial of reimbursement.
- 21. Unless explicitly stated, the indications in this document indicate only whether vascular

ultrasound or physiological testing by itself is reasonable. The indications do not address whether it is reasonable to perform vascular ultrasound or physiological testing instead of or in conjunction with another test, either before or after the test.

# 4. Definitions

1. Physiological testing:

Evaluation of the peripheral venous circulation based on measurement of limb blood flow using plethysmographic sensors (e.g., air, strain gauge, or photoplethysmography) with physiological maneuvers (e.g., limb positioning, limb exercise, tourniquet application), or other parameters, without utilizing data from direct imaging of the blood vessels.

2. Screening examination:

Testing conducted to determine the presence or absence of disease in an asymptomatic patient.

3. Surveillance examination:

Testing conducted to monitor disease progression based solely on the passage of time since initial diagnosis or revascularization (e.g., calf vein thrombosis with contraindication to anticoagulation). It is assumed that baseline testing has already been conducted.

# 5. Abbreviations

AVF = autogenous arteriovenous fistula (including venous transpositions)

- AVG = prosthetic arteriovenous graft
- CHF = congestive heart failure
- DVT = deep vein thrombosis
- IAC = Intersocietal Accreditation Commission
- ICU = intensive care unit
- IVC = inferior vena cava
- RPVI = registered physician in vascular interpretation
- RVT = registered vascular technologist
- RVS = registered vascular sonographer
- TIPS = transjugular intrahepatic portosystemic shunt

# 6. Peripheral Vascular Ultrasound and Physiological Testing Part II: Testing for Venous Disease and Evaluation of Hemodialysis Access Appropriate Use Criteria (by Indication)

Section 1: Upper Extremity Venous Duplex Ultrasound

#### Table 1. Venous Duplex of the Upper Extremities for Patency and Thrombosis

Indication		Appropriate Use Rating
Limb Swelling		
1.	Unilateral—acute	A (9)
2.	Unilateral—chronic, persistent	A (7)
3.	Bilateral—acute	A (8)
	Suspected central venous obstruction	
4.	Bilateral—chronic, persistent	A (7)
	No alternative diagnosis identified (e.g., no CHF or anasarca from hypoalbuminemia)	
	Suspected central venous obstruction	
5	Limb Pain (without Sweiing)	M (5)
5. 6	Nonarticular pain in the upper extremity (no indwelling upper extremity venous catheter)	M (3)
0. 7	Nonarticular pain in the upper extremity with indwelling upper extremity venous catheter	A (7)
1.	Iender, paipable cord in the upper extremity      Shortness of Brooth	A (8)
8.	Silotitiess of bleating	M (4)
9	Suspected pulmonary embolies (no indiversing upper extremity venous catheter)	M (6)
10	Suspected pulmonary embolus with indivening upper extremity venous catheter	M (4)
11	Diagnosed pulmonary embolus (no inducening upper extremity venous catheter)	M (6)
	Diagnosed pulmonary empolus with indwelling upper extremity venous catheter	M (0)
12.	Eaver of unknown origin (no indwelling unner extremity yenous catheter)	R (2)
13.	Fever with indwelling unner extremity venous catheter	M (4)
	Known Upper Extremity Venous Calificer	
14.	New upper extremity pain or swelling while on anticoagulation	A (7)
15.	New upper extremity pain or swelling, not on anticoagulation (i.e., contraindication to anticoagulation)	A (7)
16.	Before anticipated discontinuation of anticoagulation treatment	M (5)
17.	Shortness of breath in a patient with known upper extremity DVT	R (3)
18.	Surveillance after diagnosis of upper extremity superficial phlebitis	M (6)
	<ul> <li>Not on anticoagulation, phlebitis location &lt;5 cm from deep vein junction</li> </ul>	. ,
19.	Surveillance after diagnosis of upper extremity superficial phlebitis	M (4)
	• Not on anticoagulation, phlebitis location $\geq$ 5 cm from deep vein junction	
	Vein Mapping Prior to Bypass Surgery (Coronary or Peripheral)	
20.	In the absence of adequate leg vein for harvest	A (8)
21.	In the presence of adequate leg vein for harvest	M (4)
Screening Examination for Upper Extremity DVT*		
22.	Prior to pacemaker or implantable cardiac defibrillator placement	R (3)
23.	• Prolonged ICU stay (e.g., >4 days)	R (2)
	No indwelling upper extremity venous catheter	
24.	Prolonged ICU stay (e.g., >4 days) with indwelling upper extremity venous catheter	R (3)
25.	Monitoring indwelling upper extremity venous catheter that is functional	R (2)
26.	In those with high risk: acquired, inherited, or hypercoagulable state	R (2)
27.	Positive D-dimer test in a hospital inpatient	R (1)

\*Screening examination performed in the absence of upper extremity pain or swelling.

 $A = appropriate; \ CHF = congestive heart failure; \ DVT = deep vein thrombosis; \ ICU = intensive care unit; \ M = maybe appropriate; \ R = rarely \ R = rarel$ 

#### Summary: Upper Extremity Venous Duplex Ultrasound

Upper extremity venous duplex ultrasound was rated as an appropriate test in the setting of limb swelling, nonarticular upper extremity pain or palpable cord, and when new pain or swelling is noted in the presence of known upper extremity deep vein thrombosis (DVT). It was deemed rarely appropriate to perform an upper extremity venous ultrasound for evaluation of fever of unknown origin in the absence of an indwelling upper extremity venous catheter or for evaluation of shortness of breath in a patient with known upper extremity DVT.

Screening for upper extremity DVT in an asymptomatic patient was rated as rarely appropriate across 6 of 6 clinical scenarios, including the patient with prolonged intensive care unit (ICU) stay (with or without an upper extremity venous catheter), prior to pacemaker or defibrillator placement, for monitoring of a functional upper extremity venous catheter, or for upper extremity DVT screening in those with hypercoagulable state or with positive D-dimer test.

Upper extremity vein mapping (e.g., of cephalic and basic veins) prior to coronary or peripheral bypass surgery was rated as an appropriate test in the absence of adequate leg vein for harvest and as maybe appropriate in certain settings when adequate leg vein conduit is present.

## Section 2: Lower Extremity Venous Duplex Ultrasound

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#### Table 2. Venous Duplex of the Lower Extremities for Patency and Thrombosis

Indicat	tion	Appropriate Use Rating	
	Limb Swelling		
28.	Unilateral—acute	A (9)	
29.	Unilateral—chronic, persistent	A (7)	
30.	Bilateral—acute	A (8)	
31.	Bilateral—chronic, persistent	M (6)	
	No alternative diagnosis identified (e.g., no CHF or anasarca from hypoalbuminemia)		
	Limb Pain (Without Swelling)		
32.	Nonarticular pain in the lower extremity (e.g., calf or thigh)	A (7)	
33.	Knee pain	M (4)	
34.	• Tender, palpable cord in the lower extremity	A (8)	
	Shortness of Breath		
35.	Suspected pulmonary embolus	A (8)	
36.	Diagnosed pulmonary embolus	A (7)	
	Fever		
37.	Fever of unknown origin (no indwelling lower extremity venous catheter)	M (5)	
38.	Fever with indwelling lower extremity venous catheter	M (5)	
	Known Lower Extremity Venous Thrombosis		
39.	<ul> <li>Surveillance of calf vein thrombosis for proximal propagation in patient with contraindication to anticoagulation (within 2 weeks of diagnosis)</li> </ul>	A (7)	
40.	New lower extremity pain or swelling while on anticoagulation	A (7)	
41.	New lower extremity pain or swelling, not on anticoagulation (i.e., contraindication to anticoagulation)	A (8)	
42.	Before anticipated discontinuation of anticoagulation treatment	M (5)	
43.	Shortness of breath in a patient with known lower extremity DVT	M (5)	
44.	Surveillance after diagnosis of lower extremity superficial phlebitis	A (7)	
	• Not on anticoagulation, phlebitis location $\leq$ 5 cm from deep vein junction		
45.	Surveillance after diagnosis of lower extremity superficial phlebitis	M (5)	
	• Not on anticoagulation, phlebitis location $\geq$ 5 cm from deep vein junction		
	Vein Mapping Prior to Bypass Surgery (Coronary or Peripheral)		
46.	In the absence of prior lower extremity vein harvest or ablation procedure	A (8)	
47.	In the presence of prior lower extremity vein harvest or ablation procedure	A (8)	
	Screening Examination for Lower Extremity DVT*	- (-)	
48.	After orthopedic surgery	R (3)	
49.	• Prolonged ICU stay (e.g., >4 days)	R (3)	
50.	In those with high risk: acquired, inherited, or hypercoagulable state	R (3)	
51.	Positive D-dimer test in a hospital inpatient	R (2)	
50	Post-Endovenous (Great or Small) Saphenous Ablation		
52.	Lower extremity swelling or pain	A (8)	
53.	Routine post-procedural follow-up, no lower extremity pain or swelling Within 10 days post-procedure	A (7)	
Other Symptoms or Signs of Vascular Disease			
54.	Physiological testing positive for venous obstruction	A (7)	
55.	Patent foramen ovale with suspected paradoxical embolism for patient without lower extremity pain or swelling obstruction	A (7)	

\*Screening examination performed in the absence of lower extremity pain or swelling.

A = appropriate; DVT = deep vein thrombosis; ICU = intensive care unit; M = maybe appropriate; R = rarely appropriate.

Summary: Lower Extremity Venous Duplex Ultrasound

Lower extremity venous duplex ultrasound (Table 2) was rated an appropriate test in the setting of limb swelling, nonarticular lower extremity pain or palpable cord, pulmonary embolism, and when new pain or swelling is noted in the presence of known lower extremity DVT. Testing was also rated as appropriate for certain surveillance indications, namely surveillance of calf vein thrombosis for proximal extension of DVT when anticoagulation is contraindicated and for superficial thrombophlebitis of the legs (i.e., great or small saphenous vein) located near a deep vein junction. Venous ultrasound was rated as appropriate for early procedural follow-up after endovenous saphenous ablation procedures (in the patient with or without symptoms). Lower extremity venous duplex ultrasound was rated as appropriate for further evaluation of the patient with patent foramen ovale with suspected paradoxical embolism and for the patient with evidence of lower extremity venous obstruction on venous physiological testing (plethysmography) that suggests the possibility of DVT.

Screening for lower extremity DVT with duplex ultrasound in an asymptomatic patient was rated as rarely appropriate across multiple clinical scenarios, including the patient with a prolonged ICU stay, following orthopedic surgery, for those with hypercoagulable state, or with a positive D-dimer test. This was consistent with the rarely

#### Table 3. Duplex Evaluation for Venous Incompetency

Indication		Appropriate Use Rating
	Venous Insufficiency (Venous Duplex With Provocative Maneuvers for Incompetency)	
56.	Active venous ulcer	A (9)
57.	Healed venous ulcer	A (7)
58.	Spider veins (telangiectasias)	R (3)
59.	Varicose veins, entirely asymptomatic	M (5)
60.	Varicose veins with lower extremity pain or heaviness	A (7)
61.	Visible varicose veins with chronic lower extremity swelling or skin changes of chronic venous insufficiency (e.g., hyperpigmentation, lipodermatosclerosis)	A (7)
62.	• Skin changes of chronic venous insufficiency without visible varicose veins (e.g., hyperpigmentation, lipodermatosclerosis)	A (7)
63.	Lower extremity pain or heaviness without signs of venous disease	M (5)
64.	Mapping prior to venous ablation procedure	A (8)
65.	• Prior endovenous (great or small) saphenous ablation procedure with new or worsening varicose veins in the ipsilateral limb	A (8)
66.	Prior endovenous (great or small) saphenous ablation procedure with no residual symptoms	R (3)

A = appropriate; M = maybe appropriate; R = rarely appropriate.

# Table 4. Venous Physiological Testing (Plethysmography) With Provocative Maneuvers to Assess for Patency and/or Incompetency

Indication		
	Limb Pain, Swelling, or Other Signs of Venous Disease	
67.	Active venous ulcer	A (7)
68.	Varicose veins, entirely asymptomatic	M (5)
69.	Varicose veins with lower extremity pain or heaviness	A (7)
70.	Varicose veins with chronic lower extremity swelling or skin changes of chronic venous insufficiency (e.g., hyperpigmentation or lipodermatosclerosis)	A (7)
71.	• Skin changes of chronic venous insufficiency without visible varicose veins (e.g., hyperpigmentation or lipodermatosclerosis)	A (7)
72.	Lower extremity pain or heaviness without signs of venous disease	M (6)
73.	Limb swelling: unilateral—acute	R (3)
	Suspected acute venous thrombosis	
Shortness of Breath		
74.	Suspected pulmonary embolus	R (2)

A = appropriate; M = maybe appropriate; R = rarely appropriate.

appropriate ratings for upper extremity venous duplex ultrasound discussed in the preceding text.

Lower extremity vein mapping (of the saphenous veins) prior to coronary or peripheral bypass surgery was rated as an appropriate test regardless of whether or not the patient has previously undergone lower extremity vein harvest or ablation procedure.

Similar to the upper extremities, lower extremity venous duplex ultrasound for evaluation of fever of unknown etiology was rated as maybe appropriate in certain clinical scenarios, though the evidence to support this practice is limited (5–7).

Duplex ultrasound evaluation for venous incompetency, with provocative physiological maneuvers such as distal limb augmentation and/or Valsalva, was rated as appropriate in the setting of significant clinical symptoms and signs of venous disease, including: active or healed venous ulcer, varicosities with lower extremity discomfort, swelling, or chronic skin changes (Table 3). Duplex ultrasound for venous incompetency was rated as maybe appropriate for evaluation of the patient with significant, though asymptomatic, varicose veins (e.g., large, disfiguring varicose veins) or for the patient with lower extremity pain or heaviness without signs of venous disease.

Duplex ultrasound was rated as rarely appropriate for evaluation of isolated spider veins (telangiectasias) without other stigmata of venous disease or for the patient with prior saphenous vein ablation with no residual symptoms (although initial follow-up duplex for within the initial 10 days after the procedure was rated as appropriate, see the preceding text).

#### Summary: Venous Physiological Testing

Selected clinical indications for venous physiological testing (plethysmography) with provocative maneuvers were evaluated. Venous physiological testing was rated as appropriate in the setting of significant clinical symptoms and signs of chronic venous insufficiency, including: active venous ulcer, symptomatic varicose veins, and chronic skin changes such as lipodermatosclerosis or hyperpigmentation. Similar to the indications for venous duplex ultrasound for venous incompetency, venous physiological testing was rated as maybe appropriate for evaluation of the

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#### Table 5. Duplex of the IVC and Iliac Veins for Patency and Thrombosis

Indication		Appropriate Use Rating	
	Prior to IVC Filter Placement		
75.	Prior to IVC filter placement	M (6)	
	For procedural access planning		
	Evaluation for Suspected Deep Vein Thrombosis		
76.	<ul> <li>Lower extremity swelling—unilateral or bilateral—as a "stand-alone test" without a venous duplex of the lower extremities</li> </ul>	R (3)	
77.	Lower extremity swelling—unilateral or bilateral—combined routinely with a venous duplex of the lower extremities	M (4)	
78.	<ul> <li>Lower extremity swelling—unilateral or bilateral—performed selectively—when the lower extremity venous duplex is normal</li> </ul>	M (6)	
79.	<ul> <li>Lower extremity swelling—unilateral or bilateral—performed selectively—when the lower extremity venous duplex is positive for acute proximal DVT</li> </ul>	A (7)	
80.	Selectively—when the flow pattern in 1 or both common femoral veins is abnormal	A (8)	
	Evaluation for Suspected Pulmonary Embolus		
81.	<ul> <li>Pulmonary symptoms (suspected pulmonary embolus)—as a "stand-alone test" without a venous duplex of the lower extremities</li> </ul>	R (2)	
82.	<ul> <li>Pulmonary symptoms (suspected pulmonary embolus)—combined routinely with a venous duplex of the lower extremities</li> </ul>	M (4)	
Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease			
83.	Abdominal pain	R (3)	
84	Abdominal bruit	R (3)	
85.	Fever of unknown origin	R (3)	

A = appropriate; DVT = deep vein thrombosis; IVC = inferior vena cava; M = maybe appropriate; R = rarely appropriate.

patient with asymptomatic varicose veins or for the patient with lower extremity pain or heaviness without signs of venous disease.

Importantly, venous physiological testing was rated as rarely appropriate for evaluation of the patient with suspected acute lower extremity DVT or pulmonary embolism. In the case of suspected acute lower extremity DVT, duplex ultrasound would be the best initial test.

# Section 3: Duplex Evaluation of the Inferior Vena Cava and Iliac Veins

# Summary: Duplex Evaluation of the Inferior Vena Cava and Iliac Veins

In the setting of evaluation for suspected DVT, iliocaval duplex was rarely appropriate as a "stand-alone test," but was rated as appropriate or maybe appropriate for use either routinely or selectively in conjunction with lower extremity venous duplex scanning (Table 5). Scanning of the inferior vena cava (IVC) and iliac veins was rated as appropriate when performed selectively with a positive lower extremity venous duplex demonstrating proximal DVT or when an abnormal flow pattern was found in 1 or

Table 6. Duplex of the Hepatoportal System (Portal Vein, Hepatic Veins, Splenic Vein, Superior Mesenteric Vein, Inferior Vena Cava) for Patency, Thrombosis, and Flow Direction\*

Indication		Appropriate Use Rating
	Evaluation of Hepatic Dysfunction or Portal Hypertension	•
86.	Abnormal liver function tests	M (6)
	<ul> <li>No alternative diagnosis identified (e.g., medication related or infectious hepatitis)</li> </ul>	
87.	Cirrhosis with or without ascites	A (7)
88.	Jaundice	R (3)
	As an initial diagnostic test	
89.	Jaundice	M (6)
	<ul> <li>No alternative diagnosis identified after initial evaluation (e.g., no biliary obstruction)</li> </ul>	
90.	Hepatomegaly and/or splenomegaly	A (7)
91.	Portal hypertension	A (7)
	Surveillance Following Portal Decompression Procedure	
92.	Follow-up of a TIPS	A (8)
	Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease	
93.	Abdominal pain	M (4)
94.	Fever of unknown origin	R (3)
Evaluation of Cardiac and/or Pulmonary Symptoms		
95.	Pulmonary symptoms (suspected pulmonary embolus)	R (3)
96.	Cor pulmonale	R (3)

\*Testing indications refer to evaluation of native hepatoportal venous system only (i.e., hepatic transplant sites and arterial system excluded).

 $\mathsf{A} = \mathsf{appropriate}; \ \mathsf{TIPS} = \mathsf{transjugular} \ \mathsf{intrahepatic} \ \mathsf{portosystemic} \ \mathsf{shunt}; \ \mathsf{M} = \mathsf{maybe} \ \mathsf{appropriate}; \ \mathsf{R} = \mathsf{rarely} \ \mathsf{appropriate}.$ 

#### Table 7. Duplex of the Renal Veins for Patency and Thrombosis\*

Indicati	Appropriate Use Rating				
Evaluation for Suspected Renal Vein Thrombosis—Potential Signs and/or Symptoms					
97.	Gross hematuria	R (3)			
98.	Acute renal failure	M (5)			
99.	Acute flank pain	M (5)			
Evaluation of Cardiac and/or Pulmonary Symptoms					
100.	Pulmonary symptoms (suspected pulmonary embolus)	R (3)			
Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease					
101.	Drug-resistant hypertension (suspected renal artery stenosis)	R (3)			
102.	Microscopic hematuria (prior to urological evaluation)	R (2)			
103.	Fever of unknown origin	R (2)			
104.	Epigastric bruit	R (2)			

\*Testing indications refer to evaluation of native renal veins only for patency (i.e., renal transplant sites and renal arteries excluded).

A = appropriate; DVT = deep vein thrombosis; IVC = inferior vena cava; M = maybe appropriate; R = rarely appropriate.

both common femoral veins. Similarly, in the setting of suspected pulmonary embolism, iliocaval duplex was rated as rarely appropriate as a "stand-alone test" but as maybe appropriate when combined routinely with a lower extremity venous duplex examination in this setting. The indications of abdominal pain, abdominal bruit, and fever of unknown origin were all rated as rarely appropriate for IVC and iliac vein duplex. Duplex ultrasound of the IVC and iliac veins was rated as maybe appropriate for procedural planning prior to IVC filter placement.

## Section 4: Hepatoportal and Renal Venous Evaluation

## Summary: Hepatoportal and Renal Venous Duplex Ultrasound

Duplex scanning of the hepatoportal system (Table 6) was rated as appropriate for the evaluation of cirrhosis without ascites, hepatomegaly and/or splenomegaly, and portal hypertension. Duplex scanning was rated as rarely appropriate as an initial diagnostic test in patients with jaundice but maybe appropriate for evaluation of patients with abnormal liver function tests and jaundice with no alternative diagnosis identified after an initial workup. Followup after a transjugular intrahepatic portosystemic shunt (TIPS) procedure was rated as appropriate for duplex scanning. Hepatoportal scanning was rated as maybe appropriate for abdominal pain and rarely appropriate for fever of unknown origin and cor pulmonale or pulmonary symptoms.

Likely reflecting the uncommon nature of isolated renal vein pathology as a cause of genitourinary symptoms or signs, there were no clinical indications rated as appropriate for assessment of the native renal veins with duplex ultrasound (Table 7) in this document. For the indications of acute renal failure and acute flank pain, symptoms of

#### Table 8. Pre-Operative Planning and Post-Operative Assessment of a Vascular Access Site\*

Indicati	Appropriate Use Rating					
Assessment Prior to Access Site Placement*						
105.	• Pre-operative mapping study (upper extremity arterial and venous duplex) $\geq$ 3 months prior to access placement	R (3)				
106.	• Pre-operative mapping study (upper extremity arterial and venous duplex) <3 months prior to access placement	A (8)				
"Failure to Mature"						
107.	<ul> <li>"Failure to mature" on basis of physical examination 0-6 weeks after placement</li> </ul>	M (6)				
108.	"Failure to mature" on basis of physical examination >6 weeks after placement	A (8)				
Symptoms and Signs of Disease†						
109.	<ul> <li>Signs of access site malfunction during dialysis (e.g., low blood flows, kt/V, recirculation times, or increased venous pressure)</li> </ul>	A (8)				
110.	Mass associated with an AVF/AVG	A (8)				
111.	Loss of palpable thrill of AVF/AVG	A (8)				
112.	Arm swelling	A (8)				
113.	Hand pain, pallor, and/or digital ulceration (i.e., evaluation for suspected arterial steal syndrome)	A (8)				
114.	Cool extremity	R (3)				
	Without pain, pallor, or ulceration					
115.	Difficult cannulation by multiple personnel on multiple attempts	A (8)				
Asymptomatic†						
116.	Routine surveillance of a functioning AVF or AVG	R (3)				

\*Ultrasound assessment prior to creation of dialysis access (AVF or AVG) typically includes a combined arterial and venous duplex examination that is performed to determine the adequacy of superficial veins (patency, size, and length of conduit), patency of central venous outflow, and adequacy of adequate arterial inflow. Determination of central venous patency is particularly important for patients with a history of prior central venous catheter(s). †In a mature AVF or AVG that is being accessed for hemodialysis.

A = appropriate; AVF = autogenous arteriovenous fistula (including venous transpositions); AVG = prosthetic arteriovenous graft; M = maybe appropriate; R = rarely appropriate.

renal vein thrombosis, renal vein duplex ultrasound was rated as maybe appropriate. Renal venous duplex was rated as rarely appropriate for evaluation of gross or microscopic hematuria, pulmonary symptoms, or fever of unknown origin. Renal venous duplex was rated as rarely appropriate for evaluation of epigastric bruit or drug-resistant hypertension, scenarios for which arterial duplex testing would be a more appropriate test (1).

### Section 5: Hemodialysis Vascular Access Duplex Ultrasound

# Summary: Hemodialysis Vascular Access Duplex Ultrasound

For vascular assessment (or mapping) prior to the placement of hemodialysis access, duplex ultrasound was rated as appropriate when performed less than 3 months prior to the procedure. Vascular assessment prior to access placement was rated as rarely appropriate when performed earlier than this time, reflecting the potential for interval development of vascular lesions in the hemodialysis patient (e.g., superficial or deep vein thromboses). Following dialysis access placement, indications were rated according to presence and nature of symptoms and time interval following access placement. For the assessment of access that has failed to mature on the basis of physical examination findings, duplex ultrasound was rated as an appropriate test beyond 6 weeks after access placement and maybe appropriate within 0 to 6 weeks of placement. Duplex ultrasound was rated as an appropriate test for most clinical scenarios related to upper extremity symptoms in the patient with mature dialysis access, including mass associated with an autogenous arteriovenous fistula (AVF)/prosthetic arteriovenous graft (AVG), arm swelling, or signs of digital ischemia due to steal phenomenon (hand pallor, pain, or ulceration). Similarly, duplex ultrasound was rated as an appropriate test for signs of malfunction and/or occlusion in a mature and previously functional AVF/AVG, including repeated difficulties with access cannulation, low flow or other signs of malfunction during dialysis sessions, and loss of palpable thrill over the access. Evaluation of a cool, but otherwise entirely asymptomatic, upper extremity with duplex ultrasound was rated as rarely appropriate. The technical panel rated routine duplex surveillance of a functional AVF/AVG in an asymptomatic patient with no signs of access malfunction as rarely appropriate.

# 7. Discussion

The noninvasive vascular laboratory plays a central role in the evaluation and surveillance of peripheral vascular disorders. The scope of this document includes common and less common clinical indications encountered among patients with suspected or known venous disease, the most common of which being venous thromboembolism (e.g., DVT, pulmonary embolism, and superficial thrombophlebitis) and chronic venous insufficiency, either due to primary varicose veins or secondary to prior DVT (postthrombotic syndrome) or other nonthrombotic venous pathology (e.g., congenital venous anomaly). Indications for vascular testing prior to or after placement of hemodialysis access are included in this document, as evaluation of the superficial, deep, and central veins of the upper extremity constitutes a large component of these examinations. It is assumed that protocols for assessment prior to and following hemodialysis access will also include imaging of the arterial system, as determined by the clinical indication and type of dialysis access.

Due to the diversity of peripheral vascular disorders, it is likely that many potential clinical indications are not included in this document. Rather than an exhaustive compendium of clinical indications, it is intended that this document address the most common and important clinical scenarios encountered in the patient with manifestations of peripheral vascular disease. Although this document largely focuses on ratings for duplex ultrasound, some common clinical indications for venous physiological testing were included, recognizing that physiological testing is used in some clinical centers as a tool for evaluation of the patient with lower extremity symptoms suspicious for venous disease. Importantly, venous physiological testing was rated as rarely appropriate for evaluation of the patient with acute lower extremity swelling and suspected DVT, for whom venous duplex ultrasound was rated an appropriate test.

It is intended that this document, along with appropriate use criteria for arterial testing published in 2012 (1), will provide guidance for clinicians in maximizing the appropriate use of the noninvasive vascular laboratory for the care of patients with suspected or known peripheral vascular disorders. In addition, it is intended that this document identify critical evidence gaps in the field and serve as a reference for policy makers with regard to noninvasive vascular testing. Although the Part I and Part II Peripheral Vascular Ultrasound AUC documents share a common intent, methodology, and structure, there are important differences to note. In the Part I document, 159 clinical indications related to arterial testing were rated, including numerous indications which rated timing of surveillance studies either prior to (e.g., asymptomatic carotid artery stenosis) or following revascularization (e.g., testing for patency and restenosis of lower extremity bypass grafts and stents). Reflecting the more focused spectrum of pathology in the venous system, as well as fewer distinct vascular beds to image, this venous testing document presents ratings for 116 clinical indications. In the venous document, there are fewer indications related to repeated testing or surveillance of known disease. Although vascular testing is commonly repeated for surveillance of arterial atherosclerotic disease or aneurysms to determine the need for revascularization or repair (e.g., severe internal carotid

artery stenosis or large abdominal aortic aneurysm), there are far fewer clinical scenarios in which surveillance testing for venous disease is performed (e.g., for surveillance of known calf DVT with contraindication to anticoagulation). Similarly, unlike the arterial document in which multiple clinical indications for testing following surgical or endovascular treatment were rated, the role of duplex ultrasound for follow-up after venous procedures (e.g., pharmacomechanical thrombolysis or venous stenting for DVT) is not as well established. Finally, it is important to note that the Part II venous testing document incorporates clinical indication classification terminology that has been revised since publication of the arterial document (appropriate care, maybe appropriate care, rarely appropriate care).

## Summary of Evidence and Call for Additional Research

The current evidence base and clinical practice guidelines were used to develop and rate the clinical indications whenever available, although for a large number of clinical indications, the available scientific literature was limited and clinical consensus or expert opinion played a larger role. Clinical practice guidelines and additional literature reviewed are presented in the Online Appendix. Specifically, with regard to diagnosis of DVT, the writing committee reviewed recently published guidelines from the American College of Chest Physicians (ACCP) (8) and recognized that the ACCP document serves to provide global diagnostic algorithms for venous thromboembolism that incorporate pre-test probability assessment, D-dimer testing, and alternative imaging modalities, the scope of which is beyond that of this appropriate use document that focused on venous duplex ultrasound and physiological testing. In addition, the consensus of the writing committee, in contrast with that of the ACCP guidelines, is that the entire lower extremity (whole-leg ultrasound including the calf veins) should be evaluated in cases of suspected lower extremity DVT when technically possible.

As was the case for arterial testing, the writing committee recognizes a need for clinical and cost-effectiveness studies focused specifically on noninvasive testing for venous disease. The writing committee identifies the following areas as among those in greatest need of focused research:

- 1. Comparative clinical and cost effectiveness of various algorithms for diagnosis of DVT, including pre-test probability assessment tools (e.g., Wells score), D-dimer, and venous duplex ultrasound.
- 2. Comparative clinical and cost effectiveness of clinical algorithms incorporating venous duplex testing for the diagnosis of pulmonary embolism.
- 3. Role of venous duplex ultrasound in clinical algorithms to determine duration of anticoagulation therapy among patients with unprovoked DVT.

- 4. Comparison of anticoagulation therapy versus duplex ultrasound surveillance among patients with isolated calf DVT.
- 5. Accuracy and clinical benefit of venous duplex ultrasound following venous intervention (e.g., pharmacomechanical thrombolysis, angioplasty, stenting).
- 6. Optimal timing and utilization of duplex ultrasound in clinical practice for assessment of dialysis access maturity.

# **Appendix A: Additional Methods**

See the Methods section of the report for a description of panel selection, indication development, scope of indications, and rating process.

#### **Relationships With Industry and Other Entities**

The College and its partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the Appropriate Use Criteria Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by the technical panel and oversight working group member can be found in the Appendix B.

Appendix B: ACCF 2013 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part II: Testing for Venous Disease and Evaluation of Hemodialysis Access Participants

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Manesh R. Patel	None	None	None	None	None	None
Leslee Shaw	None	None	None	None	None	None
Raymond F. Stainback	None	None	None	None	None	None
Joseph M. Allen	None	None	None	None	None	None
Z. Jenissa Haidari	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by participants at the time of participation. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of \$10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation does not imply endorsement of this document.

# **Additional Materials:**

- Indications by Rating Online Appendix
- Ratings Sheet Online Appendix

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**Key Words:** ACCF Appropriate Use Criteria 

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