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APPROPRIATE USE CRITERIA

ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention

A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine

Peripheral Artery Intervention Writing Group

Steven R. Bailey, MD, FACC, MSCAI, FAHA, *Chair**
Joshua A. Beckman, MD, FACC, MSVM*
Timothy D. Dao, MD, FACC*
Sanjay Misra, MD, FSIR, FAHA†
Piotr S. Sobieszczyk, MD, RVT, FSVM‡
Christopher J. White, MD, FACC, MSCAI§

Peripheral Artery Intervention Rating Panel

L. Samuel Wann, MD, MACC, *Moderator**
Steven R. Bailey, MD, FACC, MSCAI, FAHA, *Writing Group Chair**
Timothy Dao, MD, FACC, *Writing Group Representative**
Herbert D. Aronow, MD, MPH, FACC, FSCAI, FSVM‡
Reza Fazel, MD, FACC, FSCAI, FAHA*
Heather L. Gornik, MD, FACC, FAHA, FSVM*
Bruce H. Gray, DO, MSVM, FSCAI‡
Jonathan L. Halperin, MD, FACC, FAHA, MSVM*
Alan T. Hirsch, MD, FACC*
Michael R. Jaff, DO, FACC, FSCAI, FAHA, MSVM§
Venkataramu Krishnamurthy, MBBS†
Sahil A. Parikh, MD, FACC, FSCAI*
Amy B. Reed, MD, FACS, RPVI‖
Fadi Shamoun, MD, FACC, FSVM*
Rita E. Shugart, RN, RVT, FSVU¶
E. Kent Yucel, MD, FACR, FAHA#

*American College of Cardiology Representative. †Society of Interventional Radiology Representative. ‡Society for Vascular Medicine Representative. §Society for Cardiovascular Angiography and Interventions Representative. ‖Society for Vascular Surgery Representative. ¶Society for Vascular Ultrasound Representative. #American College of Radiology Representative.

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Appropriate Use Criteria Task Force

Gregory J. Dehmer, MD, MACC, MSCAI, FAHA, *Co-Chair***
John U. Doherty, MD, FACC, *Co-Chair***

Steven R. Bailey, MD, FACC, MSCAI, FAHA††
Nicole M. Bhave, MD, FACC**
Alan S. Brown, MD, FACC, FSCAI, FAHA††
Stacie L. Daugherty, MD, FACC**
Larry S. Dean, MD, FACC, MSCAI, FAHA**
Milind Y. Desai, MD, FACC, FAHA**
Claire S. Duvernoy, MD, FACC††
Linda D. Gillam, MD, MPH, FACC, FAHA**
Robert C. Hendel, MD, FACC, FAHA††
Christopher M. Kramer, MD, FACC, FAHA‡‡
Bruce D. Lindsay, MD, FACC††
Warren J. Manning, MD, FACC††
Praveen Mehrotra, MD, FACC**
Manesh R. Patel, MD, FACC, FSCAI, FAHA§§
Ritu Sachdeva, MBBS, FACC**
L. Samuel Wann, MD, MACC††
David E. Winchester, MD, FACC**

**Current Task Force member; member during the writing effort.
††Former Task Force member; member during the writing effort.
‡‡Former Task Force Co-Chair during the writing effort.
§§Former Task Force Chair during the writing effort.

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ABSTRACT

The American College of Cardiology (ACC) collaborated with the American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine, along with several ACC Councils, to establish and evaluate Appropriate Use Criteria (AUC) for peripheral artery intervention (PAI). Although PAI has been the subject of prior single-society papers, this is the first multisocietal effort on the topic.

To initiate the AUC process, patient scenarios that are common in clinical practice were drafted, along with assumptions and definitions for those scenarios. The scenarios were created using published guidelines, trial data, and expert opinions from within the field of peripheral artery disease. The writing group developed 45 clinical scenarios with up to 6 intervention options per scenario and categorized them into 6 general sections. A separate, independent rating panel evaluated each indication using a scoring scale from 1 to 9, thereby designating each indication as "Appropriate" (score of 7 to 9), "May Be Appropriate" (score of 4 to 6), or "Rarely Appropriate" (score of 1 to 3).

Throughout the scenarios, emphasis was placed on adhering to and exhausting medical therapy to achieve maximal benefit in those situations in which symptom management was desired or incidental disease was discovered. However, situations arise in which medical therapy is insufficient, and identifying a suitable revascularization strategy is necessary. After considering factors such as symptom burden, anatomic distribution, and ischemic burden, the rating panel determined that both endovascular and surgical approaches are Appropriate in clinical scenarios involving concomitant tissue loss or end organ compromise. There was a tendency to select endovascular approaches in these scenarios, particularly in anatomic distributions below the knee and where prior endovascular or surgical revascularization has been performed. Given the dynamic landscape of cardiovascular medicine, the writing group felt it was necessary to address situations in which adjunct arterial revascularization may be necessary to facilitate other procedures such as percutaneous valve replacement or hemodynamic support. The clinical situations where this occurs often make endovascular interventions more attractive and that was reflected in the ratings.

The purpose of this particular AUC is to provide guidance to clinicians who may refer patients for revascularization treatments and to interventionalists and surgeons themselves. With the field of peripheral artery disease constantly evolving, it is imperative to offer tools and resources that physicians can utilize to provide the best care for their patients.

PREFACE

Stimulated by the potential overuse of cardiovascular imaging, the first Appropriate Use Criteria (AUC) were developed in 2005. Since then, many other topics have been explored and translated into appropriate use ratings. In an effort to address the rational use of tests and procedures in the delivery of high-quality cardiovascular care, the American College of Cardiology (ACC) and numerous partnering societies have undertaken a process to determine the appropriate use of treatment options for patients with peripheral artery disease.

AUC publications reflect an ongoing effort by the ACC and its partners to critically and systematically evaluate clinical situations in which treatments and procedures are utilized by physicians caring for patients with known or suspected cardiovascular disease. The process is based on our current understanding of the technical capabilities of the modalities and procedures examined. Although not intended to be comprehensive owing to the diversity of clinical disease, the patient indications included in this document are meant to identify common scenarios encountered by clinicians in contemporary practice. The AUC indications are often chosen on the basis of gaps and gray areas in Clinical Practice Guidelines and a lack of evidence-based data, thereby relying on clinical practice experience and physician judgment to determine the final AUC ratings.

The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner.

They are not intended to ignore the ambiguity and nuance intrinsic to clinical decision making. Local parameters, such as the availability or quality of equipment and personnel, may influence the selection of certain treatments or procedures. Thus, AUC should not be considered as substitutes for clinician judgment and practice experience.

I would like to thank the writing group for their dedication to the drafting and editing of numerous versions of this manuscript, which resulted in an essential list of clinical scenarios, and to the rating panel for scoring the scenarios numerous times and offering sage input in this process. A special tribute is extended to rating panelist Dr. Alan Hirsch, whose untimely passing created a void in the peripheral vascular community. I am also grateful to the parent AUC Task Force, which provided significant guidance and insights, and the ACC staff—Joe Allen, and especially Lara Gold—for their vital contributions and assistance in the development of this document.

Steven R. Bailey, MD, FACC, MSCAI
Chair, Peripheral Artery Intervention Writing Group

1. INTRODUCTION

Improvements in the diagnosis of peripheral artery disease (PAD) have led to an increasing number of treatment and revascularization methods, especially endovascular interventions. As new and increasingly sophisticated devices are developed, the medical community needs to understand how best to incorporate these technologies into daily clinical decision making and care, and how to choose between new and more established methods. This AUC project was initiated to respond to this need and to ensure the effective use of peripheral artery revascularization.

The purpose of this guidance document is neither to detail every clinical situation nor to describe the use of every device used in the treatment of PAD. Rather, the goal is to provide generalized guidance into the use of these devices and techniques, while understanding that each clinical situation is unique, with physicians using their best judgment and the available evidence base to craft the most beneficial approach for the patient. In all cases, it is assumed that guideline-directed medical therapy should be applied first. Moreover, in determining the appropriate use of the described treatments, the rating panel was instructed to not compare the treatment options with each other. Although it is difficult to avoid comparing "scores" for each treatment in the patient scenarios, each treatment option should be considered on its own merits and not ranked against the other options. This is necessary owing to the diffusion of expertise and availability of techniques and tools, which varies across the range of situations and settings in which care is provided to patients with PAD.

2. METHODS

To begin the AUC process, a multidisciplinary writing group consisting of representatives from several cardiovascular subspecialty societies and ACC Councils was formed. The goal of the writing group was to develop common patient scenarios experienced in clinical practice, and to categorize these scenarios on the basis of factors such as patient symptoms, anatomy, and disease state. The writing group focused on identifying typical situations encountered in daily practice, because it would be impossible to cover every conceivable patient presentation without making the number of scenarios excessive. Whenever possible during the writing process, the writing group mapped the indications to relevant guidelines, clinical trials, and other key references (see Guideline Mapping and References). Once the indications were formed, they were reviewed and critiqued by the parent AUC Task Force and numerous external reviewers representing a variety of cardiovascular subspecialty societies and ACC Councils. After the writing group incorporated this feedback, the indications were sent to an independent rating panel comprised of additional experts specializing in PAD. Panelists were also sent a guideline and clinical trial mapping document for their reference (see Guideline Mapping and References).

The rating panelists were then tasked with scoring the clinical scenarios from 1 through 9, with 1 to 3 classified as "Rarely Appropriate care," 4 to 6 as "May Be Appropriate care," and 7 to 9 as "Appropriate care." Panelists conducted this scoring via an electronic survey platform, and the median score from the 13 panelists was calculated for each scenario. Next, the panelists, several writing group representatives, and a moderator came together for an in-person rating panel meeting, where robust discussion of each indication ensued, and feedback was given to the writing group representatives. The writing group then took this input and completed further vetting of the clinical scenarios before sending the document back to the rating panel for an additional round of electronic scoring. After the second round of ratings, a few of the scenarios had scores that were misaligned with guideline recommendations and other evidence. The writing group felt this misalignment came from 2 sources. First, wording of the affected scenarios was ambiguous to some members of the rating panel. Second, as a rapidly evolving field, new evidence emerged during the rating process that confounded the scoring for some rating panel members. Therefore, the writing group edited the language

used for these scenarios to make them clearer and to make sure results from the new studies were considered in the ratings by all members of the rating panel. After additional rating of these scenarios was completed, the final round of scoring was achieved (see Final Deidentified AUC Scores). These additional rounds of review and subsequent revision ensured that multiple viewpoints were considered throughout the AUC process.

A detailed description of the methods used for rating the clinical scenarios can be found in previous AUC methodology publications, including the ACC Appropriate Use Criteria Methodology: 2018 Update (1–3). Briefly, this process combines evidence-based medicine and practice experience and engages a rating panel in a modified Delphi exercise. The composition of the rating panel is key; to prevent bias in the scoring, the majority of rating panelists chosen were generalists/nonproceduralists. Proceduralists such as surgeons and interventionalists, while offering important clinical and technical insights, might have a natural tendency to rate the indications within their specialty at a higher degree of appropriateness than nonprocedural raters. For the scoring, care was taken to provide the rating panel with objective, unbiased information, including guidelines and key references in the field (see Guideline Mapping and References).

In scoring the clinical scenarios, the rating panel was asked to assess whether the use of a specific intervention for each clinical indication should be categorized as Appropriate, May Be Appropriate, or Rarely Appropriate. It was emphasized that the treatment options should not be ranked in comparison with each other or based on physician preference, but should instead be considered on their own merits and reasonableness for the given clinical scenario. When scoring the indications, the rating panel was given the following definition of appropriate use:

An Appropriate treatment is one in which the potential benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life), exceed the potential negative consequences of the treatment strategy.

The rating panel scored each indication using the following definitions and their associated numeric ranges:

Median Score 7 to 9: **Appropriate care** for specific indication (treatment **is** generally acceptable and **is** a reasonable approach for the indication).

An appropriate option for management of patients in this 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., treatment is generally acceptable and is generally reasonable for the indication).

Median Score 4 to 6: **May Be Appropriate care** for specific indication (treatment **may** be generally acceptable and **may** be a reasonable approach for the indication). May Be Appropriate also implies that more research and/or patient information is needed to classify the indication definitively.

At times an appropriate option for management of patients in this population due to variable evidence or lack of 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., treatment may be acceptable and may be reasonable for the indication).

Median Score 1 to 3: **Rarely Appropriate care** for specific indication (treatment **is not** generally acceptable and **is not** a reasonable approach for the indication).

Rarely an appropriate option for management of patients in this 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., treatment is not generally acceptable and is not generally reasonable for the indication).

The division of the numerical scores into 3 levels of appropriateness is somewhat arbitrary, and the numeric designations should be viewed as a continuum. It is important to note that there may be diversity in clinical opinion for particular scenarios such that scores in the intermediate level of appropriate use should be labeled May Be Appropriate as critical patient or research data may be lacking or discordant. This designation should serve as a prompt to carry out definitive research in this field whenever possible. It is anticipated that AUC reports will continue to be revised as further data are generated and information from implementation of the criteria is accumulated.

The scenarios included in this document are based on our current understanding of the potential patient benefits compared with the risks of the treatment strategies involved. Each patient should be treated individually based on his or her own particular needs, so it is expected that all clinicians will occasionally care for patients with unique conditions that could result in the choice of a therapy rated as Rarely Appropriate. When this occurs, clinicians should document the specific situation and patient characteristics that support performing that procedure; the Rarely Appropriate rating should not be used as a deterrent for treating the patient or grounds for denial of reimbursement. While a Rarely Appropriate designation should not prevent a procedure from being performed, an Appropriate designation is also not a requirement or

"must do" for a given procedure. The AUC are offered to help guide patient care but should not be considered a substitute for clinical judgment and practice experience.

3. GENERAL ASSUMPTIONS

1. This document will address the use of peripheral artery revascularization using endovascular and surgical approaches. This broadly inclusive term is used so that this document may be expanded in the future as new data become available.
2. Diagnostic tests and revascularizations are performed and interpreted by qualified individual(s) in a facility that is compliant with national standards for performing peripheral artery revascularization (endovascular and surgical procedures).
3. A qualified clinician has obtained a complete clinical history and performed the physical examination such that the clinical status of the patient can be assumed to be valid as stated in the indication (e.g., an asymptomatic patient is truly asymptomatic for the condition under consideration and the patient has been questioned sufficiently).
4. In this document, the term "family history" refers to first-degree relatives only.
5. The indications are at times purposefully broad to cover an array of cardiovascular signs and symptoms and to account for the ordering physician's best judgment as to the presence of cardiovascular abnormalities. Clear documentation of the indication for revascularization should be included in the medical record. Additionally, certain clinical scenarios, such as acute limb ischemia, are not covered in this document because revascularization is indicated if feasible.
6. For patients having revascularization for more than 1 indication—e.g., chronic kidney disease, worsening hypertension, the treatment of renal artery stenosis (RAS)—the most clinically significant of the indications should be noted as that indication has been used to construct the following tables.
7. Revascularization options are rated for their level of appropriateness specific to clinical scenarios, rather than being compared in rank order against other revascularization options. The goal of this document is to identify all revascularization options that are considered reasonable for a given clinical indication, rather than determining a single best procedure for each scenario. As such, >1 intervention type or even all procedures may be considered Appropriate, May Be Appropriate, or Rarely Appropriate for any given clinical indication.
8. Cost is considered implicitly in the appropriate use determination. Clinical benefits should always be considered first, and costs should be considered in relationship to these benefits to better convey net value. For example, a procedure with moderate clinical efficacy for a given AUC indication should not be scored as more appropriate than a procedure with high clinical efficacy solely because of its lower cost. When scientific evidence exists to support clinical benefit, cost efficiency and cost effectiveness should be considered for any indication.
9. The level of appropriateness does not consider issues of local availability or skill.
10. The category of "May Be Appropriate" (M) is used when insufficient data are available for a definitive categorization or there is substantial disagreement regarding the appropriateness of that indication. The designation of "May Be Appropriate" should not be used as grounds for denial of reimbursement.
11. Indication ratings contained herein supersede the ratings of similar indications contained in previous AUC documents.
12. Patients deemed suitable for a procedure should have a lesion suitable for a revascularization procedure and have a reasonable procedure-related risk.
13. A stenosis is considered hemodynamically significant if it has a ≥70% diameter narrowing or has a hemodynamically significant gradient at rest or after a vasodilator challenge. Pressure gradient should be measured with a pressure wire or catheter ≤5-Fr.
14. All lesions represent *de novo* disease and not in-stent restenosis, unless otherwise stated.
15. Patients have received or are undergoing risk factor reduction and medical therapy, including exercise therapy (preferably supervised), as recommended by the 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease (4), unless otherwise noted. Risk factor reduction begins with improvement in lifestyle, including attainment of a healthy weight, tobacco cessation, and routine exercise. For patients with PAD, medical therapy should include antiplatelet therapy with aspirin or clopidogrel, moderate- or high-dose statin therapy, and angiotensin-converting enzyme inhibitor use. Blood pressure should be controlled as per the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (5). This guideline states that there is no major difference in the relative risk reduction in cardiovascular disease from blood pressure-lowering therapy between patients with comorbid hypertension and PAD and patients with hypertension but without PAD.

Section 1 Assumptions: RAS

16. Patients should be taking 3 appropriate blood pressure medications, which should include a diuretic.
17. Patients with newly discovered atherosclerotic RAS will be managed according to the data published in the randomized CORAL trial (Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis) (6), which endorse the use of the best medical therapy. However, patients with poorly controlled hypertension (on 3 blood pressure medicines at maximally tolerated doses, 1 of which is a diuretic) would be candidates for renal intervention as outlined in the ACC/AHA 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) document (7).
18. Full-dose medication, as defined by relevant guidelines, may not be achievable in some patients due to medication intolerance. Therefore, renal stenting may be considered for patients with uncontrolled hypertension who are intolerant of 3 antihypertensive medications given at maximal doses.
19. Intravascular ultrasound will be used as needed to optimize stent deployment and conserve contrast for RAS procedures.
20. Post-procedure renal duplex (≤30 days, 6 ± 1 months, and ≤12 ± 1 months and annually) is recommended.
21. Primary renal stent placement is indicated for atherosclerotic RAS lesions.
22. Both clinical and anatomic lesion criteria must be met for renal revascularization indications to be consistent with those in the AHA/ACC PAD Guideline (7):
    a. Clinical criteria:
        i. Accelerated hypertension, resistant hypertension, malignant hypertension, hypertension with an unexplained unilateral small kidney, and hypertension with intolerance to medication; or
        ii. Progressive chronic kidney disease with bilateral RAS, RAS to a solitary functioning kidney, or unilateral RAS; or
        iii. Recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema or recurrent unstable angina.
    b. Lesion criteria (8–10):
        i. 50% to 69% diameter stenosis by visual estimation with hemodynamic confirmation of the severity of the stenosis (i.e., a resting systolic translesional gradient [measured with a ≤5-Fr catheter or pressure wire] ≥20 mm Hg or a resting mean gradient ≥10 mm Hg, a hyperemic systolic gradient ≥20 mm Hg or a hyperemic mean gradient ≥10 mm Hg, or a fractional flow reserve performed with dopamine [50 μg/kg] or papaverine [32 mg] of <0.8);
        ii. Any stenosis ≥70% diameter; or
        iii. Any stenosis ≥70% diameter by intravascular ultrasound measurement.

Section 2 Assumptions: Lower Extremity Disease

23. Patients with intermittent claudication have lifestyle- or vocation-limiting symptoms and have undergone a trial of medical therapy and exercise therapy (supervised). For medical therapy, cilostazol should be employed for ≥3 months to improve absolute claudication distance. Per the 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease (4), to be effective, exercise therapy should constitute a supervised, structured program of exercise lasting for 30 to 45 min, 3 times/week, for a minimum of 12 weeks.
24. Popliteal artery aneurysmal disease is not included.
25. Common femoral artery disease is not included.
26. The superficial femoral artery (SFA) extends from its ostium after bifurcation of the common femoral artery to the adductor canal.
27. The below-the-knee segment extends from the origin of the anterior tibial artery to the pedal arch.
28. The trifurcation refers to the division of the popliteal artery into the anterior tibial artery and the tibioperoneal trunk, which subsequently divides into the posterior tibial and peroneal arteries.
29. Two-year survival is an estimate based upon patient characteristics and comorbidities: age ≥80 years, body mass index <18.0 kg/m^2, nonambulatory status, hemodialysis, cerebrovascular disease, left ventricular ejection fraction <40%, Rutherford class 5 or 6.

Section 3 Assumptions: Critical Limb Ischemia

30. Patients with critical limb ischemia (CLI) have ischemic limb pain at rest, nonhealing ulcerations, or gangrene.
31. Popliteal artery aneurysmal disease is not included.
32. Common femoral artery disease is not included.
33. The SFA extends from its ostium after bifurcation of the common femoral artery to the adductor canal.
34. The below-the-knee segment extends from the origin of the anterior tibial artery to the pedal arch.
35. The trifurcation refers to the division of the popliteal artery into the anterior tibial artery and the tibioperoneal trunk, which subsequently divides into the posterior tibial and peroneal arteries.
36. Two-year survival is an estimate based upon patient characteristics and comorbidities: age ≥80 years, body mass index <18.0 kg/m^2, non-ambulatory status, hemodialysis, cerebrovascular disease, left ventricular ejection fraction <40%, Rutherford class 5 or 6.

Section 4 Assumptions: Asymptomatic Artery Disease

37. This section addresses when peripheral artery procedures may be needed to facilitate arterial access to perform other cardiovascular procedures that are deemed life-saving.
38. Some patients who require large-diameter catheter access for therapy may have obstructive disease that is not causing symptoms and would not have been included in other treatment tables.
39. Alternate vascular access should be considered before peripheral artery access is deemed the best option.
40. The revascularizations in this section should not be undertaken for the management of PAD, per se, but to facilitate care that is deemed necessary and relies upon suitable arterial access. One common example would be the need for placement of a large-diameter device for hemodynamic support in the setting of cardiogenic shock or before a high-risk coronary intervention.

Section 5 Assumptions: Options for Endovascular Treatment When Deemed Appropriate or May Be Appropriate

41. Popliteal artery aneurysmal disease is not included.
42. Common femoral artery disease is not included.
43. The SFA extends from its ostium after bifurcation of the common femoral artery to the adductor canal.
44. The lesion length cutoff of 100 mm is based on the 2007 Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) document (11); and extrapolation of the FAST randomized trial (Nitinol Stent Implantation Versus Percutaneous Transluminal Angioplasty in Superficial Femoral Artery Lesions Up to 10 cm in Length: The Femoral Artery Stenting Trial) (12) and ABSOLUTE randomized trial (Balloon Angioplasty Versus Implantation of Nitinol Stents in the Superficial Femoral Artery) (13), which compared durability of balloon angioplasty and stenting in patients with femoropopliteal disease and claudication. These trials suggest that lesions <100 mm may be treated with balloon angioplasty, whereas stenting is a more durable option for longer lesions.

Section 6 Assumptions: Secondary Treatment Options for Lower Extremity Disease

45. The SFA extends from its ostium after bifurcation of the common femoral artery to the adductor canal.
46. Restenosis is defined as luminal narrowing ≥50% identified on angiography or artery ultrasound. The ultrasonographic criterion for restenosis is defined as a 2.5-fold increase in the peak systolic velocity in the narrowed segment compared with the adjacent proximal segment. In clinical practice, the recurrence of symptoms, a 20% decline in ankle-brachial index, and a >3-fold increase in peak systolic velocity ratio are combined to guide the decision regarding reintervention.
47. Treatment of asymptomatic restenosis may be considered given that restoring patency of an occluded, previously treated segment is more difficult than restoring that of a restenosed segment. No randomized studies have been conducted to determine whether this approach is clinically effective, which reintervention strategy is optimal, and what threshold should be used for consideration of reintervention.
48. For the purposes of this document, focal restenosis is defined as a lesion length ≤50 mm, whereas diffuse restenosis is defined as >50 mm (14). No consistent definition is currently found in the literature.
49. The mechanism of graft failure from implantation until 30 days is assumed to be technical in nature. This includes, but is not limited to, intrinsic vein disease, tunneling errors, hypercoagulable states, inadequate runoff, and errors in creating the anastomosis.
50. Graft failure beyond the 30-day postoperative period is most often caused by neointimal hyperplasia and/or progression of native artery disease.

4. DEFINITIONS

Angioplasty: Endovascular repair or recanalization of a blood vessel, especially by balloon dilation.

Atherectomy: Removal of atheromatous plaque from within a blood vessel by utilizing a catheter usually fitted with a cutting blade, laser, or grinding burr.

Aortoiliac: Relating to or joining the abdominal aorta and the iliac arteries.

***Claudication*:** Cramping, discomfort, and/or weakness in the legs and especially the calves when walking that resolves after short rest and is associated with inadequate blood supply to the muscles.

Common femoral artery: Continuation of the external iliac artery from the origin of the inferior epigastric artery to the bifurcation of the superficial femoral and profunda femoris arteries.

Common iliac artery: Artery that arises from the aortic bifurcation and ends when it divides into the external and internal iliac arteries.

Critical limb ischemia (CLI): Arterial insufficiency with gangrene, a nonhealing ischemic ulcer, or rest pain.

Endovascular treatment: A minimally invasive percutaneous procedure in which treatment for artery disease is delivered via catheter-based devices. Treatments include but are not limited to balloon angioplasty and stenting.

External iliac artery: Terminal branch of the common iliac artery extending from the origin of the internal iliac artery to the inferior epigastric artery.

Fontaine Classification of Limb Ischemia: Clinical staging system for describing PAD. It includes 5 stages: Stage I: Asymptomatic; Stage IIa: Mild claudication (able to walk more than 200 meters); Stage IIb: Moderate-severe claudication (walking limited to less than 200 meters); Stage III: Ischemic rest pain; Stage IV: Ulceration or gangrene.

Hemodynamically significant RAS:

a. Any narrowing ≥70% diameter stenosis by visual estimation; or
b. A stenosis in the range of 50% to 69% by visual estimation is considered significant if there is a resting or hyperemic systolic translesional gradient ≥20 mm Hg or a mean gradient ≥10 mm Hg (measured with a ≤5-Fr catheter or pressure wire), hyperemic gradients of the same magnitude, or a fractional flow reserve of <0.8.

Hyperemia for measurement of renal fractional flow reserve is induced with a 32-mg intrarenal bolus of papaverine or 50 μg/kg intrarenal bolus of dopamine. Pressure gradient measured with a nonobstructive catheter (≤5-Fr) or a 0.014-in pressure wire (8-10).

Hypertension: Abnormally high artery blood pressure that is usually indicated by a systolic blood pressure ≥140 mm Hg and/or a diastolic blood pressure ≥90 mm Hg (15). As noted previously, the 2017 Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults was published after this AUC was developed; therefore, clinicians will need to consider the role of new guideline goals in the treatment of individual patients. The cause of hypertension in most cases is unknown or is multifactorial (primary or essential hypertension). It may be attributable to a pre-existing condition (such as a renal or endocrine disorder) that typically results in a thickening and inelasticity of arterial walls and hypertrophy of the left heart ventricle, and that is a risk factor for various pathological conditions or events (such as heart attack, heart failure, stroke, chronic kidney disease, or retinal hemorrhage).

In-stent restenosis: A process of neointimal hyperplasia that occurs in up to 20% of stents within a year of implantation. Restenosis is defined as a 50% luminal narrowing identified on angiography or artery ultrasound. The ultrasonographic criterion is defined as a 2.5-fold increase in the peak systolic velocity in the narrowed segment compared with the adjacent proximal segment (16,17). In clinical practice, the recurrence of symptoms, a 20% decline in ankle-brachial index, and a >3-fold increase in peak systolic velocity ratio are combined to guide the decision regarding reintervention (17). The primary impetus behind surveillance of in-stent restenosis is that an occluded stent is more difficult to restore. However, no randomized studies have been conducted to determine whether this approach is clinically effective, which reintervention strategy is optimal, and what threshold should be used for consideration of reintervention.

Interposition graft: A piece of newly harvested vein that is sewn into the vein graft following the removal of a stenotic segment of the vein graft.

Maximal medical therapy: Guideline-directed pharmacological and lifestyle modification that includes exercise (preferably supervised) therapy given with sufficient time for titration and stabilization to occur to determine the impact of medication changes.

Pharmacomechanical thrombectomy: Thrombus dissolution and removal using percutaneous techniques involving catheter-directed thrombolytic agents combined with mechanical devices.

Popliteal artery: Arterial segment extending from the adductor canal to its bifurcation into the anterior tibial artery and tibioperoneal trunk.

Rutherford Classification of Chronic Limb Ischemia: Clinical staging system for describing PAD. It includes 7 categories: 0—Asymptomatic; 1—Mild claudication; 2—Moderate claudication (The distances that delineate mild, moderate, and severe claudication are not specified in the Rutherford classification but are mentioned in the Fontaine classification as 200 meters.); 3—Severe claudication; 4—Rest pain; 5—Ischemic ulceration not exceeding ulcer of the digits of the foot; and 6—Severe ischemic ulcers or frank gangrene. The Fontaine and Rutherford taxonomies are the 2 most commonly used systems for classifying chronic limb ischemia (**Table 1**).

Stent: A small, narrow metal or plastic tube often in the form of a mesh that is inserted into the lumen of an artery, especially to keep a previously blocked passageway open. Stents used in the peripheral vascular system include but are not limited to nitinol self-expanding stents, drug-eluting stents, and covered self-expanding stents.

Superficial femoral artery: Terminal branch of the common femoral artery extending from the origin of the profunda femoris branch to the adductor canal in the distal thigh.

Surgical treatment: Artery revascularization procedure that requires skin incision and manipulation of the target artery under direct visualization. Such surgery

TABLE 1 Classification Comparison for Chronic Limb Ischemia

FONTAINE		RUTHERFORD		
Stage	**Clinical**	**Grade**	**Category**	**Clinical**
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate-severe claudication	I	2	Moderate claudication
		I	3	Severe claudication
III	Ischemic rest pain	II	4	Ischemic rest pain
IV	Ulceration or gangrene	III	5	Minor tissue loss
		IV	6	Ulceration or gangrene

Adapted from Norgren et al. (11) and Hardman et al. (18).

may involve endarterectomy of the artery, or bypass of the artery with a prosthetic or autologous vein conduit.

Vein patch angioplasty: A vein that is opened in the longitudinal direction and used as a patch sewn over a stenotic lesion in the vein graft to increase the vein graft's lumen area.

Viable kidney: According to the ACC/AHA 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) (7), a viable kidney is defined as having a pole-to-pole linear length >7 cm.

5. ABBREVIATIONS

AUC = Appropriate Use Criteria

CLI = critical limb ischemia

PAD = peripheral artery disease

PAI = peripheral artery intervention

RAS = renal artery stenosis

SFA = superficial femoral artery

6. PERIPHERAL ARTERY INTERVENTION APPROPRIATE USE CRITERIA (BY INDICATION)

The final ratings for PAI are listed by indication in Tables 1.1 to 6.3. The final score for each indication reflects the median score of the 13 rating panel members and has been categorized as Appropriate/A (median score 7 to 9), May Be Appropriate/M (median score 4 to 6), and Rarely Appropriate/R (median score 1 to 3). In the tables, the final numerical score for each indication is shown in parentheses next to the AUC rating of A, M, or R.

Section 1 Renal Artery Stenosis

TABLE 1.1 Chronic Kidney Disease

Indications	AUC Score: Continue or Intensify Medical Therapy	AUC Score: Renal Stent Placement (Primary Stenting)—Atherosclerotic Lesions
Hemodynamically Significant RAS (With a Severe [70%–99%] RAS or 50%–69% RAS With Hemodynamic Significance)		
1. ■ Unilateral smaller kidney (<7cm pole to pole)	**A (9)**	**R (2)**
2. ■ Accelerating decline in renal function ■ Unilateral RAS	**A (9)**	**M (4)**
3. ■ Accelerating decline in renal function ■ Bilateral RAS or a solitary viable* kidney with RAS		**A (7)**

*Viable is pole to pole kidney length ≥7 cm.

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; RAS = Renal Artery Stenosis.

TABLE 1.2 Hypertension

Indications	AUC Score: Continue or Intensify Medical Therapy	AUC Score: Renal Stent Placement (Primary Stenting) — Atherosclerotic Lesions
Hemodynamically Significant RAS (With a Severe [70%–99%] RAS or 50%–69% RAS With Hemodynamic Significance)		
4. ■ New onset ■ No medical management	**A (9)**	**R (1)**
5. ■ Well-controlled blood pressure on ≥2 anti-hypertensive medications	**A (9)**	**R (1)**
6. ■ Uncontrolled on <3 antihypertensive medications	**A (9)**	**R (3)**
7. ■ Failure to control blood pressure on 3 maximally tolerated medications, 1 of which is a diuretic		**M (6)**

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; RAS = renal artery stenosis.

TABLE 1.3 Cardiac Destabilization

Indications	AUC Score: Continue or Intensify Medical Therapy	AUC Score: Renal Stent Placement (Primary Stenting) — Atherosclerotic Lesions
Hemodynamically Significant RAS (With a Severe [70%–99%] RAS or 50%–69% RAS With Hemodynamic Significance)		
8. ■ Recurrent heart failure ■ Uncontrolled on maximal medical therapy		M (6)
9. ■ Sudden-onset flash pulmonary edema		A (7)
10. ■ Uncontrolled unstable angina despite maximal medical therapy		M (6)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; RAS = renal artery stenosis.

TABLE 1.4 Incidentally Discovered RAS

Indications	AUC Score: Continue or Intensify Medical Therapy	AUC Score: Renal Stent Placement (Primary Stenting) - Atherosclerotic Lesions
Hemodynamically Significant RAS (With a Severe [70%–99%] RAS or 50%–69% RAS With Hemodynamic Significance)		
11. ■ Unilateral RAS	A (9)	R (2)
12. ■ Bilateral RAS or a solitary viable* kidney with RAS	A (9)	R (2)

*Viable is pole-to-pole kidney length ≥7 cm.

A = Appropriate; AUC = Appropriate Use Criteria; R = Rarely Appropriate; RAS = renal artery stenosis.

TABLE 1.5 Borderline (50%–69%) RAS Without Hemodynamic Confirmation of Severity

Indications	AUC Score: Continue or Intensify Medical Therapy	AUC Score: Renal Stent Placement (Primary Stenting) - Atherosclerotic Lesions
13. ■ Unilateral RAS, bilateral RAS, or a solitary viable* kidney with RAS	A (9)	R (2)

*Viable is pole to pole kidney length of ≥ 7 cm.

A = Appropriate; AUC = Appropriate Use Criteria; R = Rarely Appropriate; RAS = renal artery stenosis.

Section 1 Results and Discussion

The appropriate use recommendations for RAS intervention are based on expert consensus and evidence, including the randomized CORAL trial (Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis) (6), which recommends best medical therapy as the initial treatment for a newly diagnosed patient. The recommendations for renal intervention outlined in the ACC/AHA 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) (7) and its update, the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease (4), define both clinical and anatomic lesion criteria and additionally define optimal medical therapy as 3 antihypertensive medications, 1 of which should be a diuretic. In patients intolerant of the 3-antihypertensive medication regimen who have hemodynamically significant RAS, renal artery stenting may be considered. Primary stenting has become accepted practice, and intravascular ultrasound is a valuable tool for optimally sizing renal stents, given that undersizing may be safe but leads to a higher restenosis rate, whereas oversizing risks vessel rupture and dissection. Given that invasive angiography is unable to distinguish hemodynamic significance among moderate renal artery stenoses (50% to 69% diameter stenoses), it is necessary to confirm the severity of moderate RAS lesions by measuring translesional pressure gradients with nonobstructive catheters.

In patients with an accelerating decline in renal function and bilateral or solitary significant RAS (e.g., severe RAS [≥70% diameter stenosis]) or moderate RAS (50% to 69% diameter stenosis)] with translesional gradients that exceed threshold measurements, the rating panel finds renal stenting to be Appropriate. In patients with stable renal function and unilateral significant RAS, optimizing and intensifying medical therapy is deemed Appropriate, whereas renal stenting is deemed May Be Appropriate in some patients. In patients with small (<7 cm pole to pole) nonviable kidneys, revascularization is found to be Rarely Appropriate.

For patients with hypertension and significant RAS, the threshold for renal artery stenting is failure of ≥3 maximally tolerated antihypertensive medications, 1 of which is a diuretic, to control hypertension. The rating panel feels that newly diagnosed RAS patients should initially be treated with optimal medical therapy, not renal stenting. They also determined that patients with well-controlled hypertension and RAS, and patients with poorly controlled hypertension on <3 antihypertensive medications, are rarely candidates for renal stenting. The rating panel deems selected patients with cardiac destabilization syndromes manifested as recurrent heart failure or uncontrolled unstable angina despite maximal

medical therapy and severe RAS as May Be Appropriate for renal stenting, whereas those with sudden onset or "flash" pulmonary edema and severe RAS are Appropriate for renal stenting. Patients with incidentally discovered RAS should initially be treated with optimal medical therapy, as renal stenting in this group is considered Rarely Appropriate. Finally, patients with moderate RAS (50% to 69% diameter stenosis) with translesional gradients that fail to achieve the threshold are considered Rarely Appropriate for renal stenting (19).

Section 2 Lower Extremity Disease

TABLE 2.1 Intermittent Claudication; No Prior Guideline-Directed Medical Therapy

Indications	AUC Score: Initiate Medical Therapy	Endovascular Treatment	Surgical Treatment
14. ■ Any lower extremity disease	A (9)	R (2)	R (1)

A = Appropriate; AUC = Appropriate Use Criteria; R = Rarely Appropriate.

TABLE 2.2 Intermittent Claudication Despite Guideline-Directed Medical Therapy—Stenotic Lesions

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
15. ■ Aortoiliac	A (9)	A (8)	M (4)
16. ■ SFA and popliteal artery	A (9)	A (7)	M (6)
17. ■ Below the knee	A (9)	M (5)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; SFA = superficial femoral artery.

TABLE 2.3 Intermittent Claudication Despite Guideline-Directed Medical Therapy—Chronic Total Occlusion

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
18. ■ Aortoiliac	A (9)	A (7)	M (6)
19. ■ SFA and popliteal artery	A (9)	M (6)	M (6)
20. ■ Below the knee	A (9)	M (4)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; SFA = superficial femoral artery.

Section 2 Results and Discussion

The AUC recommendations for lower extremity revascularization in patients with claudication are based on expert consensus statements most recently summarized in the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease (4). The tables in this section define the appropriate use of revascularization therapies for patients with stable symptoms without acute limb ischemia or CLI. Revascularization therapies constitute 1 of several components of PAD management and complement the comprehensive medical therapy defined in the societal guidelines. Patients experiencing intermittent claudication should be considered for revascularization only after other, nonvascular causes of limb symptoms have been excluded. The symptoms should be lifestyle limiting despite appropriate pharmacological and exercise therapies. Angiographic presence of an intermediate-severity stenosis may not indicate a hemodynamically significant, symptom-inducing lesion. Therefore, physiological assessments demonstrating a significant flow limitation with segmental Doppler pressures, exercise ankle-brachial index testing, and/or measurement of translesional gradients are essential in selecting patients who will benefit from revascularization.

Patients with PAD and intermittent claudication should first be treated with guideline-directed medical therapy and structured exercise (19). This strategy is often successful and has been evaluated in randomized controlled trials (20,21). Revascularization of arteries should be considered only in patients who continue to have lifestyle-limiting claudication despite these noninvasive approaches. Intermittent claudication is most commonly caused by hemodynamically significant lesions in the aortoiliac and femoropopliteal artery segments. Infrapopliteal (below the knee) disease is a less common cause of claudication, so revascularizations in this segment are reserved for special circumstances. The selection of surgical or endovascular revascularization depends on the risk-benefit ratio unique to each patient and the perceived likelihood of a durable clinical benefit. Lesion characteristics, such as the anatomical location of the lesion, presence of stenosis or occlusion, and length of the lesion, will influence that choice. For example, endovascular therapy of a long-segment occlusion of the SFA is likely to result in a less durable clinical result than treatment of a short-segment stenosis in the same vessel (22,23). Iliac artery stenting, on the other hand, provides similar durability to surgical revascularization but has much lower periprocedural risk (24). The TASC II document reflects the improvement in endovascular techniques and serves as a basis for guiding the AUC recommendations (11).

Section 3 Critical Limb Ischemia

TABLE 3.1 Critical Limb Ischemia

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
21. ■ Aortoiliac		A (8.5)	A (8)
22. ■ SFA and popliteal artery		A (8)	A (8)
23. ■ Below the knee		A (8)	A (8)

A = Appropriate; AUC = Appropriate Use Criteria; SFA = superficial femoral artery.

Section 3 Results and Discussion

This table was designed to determine the appropriateness of revascularization modalities for the presentation of CLI. For these patients, the decision to continue or intensify medical therapy without any other revascularization is grayed out because it is not considered a reasonable treatment. The intervention options in this table have been divided into either endovascular or surgical treatment.

Revascularization, whether endovascular or surgical, is critical for the reduction of high morbidity and mortality rates associated with limb loss. Mortality rates have been reported to be as high as 20% within 6 months of diagnosis, and exceeding 50% after 5 years in patients left untreated (25). Furthermore, this degree of PAD is commonly associated with excessive cardiovascular events, often surpassing mortality rates associated with even symptomatic coronary artery disease. In all anatomic subsets, both endovascular treatment and surgical treatment were considered Appropriate by the rating panel and received a median score of 8. For endovascular treatment in the aortoiliac segment, the score of 8.5 was determined after calculating the median score from 12 panelists rather than the original 13 (1 panelist passed away during the rerating process).

Section 4 Asymptomatic Artery Disease

TABLE 4.1 Access in Support of Other Life-Saving Interventions

Indications	AUC Score: Endovascular Treatment	Surgical Access
24. ■ Access for coronary intervention	A (7)	A (8)
25. ■ Access for hemodynamic support	A (7)	M (4)
26. ■ Access for large vascular or valvular intervention	A (7)	M (5)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate.

Section 4 Results and Discussion

The appropriate use recommendations for asymptomatic artery disease are specific for clinical situations in which peripheral artery procedures may be needed to facilitate arterial access before other necessary cardiovascular procedures, some of which may be life-saving. As there is no published research in this area, the scores represent a consensus of experts. This section assumes that some patients who require large-diameter catheter access for therapy may have asymptomatic obstructive disease and are not included in other treatment tables. The writing group assumed that alternate vascular access had been considered and that peripheral artery access had been deemed the best option. It is emphasized that these revascularizations are not undertaken for the management of PAD, per se, but to facilitate care that is deemed necessary and is dependent upon suitable vascular access.

For example, femoral artery access is an important conduit for transcatheter aortic valve replacement and has had better outcomes than transapical access in a propensity-matched comparison study (26). Other examples include the placement of hemodynamic support devices such as an intra-aortic balloon pump or the presence of dialysis shunts in the upper extremities.

Section 5 Options for Endovascular Treatment When Deemed Appropriate or May Be Appropriate

TABLE 5.1 Isolated Common Iliac Artery

Indications	AUC Score: Atherectomy	Balloon Angioplasty	Stent
27. ■ Discrete stenosis	R (2)	A (7)	A (8)
28. ■ Diffuse disease or multiple stenoses of the CIA	R (2)	M (6)	A (8)

A = Appropriate; AUC = Appropriate Use Criteria; CIA = common iliac artery; M = May Be Appropriate; R = Rarely Appropriate.

TABLE 5.2 Isolated External Iliac Artery

Indications	AUC Score: Atherectomy	Balloon Angioplasty	Stent
29. ■ Discrete stenosis	R (2)	A (7)	A (8)

A = Appropriate; AUC = Appropriate Use Criteria; R = Rarely Appropriate.

TABLE 5.3 Diffuse Common Iliac Artery and External Iliac Artery

Indications	AUC Score: Atherectomy	Balloon Angioplasty	Stent
30. ■ Unilateral EIA stenosis with multiple CIA stenoses	R (2)	M (5)	A (8)
31. ■ Chronic total occlusion	R (2)	M (4)	A (8)

A = Appropriate; AUC = Appropriate Use Criteria; CIA = common iliac artery; EIA = external iliac artery; M = May Be Appropriate; R = Rarely Appropriate.

TABLE 5.4 SFA and Popliteal Artery

Indications	AUC Score: Atherectomy	Balloon Angioplasty	Drug-Coated Balloon	Bare Metal Stent	Drug-Eluting Stent	Covered Stent
32. ■ Length <100 mm	M (6)	A (7)	A (7)	A (7)	A (7)	M (6)
33. ■ Length ≥100 mm	M (5)	M (5)	A (7)	A (7)	A (7)	M (6)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; SFA = superficial femoral artery.

TABLE 5.5 Below the Knee

Indications	AUC Score: Atherectomy	Balloon Angioplasty	Drug-Coated Balloon	Bare Metal Stent	Drug-Eluting Stent	Covered Stent
34. ■ Length <100 mm	M (4)	A (7)	M (4)	M (5)	A (7)	R (3)
35. ■ Length ≥100 mm	M (4)	A (7)	M (4)	M (5)	M (6)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate.

Section 5 Results and Discussion

The clinical scenarios in Section 5 specifically address 3 broad treatment options for the disease states listed. Given the variability in the lesion lengths that span multiple vascular territories, the authors organized treatments above and below the inguinal ligament and below the knee. The literature review demonstrated several definitions of discrete and diffuse stenosis, with no consensus for a standardized measurement. After extensive discussions among members of the writing group, a length of 100 mm was used as the cutoff point between discrete and diffuse lesions. The table categorizes the most commonly used endovascular treatment modalities, encompassing a wide range of scenarios that operators may face when revascularizing peripheral artery lesions.

Endovascular therapies are common and increasingly used for patients with symptomatic PAD. There has been significant development in the technology available for intervention in these vascular beds. Moreover, recent data suggest that the choice of technology may vary depending on preference as much as on scientific data and clinical experience (27,28). Of note, the use of atherectomy in the iliac artery has been rated Rarely Appropriate in all clinical scenarios. This rating derives from an absence of data supporting the use of this technology compared with balloon angioplasty and stenting (29). Similarly, the use of atherectomy in the superficial femoral and popliteal arteries and below-the-knee vessels also received a lower score, again because of the lack of comparative data relative to technologies with prospectively collected data. The evidence base to judge intervention below the knees is not as developed as other lower-extremity locations, which results in more frequent use of the May Be Appropriate category. The rating panel felt that below-the-knee atherectomy once again lacked comparative evidence to support general use. Exceptions favoring atherectomy include severe calcification and undilatable lesions; however, other technologies had a better evidence base for routine revascularization in most settings (30). Given the expense and paucity of data regarding atherectomy, further comparative investigation is recommended into the risks and benefits of atherectomy in femoral popliteal lesions.

Section 6 Secondary Treatment Options for Lower-Extremity Disease

TABLE 6.1 In-Stent Restenosis

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
Recurrent Symptoms			
36. ■ Focal stenosis	A (9)	A (7)	M (5)
37. ■ Diffuse stenosis	A (9)	A (7)	M (6)
Asymptomatic			
38. ■ Focal stenosis	A (9)	M (5)	R (2)
39. ■ Diffuse stenosis	A (9)	M (4)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate.

TABLE 6.2 Venous Bypass Graft Failure

Indications	AUC Score: Endovascular Treatment Balloon Angioplasty, Stenting, and/or Catheter-Directed Thrombolysis	Surgical Treatment Vein Patch Angioplasty or Interposition Graft
Stenotic Lesions Developing After 30 days		
40. ■ Focal stenosis	A (7)	M (5)
41. ■ Diffuse stenosis	M (6)	M (6)
42. ■ Thrombosed graft	M (6)	M (6)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate.

TABLE 6.3 Prosthetic Bypass Graft Failure

Indications	AUC Score: Endovascular Treatment Balloon Angioplasty, Stenting, and/or Catheter-Directed Thrombolysis	AUC Score: Surgical Treatment Vein Patch Angioplasty or Interposition Graft
Stenotic Lesions Developing After 30 Days		
43. ■ Focal stenosis	A (7)	M (5)
44. ■ Diffuse stenosis	M (6)	M (6)
45. ■ Thrombosed graft	M (5)	M (6)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate.

Section 6 Results and Discussion

The indications in Section 6 specifically address previously treated segments that have restenosed or occluded. The clinical scenarios relate to lesions previously treated with stents, surgically bypassed using a venous conduit, or revascularized using a prosthetic conduit. The table broadly specifies the therapy by category but does not specify the device or surgical approach, as these may vary widely among physicians and facilities. It is recognized that the need for revascularization of a failing conduit, graft, or stent is a marker of adverse outcomes for all of the reparative modalities employed (31). Literature comparing treatment modalities for in-stent stenosis, venous graft failures, and arterial graft failures is very limited. Therefore, the recommendations primarily reflect consensus based upon current clinical practice.

The role of endovascular therapies and surgical revascularization for stenosis or occlusion after prior peripheral vascular procedures remains an important clinical question. The choice of therapy may vary depending on preference and clinical experience. One benefit of a broadly representative review and rating panel is the inclusion of a range of opinions, which was well-captured in the ratings of this section. The rating panel felt the use of surgical revascularization was Rarely Appropriate in the setting of in-stent stenosis, particularly in the asymptomatic patient. The rating panel also felt it was Appropriate to address focal stenoses with endovascular therapy in patients with prior surgical grafts and bioprosthetic material, whereas in patients with diffuse stenosis or thrombosed grafts, endovascular and surgical treatment were rated as May Be Appropriate. The specific type of therapy (device or surgical procedure) is at the discretion of the clinician dictated by the clinical scenario plus physician and facility experience. The generally lower ratings in this section represent the evidence base upon which determinations could be made.

7. SUMMARY

This is the first effort by the ACC and collaborating organizations to address appropriate use in the field of PAI. This was more challenging than the development of AUCs on other topics mainly because supporting literature is not as developed or robust as for other topics covered. The clinical scenarios were developed by experts in the field representing multiple subspecialty societies and ACC Councils, evaluated by numerous external reviewers and stakeholders, and scored by an independent group of experts to arrive at the final AUC ratings. This multisocietal AUC effort contributes important guidance to the field of peripheral vascular disease, which is constantly changing due to the development of new devices, technologies, and intervention methods.

Although the development of these AUC incorporated evidence where available, it is important to note the differences between clinical practice guidelines and AUC. The ACC/AHA guidelines are developed using evidence-based documents and expert opinion and are generally quite broad. Even though AUC are evidence-based, they are structured around typical patient scenarios encountered in everyday practice. Although the AUC ratings in this report provide guidance for specific treatment options in patient populations, the scores are not a replacement for clinical judgement and practice experience in determining the best options for individual patients. Each patient is unique, and the possible use of different treatment options deserves to be considered in full clinical context.

7.1. Trends and Themes in Scoring

In general, the indications rated as Appropriate include procedures in which the benefits generally outweigh the risks, the procedure is an effective option for individual care, and the procedure is generally acceptable and reasonable for the indication. The clinical scenarios scored as May Be Appropriate often involve uncertainty or require additional clinical evidence to better define the appropriateness of the treatment. There may be utility for certain treatment strategies in selected cases based upon clinical experience in the absence of comparative evidence. The appropriateness of a specific procedure in any individual must be determined by that patient's physician in consultation with the patient considering the risk to benefit ratio. The indications rated as Rarely Appropriate cluster around options for the management of a patient with either an adverse or an uncertain risk to benefit ratio that are not generally considered to be effective therapy. The procedure may be recognized to be effective in isolated situations but is not generally used for these

indications. Procedures in this category require documentation of the rationale for choosing this treatment including the individual patient circumstances.

The scenarios in this document are arranged according to the clinical decision points confronting vascular practitioners in everyday clinical practice. These include the presence or absence of symptoms, presence or absence of limb-threatening disease, severity and anatomical location of the culprit lesion, recurrent or *de novo* disease, the advantage of endovascular or surgical revascularization, and the expected durability of clinical benefit after an intervention. The general principles used to identify and define these clinical scenarios follow the 2015 ACC/AHA PAD Guideline, the TASC II document, and data from randomized controlled trials. The section on General Assumptions further details these principles. It is important to note that the spectrum of vascular interventions continues to evolve rapidly, driven by technological advances. The final scores, therefore, reflect the body of evidence and interventional treatment strategies available at the time of rating.

Several common themes were identified among the ratings of these clinical scenarios. Guideline-directed medical therapy plus lifestyle and risk factor modification are cornerstones of therapy in patients with peripheral artery disease irrespective of whether revascularization is contemplated. There was consensus that patients with incidentally discovered and clinically silent renovascular or peripheral artery disease rarely require revascularization. The therapeutic approach to these patients should focus on prevention of disease progression and reduction of cardiovascular morbidity and mortality. There was clear agreement that revascularization in patients who experience intermittent claudication should only be considered if the symptoms are lifestyle limiting and do not improve with medical and exercise therapy. The current best practice is to demonstrate the hemodynamic significance of intermediate-severity renal artery stenosis before revascularization.

Renal artery revascularization to facilitate blood pressure control is considered Rarely Appropriate in patients in whom pharmacological options have not been exhausted or lesions of intermediate severity if the hemodynamic significance of the lesion has not been confirmed. Similarly, improving perfusion of an atrophic (<7 cm) kidney is unlikely to improve renal function. In contrast, renal artery stenting is Appropriate when global renal hypoperfusion from a severely stenotic renal artery results in a decline of renal function or the development of "flash" pulmonary edema. Interventions May Be Appropriate and are guideline supported in patients with a severely stenotic renal artery and hypertension that is refractory to maximal medical therapy (defined as maximal tolerated doses of 3 medications, 1 of which is a diuretic). Such interventions have been supported by societal guideline documents, but recent randomized controlled studies have not adequately addressed this patient population. Recurrent heart failure and uncontrolled angina associated with severe RAS are complex situations; therefore, renal artery revascularization was rated as May Be Appropriate.

Sections 2 and 3 describe clinical scenarios encountered in patients with lower-extremity PAD. With the exception of claudication that imposes lifestyle- or vocation-limiting symptoms, revascularization for intermittent claudication, predominantly caused by aortoiliac and femoropopliteal disease, is only Appropriate after a trial of guideline-directed medical therapy and exercise. The ratings reflect the improved durability and reduced morbidity of endovascular therapy, particularly in patients with native artery stenoses. Surgical revascularization remains a reasonable option for patients in whom anatomical or clinical features make endovascular therapy less effective. For patients with CLI, the importance of early revascularization is critical to limb salvage. The choice of a surgical or endovascular strategy depends on anatomical severity and location of the disease and the patient's clinical characteristics. Although asymptomatic PAD rarely warrants revascularization, the advent of percutaneous cardiac support devices and valve replacement therapies described in Section 4 may require arterial interventions to facilitate vascular access.

Section 5 rates the currently available endovascular devices in specific anatomical locations and disease burden defined by lesion length. These ratings tend to reflect the favorable data regarding the durable patency of drug-coated balloons and drug-eluting stents in the femoral arteries over conventional angioplasty, particularly in longer lesions. Drug-coated balloons have not been rigorously evaluated in the iliac arteries and have not been included as a treatment option in this anatomic region. Atherectomy is not well-suited for iliac arteries and is Rarely Appropriate in these vessels. Covered stents are Rarely Appropriate in the infrapopliteal vessels because of the small vessel size and risk of thrombosis.

Section 6 addresses an area of controversy driven by a paucity of well-designed studies comparing various forms of revascularization and medical therapy. The optimal therapy for symptomatic femoral artery in-stent restenosis is unclear, although an endovascular treatment is usually preferred as the first strategy. In general, revascularization is Rarely Appropriate in patients without symptoms. Surgical graft failure, involving a vein or prosthetic graft, is commonly addressed with endovascular intervention if the culprit lesion is a focal stenosis. The ratings reflect this common clinical practice. The decision whether to intervene at all and the choice

of endovascular or surgical intervention in more complex graft lesions depend on clinical symptoms, anatomical features, and patient characteristics.

The final trend noted in these AUC scenarios and their ratings reflects the anatomical complexity of artery disease and the presence of coexisting medical comorbidities influencing treatment decisions. Thus, a similar anatomical lesion and set of symptoms with varying coexisting medical comorbidities may warrant a different rating for medical, endovascular, or surgical treatment.

7.2. Use of AUC to Improve Care

The writing group foresees several important applications of these AUC for both clinicians and patients. The most obvious use of this document will be to support the clinical decision making of a physician as to the appropriateness of care that they deliver to an individual patient. It is important to acknowledge that an Appropriate rating in this document should not be misconstrued as a mandate to perform a specific intervention in every patient that meets the indications described herein. Rather, it should be interpreted as something that would be reasonable to do if the intervention performed could benefit the patient.

It is also important to note that a Rarely Appropriate rating should not be misinterpreted as denoting an indication in which an intervention should never be performed. This category was entitled "Inappropriate" in prior AUC documents, but due to substantial misunderstandings, the AUC Task Force changed the terminology to Rarely Appropriate in 2013. This change emphasized the role of clinical judgment and the existence of individual patient circumstances that could make it reasonable to perform an intervention. Instead of functioning as the arbitrator for individual cases, the purpose of the AUC lies more in identifying practice patterns that deviate from the expected distribution. Indications rated as May Be Appropriate should be considered reasonable for an intervention, particularly if the physician determines that it could help the patient. These 2 categories should not be considered as the basis for denying insurance coverage or reimbursement for the procedure, as individual decision making is required to determine what is best for each patient. Nevertheless, it is important for the clinicians performing these procedures to recognize that healthcare facilities, accreditation bodies, and payers may use this document to ensure quality patient care and proper management of financial resources.

Ideally, this document will serve as an educational and quality improvement tool for addressing Rarely Appropriate revascularizations either performed or referred by individual clinicians. Experience with prior AUC topics has shown that physician engagement in quality improvement programs, plus tracking and benchmarking of ordering behavior, has reduced the percentage of Rarely Appropriate interventions. Finally, the AUC provide physician-driven and peer-reviewed recommendations that may reduce administrative controls or government regulation if proven to be effective in reducing Rarely Appropriate revascularizations.

8. CONCLUSION

This AUC report provides a guide for clinicians in determining the role of different revascularization options in the care of patients with PAD. Future studies to evaluate implementation of these AUC in clinical settings will be useful not only in identifying any deficiencies in the current document, but also in defining patterns of care for individual practitioners and understanding variations in the delivery of care. The study of PAD is continuously changing as new devices, techniques, and approaches are developed, and a regular review of these clinical scenarios will be imperative in moving the field forward.

ACC PRESIDENT AND STAFF

C. Michael Valentine, MD, FACC, President
Timothy W. Attebery, DSc, MBA, FACHE, Chief Executive Officer
William J. Oetgen, MD, FACC, Executive Vice President, Science, Education, Quality, and Publishing
Joseph M. Allen, MA, Senior Director, Clinical Policy and Pathways
Lara M. Gold, MA, Senior Research Specialist, Appropriate Use Criteria
Amelia Scholtz, PhD, Publications Manager, Clinical Policy and Pathways

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KEY WORDS ACC Appropriate Use Criteria, peripheral artery disease, peripheral artery intervention

APPENDIX A. RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES

Appropriate Use Criteria for Peripheral Artery Intervention: Members of the Writing Group, Rating Panel, External Reviewers, and AUC Task Force—Relationships With Industry and Other Entities (Relevant)

The ACC and the AUC Task Force continue to focus considerable attention on avoiding real or perceived relationships with industry (RWI) and other entities that might affect the rating of a test/procedure. The ACC maintains a database that tracks all relevant relationships for all ACC members and persons who participate in ACC activities, including the development of AUC. A table of relevant disclosures by the writing group, rating panel, external reviewers, and AUC Task Force can be found below. In addition, to ensure complete transparency, a full list of disclosure information—including relationships not pertinent to this document—is available as an Online Appendix.

A more specific RWI policy applies to the Writing Group and Rating Panel of AUC documents:

- Writing Group: AUC Writing Groups must be chaired by a person with no relevant RWI. Although Writing Group members play an important role in the development of the final published document for a given set of AUC, they do not have any role in the AUC rating process and therefore have limited impact on how the documents will guide clinical care. Accordingly, RWI restrictions are not applied to Writing Group members, other than the Chair.
- Rating Panel: To avoid the potential for bias in the actual indication rating, fewer than 50% of Rating Panel members may have relevant RWI. AUC documents utilize a modified Delphi consensus method as outlined in the RAND Appropriateness Criteria Method paper and the ACC AUC Methodology paper. This method utilizes a 2-step process: Delphi Method Step 1) writing committee members develop a list of typical clinical scenarios/indications; Delphi Method Step 2) technical panel members review and rate the individual clinical scenarios. The RAND Delphi method allows for the contribution of a wide range of viewpoints while minimizing and controlling bias through an independent rating panel, a review of score dispersion, use of the median rating to determine final recommendations, and a highly structured process for determining recommendations. As such, all rating panel members, even those with RWI, are allowed to rate as part of the technical panel modified Delphi process.

APPENDIX A. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
				Writing Group				
Steven R. Bailey, MD, *Chair*	University of Texas Health Science Center at San Antonio—Program Director, Interventional Cardiology; Professor of Medicine and Radiology	ACC	None	None	None	■ Boston Scientific (DSMB)	None	None
Joshua A. Beckman, MD	Vanderbilt University Medical Center, Cardiovascular Fellowship Program—Director	ACC	None	None	None	None	None	None
Timothy D. Dao, MD	Heart Place Plano—Staff Cardiologist	ACC	None	None	None	None	None	None
Sanjay Misra, MD	Mayo Clinic, Division of Vascular and Interventional Radiology—Professor of Radiology	SIR	None	None	None	■ Flextend (DSMB)	None	None
Piotr S. Sobieszczyk, MD	Brigham and Women's Hospital and Harvard Medical School, Vascular Medicine Section, Cardiac Catheterization Lab—Associate Director	SVM	None	None	None	None	None	None
Christopher J. White, MD	Ochsner Medical Center—Chief of Medical Services; The Ochsner Clinical School, University of Queensland—Professor and Chairman of Medicine	SCAI	None	None	None	None	■ Surmodics (Scientific Advisory Board)	None
				Rating Panel				
Herbert D. Aronow, MD	Lifespan Cardiovascular Institute, Interventional Cardiology—Director; Rhode Island and The Miriam Hospitals, Cardiac Catheterization Laboratories—Director; Warren Alpert Medical School of Brown University—Assistant Professor of Medicine	SVM	None	None	None	■ PORTRAIT (Co-PI)*	■ Abbott Vascular† ■ Bard† ■ Gardia Medical† ■ Gore†	■ Plaintiff, peripheral coronary and vascular intervention appropriateness, 2014‡
Reza Fazel, MD	Brigham and Women's Hospital, Division of Cardiology—Associate Physician	ACC	None	None	None	None	None	None

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APPENDIX A. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Heather L. Gornik, MD	Cleveland Clinic Foundation Cardiovascular Medicine, Vascular Medicine—Section Head; Cleveland Clinic Learner College of Medicine of Case Western Reserve University—Associate Professor of Medicine	ACC	None	None	■ Summit Doppler Systems*	■ AstraZeneca – Euclid Trial (PI)‡	None	None
Bruce H. Gray, D.O.	Greenville Health System, Endovascular Service—Director; University of South Carolina School of Medicine—Professor of Surgery/Vascular Medicine	SVM	None	None	None	■ Abbott*	■ Cordis† ■ Gore†	None
Jonathan L. Halperin, MD	Mount Sinai Medical Center—Professor of Medicine	ACC	None	None	None	None	None	None
Alan T. Hirsch, MD	University of Minnesota Medical School—Professor of Medicine, Epidemiology, and Community Health; Vascular Medicine Program—Director	ACC	None	None	None	None	None	
Michael R. Jaff, DO	Newton-Wellesley Hospital—President; Harvard Medical School—Professor of Medicine	SCAI	■ Vascular Therapies ■ Volcano/Philips	None	■ Embolitech‡ ■ Gemini ■ Northwind ■ PQ Bypass ■ Sano V ■ Valiant Medical ■ Venarum	None	■ Abbott Vascular (Advisor)* ■ Boston Scientific (Advisor)* ■ Cordis (Advisor)* ■ Medtronic Vascular (Advisor)*	None
Venkataramu Krishnamurthy, MBBS	VA Ann Arbor Health System—Chief of Radiology Services; University of Michigan Hospitals—Clinical Professor of Radiology and Vascular Surgery	SIR	None	None	None	None	None	None
Sahil A. Parikh, MD	Columbia University Irving Medical Center/ NY Presbyterian Hospital, Center for Interventional Vascular Therapy, Endovascular Services—Director; Columbia University Vagelos College of Physicians and Surgeons—Associate Professor of Medicine	ACC	■ Abbott Vascular‡ ■ Asahi ■ Boston Scientific‡ ■ Medtronic‡ ■ Spectranetics ■ St. Jude Medical ■ Terumo	■ Lutonix/CR Bard ■ Spectranetics ■ St. Jude Medical ■ Terumo‡	None	■ AstraZeneca Pharmaceutical* ■ Lutonix/CR Bard ■ Medtronic ■ Shockwave Medical* ■ TriReme Medical*	■ Abbott (Advisory Board)* ■ Boston Scientific (Advisory Board)* ■ Medtronic (Advisory Board)* ■ Spectranetics (Advisory Board)* ■ TriReme Medical†	None
Amy B. Reed, MD	Fairview Vascular Services—Director; University of Minnesota, Vascular and Endovascular Surgery—Professor and Chief	SVS	None	None	None	None	None	None

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APPENDIX A. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Fadi Shamoun, MD	Mayo Clinic, Anticoagulation Clinic—Medical Director; Division of Cardiovascular Diseases, Vascular Medicine—Assistant Professor of Medicine	ACC	None	None	None	None	None	None
Rita E. Shugart, RN, RVT	Shugart Consulting—Vascular Ultrasound	SVU	None	None	None	None	None	None
E. Kent Yucel, MD	Tufts Medical Center—Chair and Professor of Radiology	ACR	None	None	None	None	None	None
			External Reviewers					
Christopher J. Abularrage, MD	The Johns Hopkins Hospital, Diabetic Foot and Wound Clinic—Director and Associate Professor of Surgery	SVS	■ Medtronic	None	None	None	None	None
H. Vernon Anderson, MD	Memorial Hermann Heart and Vascular Institute, McGovern Medical School, and University of Texas Health Science Center—Professor of Medicine and Cardiology	ACC	None	None	None	None	None	None
Ehrin J. Armstrong, MD, MSc	VA Eastern Colorado Healthcare System, Interventional Cardiology—Cardiology Director; and Vascular Laboratory—Co-Director; University of Colorado—Associate Professor of Medicine	AHA	■ Abbott Vascular ■ Abiomed ■ Boston Scientific ■ Cardiovascular Systems ■ Medtronic ■ Spectranetics	None	None	None	None	None
Mark Otto Baerlocher, MD	Royal Victoria Hospital, Interventional Radiology—Chief	SIR	■ Boston Scientific	None	None	None	None	None
Michael Conte, MD	University of California San Francisco, Division of Vascular and Endovascular Surgery—Professor and Chief; UCSF Heart and Vascular Center—Co-Director; UCSF Center for Limb Preservation—Co-Director	AHA	■ Cook Medical ■ Medtronic	None	None	■ Bard (DSMB)	None	None
Sean R. Dariushnia, MD	Emory University School of Medicine, Department of Radiology and Imaging Sciences, Division of Interventional Radiology and Image-Guided Medicine—Assistant Professor	SIR	None	None	None	None	None	None

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Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Alain T. Drooz, MD	INOVA Fairfax Hospital—Staff Physician	SVM	■ Philips/ PercuNav* ■ Possis Medical/ Boston Scientific*	None	None	■ Bard (DSMB) ■ Cordis	None	None
Joseph P. Hughes, RVT, RVS	NAVIX Diagnostix—Director of Business Development; Society for Vascular Ultrasound—President	SVU	None	None	None	None	None	None
J. Kevin McGraw, MD	Riverside Methodist Hospital, Interventional Radiology—Section Head; Riverside Radiology and Interventional Associates	SIR	None	None	None	None	None	None
George H. Meier, MD, RVT	University of Cincinnati College of Medicine, Vascular Surgery—Professor, Chief, and Program Director	SVU	None	None	None	None	None	None
Jeffrey W. Olin, DO	Icahn School of Medicine at Mount Sinai, Cardiovascular Institute and Center for Cardiovascular Health, Vascular Medicine and Vascular Diagnostic Laboratory—Director and Professor of Medicine (Cardiology)	ACC	None	None	■ Northwind‡	None	None	None
Gregory Piazza, MD	Brigham and Women's Hospital, and Harvard Medical School—Assistant Professor of Medicine	ACC	■ BIO2	None	None	■ Bristol-Myers Squibb‡ ■ Daiichi ■ EKOS‡	None	None
Eva M. Rzucidlo, MD	McLeod Vascular Associates of South Carolina—Vascular Surgeon; Dartmouth Medical School—Associate Professor of Surgery	SVS	None	None	None	None	None	None
Drew C. Schemmer, MD	Royal Victoria Regional Health Center, Diagnostic Imaging, Vascular and Interventional Radiology Department—Vascular Radiologist	SIR	None	None	None	None	None	None
Marc Schermerhorn, MD	Beth Israel Deaconess Medical Center, Vascular and Endovascular Surgery Department—Chief; Harvard Medical School—Professor of Surgery	SVS	■ Abbott Laboratories‡ ■ Cook ■ Philips	None	None	■ Medtronic Vascular – ENGAGE PAS (PI)*	■ Boston Scientific Inc† ■ Medtronic Vascular† ■ W.L. Gore & Associates†	None

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APPENDIX A. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Mehdi Shishehbor, MD	Cleveland Clinic, Endovascular Services—Director	ACC	■ Abbott* ■ BioClinica* ■ Boston Scientific* ■ Medtronic* ■ Philips* ■ Shockwave Medical* ■ Spectranetics* ■ Terumo* ■ Volcano*	None	None	None	■ Volcano/ Philips†	None
David P. Slovut, MD, PhD, MHA	Network Performance Group—Director of Cardiovascular Quality; Montefiore Medical Center, Cardiology, Patient Safety and Quality—Vice Chief; TAVR—Co-Director; Medicine and Cardiovascular and Thoracic Surgery—Professor	SVM	None	None	None	None	None	None
Eric H. Yang, MD	Mayo Clinic of Arizona, Cardiac Catheterization Laboratory—Director	AHA	None	None	None	None	None	None

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*No financial benefit.

†Clinical Trial Enroller.

‡Significant relationship.

ACC = American College of Cardiology; ACR = American College of Radiology; AHA = American Heart Association; AUC = Appropriate Use Criteria; Co-PI = Co-Principal Investigator; DSMB = Data Safety Monitoring Board; PI = Principal Investigator; SCAI = Society for Cardiovascular Angiography and Interventions; SCVS = Society for Clinical Vascular Surgery; SIR = Society of Interventional Radiology; SVM = Society for Vascular Medicine; SVS = Society for Vascular Surgery; SVU = Society for Vascular Ultrasound; TAVR = transcatheter aortic valve replacement.