Society for Vascular Surgery appropriate use criteria methodology and rating Terminology

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DOC STATEMENT

Independent peer review and oversight has been provided by the members of the SVS Document Oversight Committee (Marc Schermerhorn, Chair, Britt Tonnessen, Vice Chair, Trissa Babrowski, Brittany Fraser, Peter Henke, Vikram Kashyap, Ahmed Kayssi, Chris Kwolek, Erika Mitchell, Patrick Muck, Kenton Rommens, Palma Shaw, Chris Smolock, Ravi Veeraswamy, Chandu Vemuri, and Grace Wang).

The purpose of this document is to outline the rationale and methodology used by the Society for Vascular Surgery (SVS) to develop appropriate use criteria (AUC) priorities and the methods of AUC development.

Vascular surgery as a specialty has been transformed over recent decades with the development of minimally invasive techniques and advanced imaging, along with advances in medical management and periprocedural care. These rapid changes have improved the care of our patients, but have also placed unique strains on decision-making around procedural selection and appropriate care before and after an intervention. The cost of health care has increased substantially along with these rapid advances, and reimbursement to physicians and potentially unnecessary or low value care are frequent targets of scrutiny regarding health care expenditure.

Clinical practice guidelines (CPGs) include evidence-based recommendations that are systematically developed by experts for specific disease processes and interventions. Guidelines advise the everyday care of patients with vascular disease, and AUC complement guidelines, and provide additional guidance to clinicians. Like CPGs, AUC are also based on the scientific literature and physicians' clinical practice experience and judgment. They are not intended to be prescriptive or replace individual patient-centered clinical decision-making, nor can they replace clinician judgment or patient preference in shared decision-making. It is imperative that AUC are developed by experts who represent diverse perspectives.

As an overarching premise, the SVS considers concerns and queries from clinicians, payers, and regulators to produce a balanced, evidence-based, and practical means of guiding procedural and diagnostic test utilization to optimize patient selection and outcomes. The process of AUC development and implementation will continue to evolve based on physicians, patients' needs and new data.

The AUC development process has been modeled after the RAND Corporation (RAND) and the University of California, Los Angeles (UCLA) Appropriateness Method. It includes the development of specific question(s) for which a systematic review of evidence is then undertaken. Informed by this systematic review, the writing panel drafts a number of clinical scenarios, varying the factors that may influence clinical decision-making. In round 1 of the RAND process, the rating panel is provided with the results and references from the systematic review. They then review and rate the various clinical scenarios, as drafted by the writing panel. In round 2, there is a moderator who guides discussion by the rating panel of not only the scenarios, but also the assumptions, definitions, and even the scope of the questions. The rating panelists work with the moderator to revise any of the details set forth by the writing panel to arrive at a final roster of clinical scenarios they then independently rate. Although this could be considered a form of modified Delphi process, it is important to note that there is no attempt to force a consensus among the rating panelists. Consistent with the RAND/UCLA method, appropriateness weighs the benefits and the risks/harms of a

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procedure or medical/surgical intervention for each specific scenario.[1-3]

The SVS AUC development process includes the identification of relevant clinical scenarios, a systematic synthesis of available evidence, ratings of these scenarios using a formal process that evaluates levels of agreement/disagreement, and a final document draft based on combined ratings and discussions. Additionally, relevant published best practices/consensus statements by relevant professional specialty societies will be considered as part of the evidence assessment. While patient treatment/care is based on physician judgment, the condition of individual patients, and patient values and preferences, AUC support clinical practice by:

1. Addressing methods of diagnosis, treatment, and clinical management with reference to existing CPGs;
2. Identifying areas in which evidence is needed to accurately assess the appropriateness of a treatment/procedure, particularly where randomized trials are not available or possible; and
3. Assisting physicians in timely clinical decision-making to improve overall quality of patient care.

AUC PRIORITIZATION

When developing AUC priorities, the following criteria will be considered.

Importance. The AUC document should address vascular clinical conditions of high prevalence, severe symptoms, ongoing controversy, significant societal health and financial burden, or health disparity.

Feasibility. The topic chosen for AUC should be manageable and feasible for the rating methodology. It must be focused enough that a manageable number of scenarios can be generated and rated.

Update. The AUC document will be reviewed every 5 years, at which time it will be determined whether the AUC will be updated or sunset. If the topic remains important and new literature has become available that may change the findings of the current document, the existing AUC will be updated.

AUC PROCESS

The SVS AUC process (outlined below and in the Fig) combines evidence from a systematic review (and meta-analysis, if possible) of published literature with clinical practice experience and expert judgment.[1,3] The AUC document supports clinical decision making by defining when it is acceptable (or not) to use or perform a specific procedure, test, or therapy in the diagnosis and care of patients with vascular disease in specific clinical scenarios. Cost is a relevant consideration, but panelists focus their ratings on the effectiveness of the selected procedure.

> An appropriate intervention is one in which the anticipated clinical benefits exceed the potential risks of the intervention for a specific clinical situation.[1,4,5]

Process overview. Very broadly speaking, the RAND/UCLA Appropriateness Method includes the selection of (1) a topic, (2) members of a writing panel, (3) members of a rating panel, (4) two rounds of rating of scenarios (by the rating panelists), and (5) scoring and presentation of the results in a formal scientific report (by the writing and rating panelists). The SVS has defined additional steps in the process of creating the AUC to include oversight of some of these steps by various key stakeholders which include the Executive Board of Directors (EB), the Quality Council, the Document Oversight Committee, Appropriateness Committee, and the SVS membership.

AUC topic selection. The selection of a topic for an AUC document depends on several factors: there is a current CPG on the topic, the selected topic is prevalent in large populations, it has value to the specialty, and it could impact coverage by the Centers for Medicare and Medicaid Services and other payers. The appropriateness committee considers these factors to select potential AUC topics that are presented to the SVS Quality Council for consideration and approval. The Quality Council recommends the topics to the EB for review and approval.

AUC conduct. The AUC writing panel members are chosen after a call for expressions of interest to the entire SVS membership. Applications are reviewed by the Appropriateness Committee, with the finalists reviewed by the Quality Council and then approved by the EB. Panel members are chosen to reflect diversity of expertise, practice environment, and background. The chair of the writing panel and the Quality Council will also determine what other health care professionals (non-SVS members) should be sought for inclusion.

- The writing panel defines specific questions for the systematic review to address; this includes defining the variables that are anticipated to influence clinical decision-making. The results will be used by the rating panel to inform their ratings in round 1.
- The SVS conducts or commissions a formal systematic literature review (and meta-analysis when the data is robust enough to permit).
- The writing panel creates a list of clinical indications and scenarios.
- The writing panel develops definitions and assumptions for indications and clinical scenarios.
- The review panel is composed of the members of the Appropriateness Committee. The review panel reviews the proposed clinical scenarios, definitions, and assumptions developed by the writing panel. Once approved, the rating panel reviews the

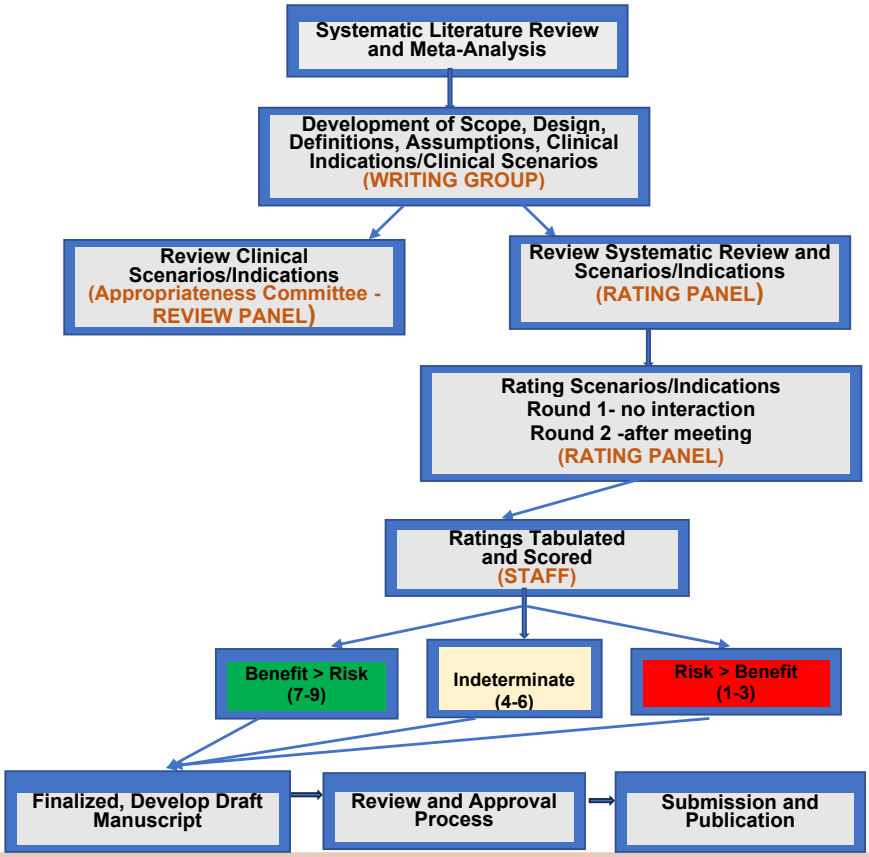

Fig. Schematic overview of the appropriate use criteria (AUC) development process.

Table I. The Society for Vascular Surgery (SVS) rating scale and description

Rating SCORE	Description
7-9	Benefit > risk for the described scenario and is generally considered acceptable and/or necessary.
4-6	Indeterminate for the described scenario. Additional clinical variables and patient preference may influence a final determination. More research and/or patient information is needed to classify the indication.
1-3	Risk > benefit for the described scenario and is generally not considered acceptable or reasonable.

Modified from Fitch et al.[1]

Table II. Nine-point appropriateness scale

Level of appropriateness	Description
Benefit > risk	Median panel rating scores between 7 and 9 and no disagreement
Indeterminate	Median panel rating scores between 4 and 6 or any score where there was disagreement according to the interpercentile range adjusted for symmetry methods[1]
Risk > benefit	Median panel rating between 1 and 3 and no disagreement

systematic review and proposed clinical scenarios, definitions, and assumptions.

- In round 1, the rating panelists are given a series of instructions on the process, as well as the systematic review document and all the cited literature. The rating panelists then independently rate all scenarios. Their scores are tallied using the modified RAND appropriateness method detailed in Tables I and II.
- The rating panel rates each scenario, using a one to nine scale, based on the rating criteria as risk > benefit, indeterminate, or benefit > risk[6] (Tables I and II). The SVS, as well as most medical societies, are using modified RAND terminology[1,7] (Table III). However, the SVS has elected to use less pointed terminology[7] owing to the subjectivity of what is considered appropriate in routine daily practice outside of hyperbolic clinical scenarios.
- For round 2, the rating panel reviews the scores from round 1; they review all aspects of the scenarios, assumptions, definitions, and scoring, revising any of these as they deem necessary. The resultant revised scenarios are then all re-rated independently by the panelists. Complete details of this process are beyond

Table III. Terminology and comparative rating scale for appropriate use criteria (*AUC*) established by different medical societies

Year	Authors	Professional societies	Pathology	Intervention	Categories	Rating panel composition	Wording	No. of AUCs
2009	Patel et al.	ACCF, SCAI, STS, AATS, AHA, ASNC	Coronary artery disease	PCI, CABG	Initial AUC	Cardiologist, interventional cardiologists, cardiothoracic surgeon, health outcome research, health plan medical officer	Appropriate, uncertain, inappropriate	180
2012	Patel et al.	ACCF, SCAI, STS, AATS, AHA, ASNC, ASE, HFSA, HRS, SCCM, SCCT, SCMR	Coronary artery disease	Diagnostic catheterization	Initial AUC	Cardiologist, interventional cardiologist, health outcome researcher, health plan medical officer	Appropriate, uncertain, inappropriate	169
2012	Patel et al.	ACCF, SCAI, STS, AATS, AHA, ASNC, HFSA, SCCT	Coronary artery disease	PCI, CABG	Update AUC	Cardiologist, interventional cardiologists, cardiothoracic surgeon, health outcome researcher, health plan medical officer	Appropriate, uncertain, inappropriate	15
2013	Russo et al.	ACCF, SCAI, AHA, ASE, HFSA, SCCT, SCMR	Coronary artery disease, valvular disease, heart failure, arrhythmia	ICD/CRT	Initial AUC	Cardiologist, interventional cardiologists, electrophysiologist, cardiac imaging specialists	Appropriate, may be appropriate, rarely appropriate	369
2014	Gray et al.	SCAI	Infrapopliteal arterial disease	Endovascular revascularization options	Initial AUC	Interventional cardiologist	Appropriate, may be appropriate, rarely appropriate	10
2014	Klein et al.	SCAI	Aortoiliac arterial disease	Medical therapy, endovascular and hybrid revascularization options	Initial AUC	Interventional cardiologist	Appropriate, may be appropriate, rarely appropriate	9
2014	Klein et al.	SCAI	Femoral-popliteal arterial disease	Medical therapy, endovascular revascularization options	Initial AUC	Interventional cardiologist	Appropriate, may be appropriate, rarely appropriate	10
2014	Parikh et al.	SCAI	Renal artery stenosis	Endovascular revascularization options	Initial AUC	Interventional cardiologist	Appropriate, may be appropriate, rarely appropriate	10
2016	Patel et al.	ACCF, SCAI, STS, AATS, AHA, ASNC, ASE, SCCT	Acute coronary syndrome	Fibrinolytic therapy, PCI, CABG	Update AUC	Health outcome researchers, interventional cardiologists, cardiothoracic surgeons, cardiologists	Appropriate, may be appropriate, rarely appropriate	17
2017	Patel et al.	ACCF, SCAI, STS, AATS, AHA, ASNC, ASE, SCCT	Stable ischemic heart disease	PCI, CABG	Update AUC	Health outcome researchers, interventional cardiologists, cardiothoracic surgeons, cardiologists	Appropriate, may be appropriate, rarely appropriate	448

Table III. Continued.

Year	Authors	Professional societies	Pathology	Intervention	Categories	Rating panel composition	Wording	No. of AUCs
2017	Bonow et al.	ACCF, SCAI, STS, AATS, AHA, ASE, SCCT, SCMR, HVS, EACTS, SCA	Aortic stenosis	Balloon valvuloplasty, TAVR, and SAVR; additional combinations with adjuncts	Initial AUC	Cardiologists, cardiovascular surgeons, interventional cardiologists, radiologist	Appropriate, may be appropriate, rarely appropriate	349
2017	Copelan et al.	American College of Radiology	Iliac artery occlusive disease	Medical management, endovascular options, surgical revascularization	Initial AUC	Interventional radiologists, vascular surgeon	Usually appropriate, may be appropriate, usually not appropriate	45
2017	Fidelman et al.	American College of Radiology	Mesenteric ischemia	Medical management, endovascular options, surgical revascularization	Initial AUC	Interventional radiologists, gastroenterologist, vascular surgeon,	Usually appropriate, may be appropriate, usually not appropriate	22
2017	Klein et al.	SCAI	Peripheral arterial disease, including renal stenosis	Endovascular revascularization options	Update AUC	Vascular medicine, interventional cardiologist	Appropriate, may be appropriate, rarely appropriate	438
2018	Ijsselmuiden et al.	Netherlands Society of Cardiology	Coronary artery disease	Optical coherence tomography guidance in PCI	Initial AUC	Interventional cardiologists	Appropriate, may be appropriate, rarely appropriate	49
2018	Bailey et al.	ACCF, SCAI, AHA, SIR, SVM	Peripheral arterial disease, including renal stenosis	Medical therapy, endovascular options, surgical revascularization	Initial AUC	Interventional cardiologists, vascular medicine, interventional radiologist, cardiologists, vascular surgeon, vascular ultrasound specialist	Appropriate, may be appropriate, rarely appropriate	117
2019	Minocha et al.	American College of Radiology	Venous thromboembolism	Medical therapy, endovascular options, referral to surgery	Initial AUC	Interventional radiologists, vascular surgeon	Usually appropriate, may be appropriate, usually not appropriate	32
2020	Farsad et al.	American College of Radiology	Iliofemoral venous thromboembolism	Medical therapy, compression, endovascular options, surgery	Initial AUC	Interventional radiologists, vascular surgeon	Usually appropriate, may be appropriate, usually not appropriate	25
2020	Masuda et al.	AVF, AVLS, SVS, SCAI	Chronic lower extremity venous disease	Ablation, sclerotherapy, phlebectomy, iliac stenting	Initial AUC	Vascular surgeon, interventional radiologist, dermatologist	Appropriate, may be appropriate, rarely appropriate	126
2021	Osborn and Schmidt	American Academy of Orthopaedic Surgeons	Acute compartment syndrome	Observation, repeat markers/ measurements, fasciotomy	Initial AUC	Orthopedic surgeon, vascular medicine	Appropriate, may be appropriate, rarely appropriate	135

(Continued on next page)

Table III. Continued.

Year	Authors	Professional societies	Pathology	Intervention	Categories	Rating panel composition	Wording	No. of AUCs
2022	Lam et al.	American College of Radiology	Mesenteric ischemia	Medical management, endovascular options, surgical revascularization	Update AUC	Interventional radiologists, gastroenterologist, vascular surgeon,	Usually appropriate, may be appropriate, usually not appropriate	28
2022	Woo et al.	Society for Vascular Surgery	Intermittent claudication	Exercise therapy, open and endovascular revascularization	Initial AUC	Vascular surgeons, interventional radiologists, cardiologists	Benefit outweighs risk, indeterminate, risk outweighs benefit	1948
2023	Inohara et al.	Japanese Expert Panel	Aortic stenosis	TAVR, SAVR, with combinations of adjuncts	Initial AUC	Interventional cardiologist, cardiovascular surgeon, imaging specialist, heart failure specialist	Appropriate, may be appropriate, rarely appropriate	264

AATS, American Association for Thoracic Surgery; *ACCF,* American College of Cardiology Foundation; *AHA,* American Heart Association; *ASE,* American Society of Echocardiography; *ASNC,* American Society of Nuclear Cardiology; *AVF,* American Venous Forum; *AVLS,* American Venous and Lymphatic Society; *CABG,* coronary artery bypass surgery; *CRT,* cardiac resynchronization therapy; *EACTS,* European Association for Cardiothoracic Surgery; *HFSA,* Heart Failure Society of America; *HRS,* Heart Rhythm Society; *HVS,* Heart Valve Society; *ICD,* implantable cardioverter-defibrillator; *PCI,* percutaneous coronary intervention; *SAVR,* surgical aortic valve replacement; *SCA,* Society of Cardiovascular Anesthesiologists; *SCAI,* Society for Cardiovascular Angiography & Interventions; *SCCM,* Society of Critical Care Medicine; *SCCT,* Society for Cardiovascular Computed Tomography; *SCMR,* Society for Cardiovascular Magnetic Resonance; *SIR,* Society of Interventional Radiology; *STS,* Society of Thoracic Surgeons; *SVM,* Society for Vascular Medicine; *SVS,* Society for Vascular Surgery; *TAVR,* transcatheter aortic valve replacement.
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the scope of this document but are detailed in the RAND/UCLA Appropriateness Method user's manual.[1]

- The results are compiled, and the writing panel drafts the AUC document. The rating panelists are invited to review and participate as coauthors.

Review of AUC document.

- The final AUC manuscript is reviewed by the SVS Document Oversight Committee (DOC), and the review process includes a period of commentary from SVS members. The DOC recommends consideration for endorsement and approval by the Executive Board of the SVS.
- Once the AUC manuscript receives endorsement by the Executive Board, it is submitted to the *Journal of Vascular Surgery* for publication without additional peer review, in keeping with SVS's policy of peer review of SVS-generated documents. If the EB chooses not to endorse the manuscript, the authors are able to submit the work to another journal of their choosing, but without formal SVS endorsement.
- The final AUC document is disseminated.

COMPREHENSIVE PROCESS

Systematic literature review and analysis. The systematic literature review and any meta-analyses are conducted using standard methodology. The scope for the review is based on the use of the clinical Population, Intervention, Comparator, Outcome (PICO) framework as developed by the chairs of the AUC writing panel. The systematic review informs the decisions relevant to the indications identified in the PICO framework. This report serves as evidence for the development of AUC and to determine a rating score for each of the clinical scenarios created by the writing panel. The writing panel members review the report and can suggest adding or removing articles that do not address the clinical scenario.

SVS COI disclosure. AUC will be developed in accordance with the SVS conflict-of-interest (COI) disclosure policy. All panel members are required to complete their SVS disclosures. The majority (51%) of members of the writing panel and review panel cannot have any relevant financial COI. For the rating panel, no panelist is permitted to have any relevant financial COI pertaining to the selected topic including the moderator. A nonconflicted ratings panel member who acquires a new relevant conflict during the development of AUC will not be able to participate on the rating panel and will be replaced by a nonconflicted rating panelist so that all rating panel members remain free of relevant financial conflicts for the selected topic.

Funding of AUC development. Direct funding of AUC by the medical and pharmaceutical industry is strictly prohibited.

ORGANIZATION OF PANELS

Solicit panel members

The SVS solicits volunteer members for the writing and rating panels from the entire membership. The selection of panel members is based on evaluation of a member's

application, curriculum vitae, and COI disclosures. Whenever possible, a multidisciplinary panel will be selected with representation from other medical specialty societies, when indicated.

Writing panel

The writing panel members are experts in the field of the selected topic. This panel is responsible for creating the content for AUC, based on their familiarity with the relevant literature on the selected topic. The panel members evaluate the systematic review undertaken in support of the AUC. The writing panel selects clinically relevant indications and develops definitions. The panel also develops assumptions for the clinical scenarios. An individual on the writing panel cannot also serve on the rating or review panel, except for the moderator (who is the chair or vice chair), who may participate in the writing panel meetings and moderate the rating panel discussions.

AUC rating panel

Moderator. The AUC moderator provides clinical and methodological oversight as a nonvoting participant on the writing panel calls and virtual and in-person meetings. The moderator will be responsible for leading the rating panelists' discussions on the clinical scenarios that resulted in disagreement after the first round of voting.

Review panel

The review panel will consist of approximately 10 members. The members of the review panel are selected from the Appropriateness Committee. These panelists review the systematic review and the drafted clinical scenarios by the writing panel. They validate and approve clinical scenarios and supporting information prior to the commencement of the rating process. They do not review the clinical scenarios after the rating process has started.

Ratings panel

The ratings panel is a multidisciplinary group consisting of seven to fifteen members. Ratings panel members are selected by the writing panel, approved by the chair of the Quality Council, and are confirmed by the EB. Appropriate use ratings are determined by the ratings panel in a modified Delphi exercise based on the RAND/UCLA appropriateness method.[1] The panel is responsible for the independent rating of the clinical scenarios to determine a final rating.

The ratings panel members review the entire process by which the AUC document is developed to understand the overall responsibilities of each group in AUC development methodology. The panel members also review the systematic review report, meta-analysis (if prepared), the definitions, assumptions, and scenarios to determine an appropriate use score for each of the clinical scenarios. The members review the rating process for the AUC to understand how final scores will be determined for each clinical scenario prior to rating, as well. All rating panelists participate in two rounds of voting. The members of the rating panel cannot modify the clinical scenarios that were written by the writing panel during round 1 voting. Any changes will be discussed during the second round before voting.

Round one rating

In the first round, the rating panelists rate indications independently without any interaction with other panel members. The panelists' names are not disclosed at this time. Each panelist must use the 9-point scale (Table I) to record their response for each scenario based on evidence and best clinical judgement. An appropriate use score between 1 and 9 is designated for each clinical scenario.

Data compilation. The scores are tabulated. Composite scores are shared with panel members after the first round of voting. The summary of the scores will have no identification of individual panelists.

Round two rating

The rating panel members meet and review the scores from round 1; they review all aspects of the scenarios, assumptions, definitions, and scoring, revising any of these as deemed necessary. The resulting revised scenarios are then re-rated independently by the panelists. The discussion is led by the AUC moderator. This second round provides an opportunity for panelists to discuss the scenarios. After this meeting, the rating panel members will consider the ratings from round 1 and revise their own scores, if desired. The panel members can re-rate clinical scenarios individually after the discussion. During this second round, there will not be any attempt to obtain consensus among the panel members on the ratings.

Final rating

The final appropriate use category will correspond to the median score for each indication where agreement has been achieved. Agreement is defined according to the interpercentile range adjusted for symmetry formula described in the RAND manual[1,8]; that is, two-thirds of the panel members rating the procedure within the same three-score category (benefit > risk, indeterminate, and risk > benefit). Clinical scenarios for which the panel cannot reach agreement will be marked as indeterminate (but without a numeric score) regardless of where the median score falls in the 1 to 9 range shown in Table I.

Review and approval process. The completed AUC manuscript will be submitted to the DOC for peer review, which includes a period for SVS member commentary. Comments from the DOC are considered for incorporation by the authors, who submit a revised manuscript to

the DOC. The revised manuscript is reviewed by the DOC. The revisions requested by the DOC will only address the narrative text of the manuscript, but not the scenarios, assumptions, definitions, or ratings developed by the ratings panel. Once a vote for approval/rejection of the manuscript by the DOC has occurred, the final manuscript will be sent for review to the EB. The DOC chair will present the DOC comments to the EB and convey the committee's recommendation of approval or rejection.

Publication. The final manuscript approved by the EB is submitted to the *Journal of Vascular Surgery* for publication by the lead author(s). The first tier of authors listed on the manuscript are the writing group members. The second tier of authors includes all the members of the ratings panel. The members of the review panel are mentioned in the acknowledgements.

DISCLAIMER

The SVS develops evidenced-based documents as a resource to assist members in the practice of vascular surgery. These AUC contain guidance on the topic and were determined following a recent review of the reported evidence and expert opinion. These AUC reflect the available body of evidence, and their applicability reflects the limitations of those data and are subject to reassessment and revision as new knowledge emerges. Given these limitations, AUC do not represent a statement of the standard of care, nor can they substitute for clinician judgment or supplant patient preference or shared decision-making. The SVS recognizes that departure from the AUC could be warranted when, in the reasonable judgment of the treating clinician, such a course of action is indicated by the clinical presentation of the patient, limitations of the available resources, advances in knowledge or technology, and/or patient preference. Readers must rely solely on their own judgment to determine which practices and procedures, whether included in this document, are appropriate for them, their patient, their institution, or their practice.

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