July 25, 2025

Health Technology Assessment Program
Washington State Health Care Authority
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Via email: shtap@hca.wa.gov

RE: Angioplasty and Stenting for Peripheral Artery Disease (PAD) -- Draft Evidence Report

To Members of the Health Technology Assessment Program Committee:

The **American College of Radiology, Outpatient Endovascular and Interventional Society, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Surgery** appreciate the opportunity to comment on the Draft Evidence Report entitled **Angioplasty and Stenting for Peripheral Artery Disease (PAD)** dated June 24, 2025, prepared by Aggregate Analytics, Inc. for the Washington State Health Care Authority and for the consideration of its Health Technology Clinical Committee (HTCC). The report is based on the methodology given to Aggregate Analytics by HTCC. That approach gives more weight to randomized controlled trials (RCTs) and seeks to describe the biases uncovered in all publications included in the Draft Report. The Draft Report makes the important step of identifying the Strength of Evidence (SoE) of each finding. The societies signing this letter know that this is a difficult process because we have collaborated numerous times to develop clinical practice guidelines that describe the

Standard of Care (SoC) for the treatment of peripheral artery disease.[1,2,3,4,5,6] We have been addressing this issue together for over two decades now. We commend you for your effort on this important task.

Every day the members of our societies are striving to help patients who struggle with intermittent claudication (ICs), in the State of Washington and across the USA, to complete normal daily activities without significant leg pain and to help patients with critical limb threatening ischemia (CLTI) keep their legs. We wish these were easy challenges, but unfortunately they are not. We wish that our members and their patients were always successful, but regrettably they are not. Each of our societies individually and, as a group, collectively, believe that the SoC that provides the best care for patients is achieved when physicians treat their patients in accordance with our clinical practice guidelines.

In developing our clinical practice guidelines, we take a different methodological approach than that used in the Draft Report. We describe just a few of those differences in detail below, and, no doubt, other letters will address these or other issues. We provide our comments with respect as HTCC has the power to modify or even to discontinue coverage of certain endovascular procedures to approximately 2.3 million of the 8.1 million total Washingtonians, which is almost 30% of those living in the state. Decisions made by the HTCC could have a substantially disruptive impact to Washingtonians whose medical care is paid for by the State of Washington Employees Health Benefit Plan, the State of Washington Medicaid Program, and the Washington Workers' Compensation Program. We have a simple request:

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[1] Gornik HL, *et al*. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024;149:e1313-e1410. https://doi.org/10.1161/CIR.0000000000001251

[2] Gerhard-Herman MD, *et al*. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2017;135:e686–e725. https://doi.org/10.1161/CIR.0000000000000470

[3]Rooke TW, *et al*. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;*124*:2020–45.

[4] Hirsch AT, *et al*. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary: a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease). *Circulation*. 2006;*113*:e463–654.

[5] American College of Radiology. ACR–SIR–SPR practice parameter for the performance of arteriography. 2022; Available at https://gravitas.acr.org/PPTS/GetDocumentView?docId=128.Accessed July 24, 2025.

[6] American College of Radiology. ACR–AIUM–SIR–SRU practice parameter for the performance of physiologic evaluation of extremity arteries.2022; Available at https://gravitas.acr.org/PPTS/GetDocumentView?docId=148&releaseId=2. Accessed July 24, 2025.

Take no action based on the Draft Report. As medical professionals who specialize in the treatment of PAD, we do not believe that the Draft Report justifies any action on the part of HTCC. After a thorough examination of the methodology, results, and conclusions, we believe that there are important and consequential omissions not addressed.

The clinical practice guidelines collaboratively developed by the societies that have signed this letter address the treatment of PAD in a comprehensive and clinically grounded manner. In contrast, the Draft Report contains a critically important statement on page i "Information in this report is not a substitute for sound clinical judgment." The Draft Report does not purport to align with clinical principles of care, of clinical evidence development or clinical evidence interpretation. There are several ways in which the Technology Assessment methodology adopted in the Draft Report conflict with an approach incorporating "sound clinical judgment," as represented in our clinical practice guidelines. In the spirit of brevity, we focus on the five most important issues. We hope that our overview helps you to conclude that HTCC should take no action on the Draft Report at the present time.

I. Scope of Draft Report

As described in the HTCC website, when the Director first selected to perform this report, its initial proposed title "**Endovascular Intervention in Lower Extremity Peripheral Arterial Disease and Intermittent Claudication**" seemed far more comprehensive.[7] The Draft Report produced has a far narrower focus consisting of just three therapies: angioplasty without stenting (BA), angioplasty with stenting (BA/S), and angioplasty with drug coated ballon (DCB).

There are several additional "endovascular procedures" that are simply not addressed by the Draft Report. These include, but are not limited to, atherectomy, atherectomy with stent, intravascular lithotripsy, intravascular ultrasound and transcatheter arterialization of the deep veins.

We certainly hope that the actions of HTCC will comply with best practices of Health Technology Assessment and limit the scope of any decisions or actions that it might consider to the technologies addressing the Draft Report: BA, BA/S, and DCB. Attempting to make determinations on procedures that are not specifically addressed in the Draft Report would be a grievous disservice to Washingtonians struggling with significant PAD.

[7] Washington Health Care Authority. Selected Technologies for 2024. Accessed at https://www.hca.wa.gov/assets/program/Director-final-topic-selection-2024.pdf, accessed on July 18, 2025.

Please limit any decisions to the three specific technologies addressed in the Draft Report (BA, BA/S, DCB). The Draft Report provides no basis for considering any other technologies.

II. The Choice to Use Structured Exercise Therapy (SET) as a Comparator

On page ES-8 of the Draft Report, Table A describes how there are 11 total RCTs (22 publications) comparing endovascular procedures to conservative care and over half of these RCTs (8) and publications (18) compare endovascular procedures with SET. However, in speaking with our member physicians who treat patients with IC and CLTI in the state of Washington, we hear that SET, for all practical purposes, is not available. From a Technology Assessment standpoint, it is reasonable to make a comparison between endovascular procedures and SET; however, any HTCC decision quickly becomes a real health care policy to be implemented across the State of Washington. Again, providing "sound clinical judgment" to this topic compels us to mention that a national survey of 900 vascular physicians performed by the Vascular and Endovascular Surgery Society; 54% of responders had no SET program at their facility, and the two top reasons for not referring patients for SET were; #1 travel distance (50%) and #2 lack of available SET centers (33%); and as a result, 49% of respondents had never referred a patient for SET.[8] If there is inadequate infrastructure for the delivery of SET at scale across Washington (as we understand to be the case from our members, as well), then SET is not a clinically practical alternative, just a hypothetical alternative addressed in the Draft Report. If HTCC were to make a decision to limit access to endovascular procedural therapy based on the analysis in the Draft Report when SET is actually not an available real treatment alternative, that decision would be a significant misstep and a disaster for Washingtonians struggling with PAD. A policy decision cannot be based on a presumption that SET is available to Washingtonians; it should only come after a thorough inventory has been completed describing the capacity for the delivery of SET to all Washingtonians with significant PAD. Our understanding is that such an inventory would find an inadequate infrastructure in place to deliver SET at scale. If HTCC were to make a decision to limit access to endovascular procedural therapies for PAD prior to confirmation that SET is actually available at scale for all Washingtonians with significant PAD, it would be a harmful decision affecting Washingtonians with significant PAD.

Please do not discontinue or significantly limit coverage for any endovascular procedure beyond the parameters presented in our clinical practice guidelines on the basis of a comparison to SET until such time as SET is broadly available across Washington. An inventory of the availability

[8] Dua A, *et al*. National assessment of availability, awareness, and utilization of supervised exercise therapy for peripheral artery disease patients with intermittent claudication.

of SET in Washington must be performed to confirm its broad availability before any decision to limit coverage of endovascular therapy is made. Based on our discussions with local physicians who treat PAD, broad availability of SET remains years away.

This analysis in the Draft Report includes, and does not differentiate, intermittent claudication (IC) from chronic limb-threatening ischemia (CLTI) in the patient population and in the literature review. From the standpoint of clinical trajectory and PAD treatments, IC and CLTI are distinct clinical diagnoses. IC patients have a different disease course ranging from mild/moderate to significant impact on patient QOL and function. This can include debilitating pain and inability to walk that severely impact activities of daily living for these patients. OMT and SET interventions prior to EVT or bypass surgery can be made on an individualized patient basis. Conversely CLTI patients (Rutherford 4-6), who have a far more severe form of PAD requiring immediate attention, should be treated primarily with EVT or bypass surgery to promote wound healing and prevent amputation. Although this is acknowledged in the report, this highlights the need for separation of IC and CLTI as discrete entities in the analysis so that patients are not inappropriately aggregated when making policy decisions.

III. What to Do When Clinical Community and Technology Assessment Process Disagree. Are Unethical Studies Necessary to Fill the Gap?

Several key questions (KQs) of the Draft Report address the comparison of procedural therapies with conservative therapy, such as OMT (optimal medical therapy). These questions are very important considerations, but the clinical perspective and technology assessment perspective may come into some conflict. After the clinical community has confirmed to its satisfaction the superiority of one therapy over another, an ethical issue arises. Continuing to treat patients in clinical trials with a known inferior treatment approach is prohibited based on the principle of nonmaleficence, a pillar in the ethics of clinical trials.[9] Page ES-8 of the Draft Report describes how the 6,256 citations identified were winnowed down to the 22 (0.35% of the total) publications describing the studies versus conservative therapy. As we review the clinical trials that survived the review process, we believe that numerous clinically important publications were simply deleted without explanation on a publication-by-publication basis as to why. This highly restrictive review process has important ramifications. After the clinical community is

[9] Varkey B. Principles of Clinical Ethics and Their Application to Practice Review. Med Princ Pract 2021;30:17–28

convinced to its satisfaction that first-generation procedural therapy is an improvement over a non-procedural therapy, then the ethics of clinical trials prohibit us from comparing newer technologies to the approaches that were found to be inferior to first-generation technologies. We would be providing less than SoC therapy to the patients receiving the established non-experimental therapy. That is unethical from a clinical standpoint. The studies completed to date have answered this question to the satisfaction of the clinical community about procedural versus, at least, OMT. Several of those studies were excluded from the Draft Report. We are confident that they are not going to be repeated due to the clinical ethics concerns we describe above.

The KQs used in developing the Draft Report focus on a comparison of endovascular procedures with conservative therapy. The comparison of the Draft Report with our clinical practice guidelines indicates that numerous publications that inform compelling elements of our clinical understanding have been deleted from the Draft Report without explanation. We believe that this overly-rigorous selection process has resulted in the Draft Report containing many questions on matters that the clinical community considers settled (such as endovascular procedures versus OMT). Should the HTCC choose to limit coverage of certain endovascular procedures based on the Draft Report, it would likely put itself in a difficult position as the clinical community would likely identify additional "procedure versus OMT trials" as unethical. We encourage you not to limit coverage of endovascular procedures simply because the number of publications that survived the review process was excessively limited. Again, we direct you to our clinical practice guidelines for an alternative approach to the data and resolving this issue. In the meantime, please do not discontinue coverage for any endovascular procedural therapies due to your methodology used in the Draft Report that discarded too many clinical studies from the analysis.

IV. Exclusion of Newer Generation Devices from the Draft Report via Device-Device Study Exclusion

The Draft Report addresses a number of biases that are intrinsic to each publication and each publication's methodology. We agree that it is important to address any systematic biases encountered. What the clinical community appreciates is that there has been much improvement to devices used in treating PAD in recent years. New generations of devices are compared against older generations, and when the newer products have superior performance, they replace the older and inferior products.

Because of this dynamic, the studies evaluating procedural therapy versus OMT used earlier, first-generation devices. Since then, the incremental product improvements that

have occurred have been documented in device versus device ("device-device") studies. These studies were systematically excluded from the Draft Report. It is understood in the clinical community that with each step forward in the progression from primary angioplasty, to bare metal stents, to first generation drug eluting stents, to each subsequent generation of drug eluting stents, there has been improvement in clinical performance (primarily stent thrombosis and progressive arteriosclerosis) described in numerous studies. The iterative innovation seen in device therapy is documented in these device-device studies, and these device-device studies represent a huge component of the clinical literature of procedural therapy for PAD. Please understand that the methodology used in the Draft Report of excluding device-device studies results in an overrepresentation of earlier generation devices that were used in the studies versus OMT. The improved performance of more recent generations of procedural therapy are, for the most part, systematically excluded from consideration in the Draft Report. We consider this a significant bias of the Draft Report that needs to be resolved before the Draft Report can be acted upon.

We again request that HTCC make no decision based on the Draft Report to limit access to any procedural therapy for PAD until such time as the results of more recent generations of procedural therapies can be incorporated. For all ethical reasons outlined above, we anticipate that the clinical community would find studies comparing newer-generation devices versus OMT as ethically challenging to undertake. For an alternative approach that appreciates how to address the ongoing improvement of technologies over time, we direct you to our clinical practice guidelines .

V. Errors Identified in the Draft Report Have Prompted Us to Perform a Detailed Analysis.

Table A on page ES-8 is critically important as it describes the publications that have been deemed to be meet the criteria of the analysis and maps those publications to the KQs they will be used to answer. Under the KQ, "Stent vs. OMT," there are 4 RCTs and 8 publications identified. One publication reference among these 8 is reference #52 which has the following citation in the Draft Report: *Gardner AW, Skinner JS, Vaughan NR, Bryant CX, Smith LK*. **Comparison of three progressive exercise protocols in peripheral vascular occlusive disease**. Angiology 1992;43:661-71. (emphasis added) We have reviewed the abstract of this reference and find it to address what the title indicates (a comparison of three progressive SET protocols). It is not, in fact, an RCT of stent vs. OMT. This publication has clearly been miscategorized in the Draft Report development process. The Draft Report contains at least one irrefutable error.

This error in the Draft Report, combined with the significant power of HTCC to restrict access to PAD services for 2.3 million Washingtonians, has prompted the societies signing this letter to task Dr. Sam Ahn to perform a meta-analysis of the literature similar to that performed by Aggregate Analytics, Inc. Dr. Ahn is a former Professor of Surgery at UCLA Medical School and the former Director of the UCLA Endovascular Surgery Program. While his efforts are still ongoing, he has been able to confirm that numerous important clinical studies have been excluded from the Draft Report that are included in their analysis. At this early point, his preliminary analysis confirms that later generation devices (which are included in his report) are more effective than devices of an earlier generation. So exclusion of device-device studies underrepresents the effectiveness of products currently on the market. Additionally, the systematic exclusion of numerous studies is likely to contribute to the low SoE findings presented in Tables B through F that we have summarized below:

Table 1: Summary of the Strength of Evidence (SoE) Findings in Summary Tables B through F of the Draft Report.

Table	B	C	D	E	F	Total
Total Cells	56	48	48	40	35	227 (100%)
No Evidence	31	25	28	23	20	127 (56%)
Insufficient Evidence	9	6	2	3	8	28 (12%)
Low Strength of Evidence	16	17	18	13	6	70 (31%)
Mod. Strength of Evidence	0	0	0	1	1	2 (1%)
High Strength of Evidence	0	0	0	0	0	0 (0%)

Our review has identified that there is at least one factual error in the Draft Report with respect to how publications are classified. Dr. Ahn's preliminary findings confirm that numerous clinically relevant publications were not included in the Draft Report that are germane to our understanding of the clinical phenomenon of significant PAD.

> **Please do not take action to limit coverage of endovascular procedures for PAD based on a Draft Report that includes at least one demonstrable error in how publications are handled and that seems to underrepresent the clinical literature on these topics resulting in SoE determinations that are biased to be low.**

In summary, the decades of "sound clinical judgment" that our organizations have accumulated while developing numerous version of the clinical practice guidelines on this topic simply compel us to conclude that it would be a mistake for the technology assessment provided by Aggregate Analytics to progress to an HTCC decision and the implementation of a policy restricting access to endovascular procedures in the treatment of PAD. It would create policies that would be poorly supported by this Draft

Report, incongruent with published multi-society clinical practice guidelines and best practices, and potentially devastating for Washingtonians who are suffering with significant PAD.

Please feel free to contact Jason McKitrick at jmckitrick@libertypartnersgroup.com with any questions.

Sincerely,

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