Washington State Health Care Authority

Angioplasty and Stenting for Peripheral Artery Disease (PAD)

Final evidence report: Peer review, comment and response

August 18, 2025

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Angioplasty and Stenting for Peripheral Artery Disease (PAD)

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August 18, 2025

Responses to clinical and peer reviewers

Aggregate Analytics Inc. is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during public comment periods are included in this document and attachments. Comments related to program decisions, process or other matters not pertaining to the evidence report, are acknowledged through inclusion only.

Specific responses pertaining to peer reviewer comments are included in **Table 1.** Draft report peer reviewers include:

- Matthew C. Smith, MD PhD, Assistant Professor of Surgery, Section Head of Vascular Surgery, UWMC Northwest Hospital; Associate Program Director, Vascular Surgery Residency and Fellowship Division of Vascular Surgery, University of Washington
- Rita Redberg, MD MS, Professor of Medicine, School of Medicine, University of California, San Francisco

Responses to public comments from medical and professional organizations may be found in **Table 2.** These include:

- Jason McKitrick, Principal of Liberty Partners Group on behalf of ACR, OEIS, SCAI, SIR, and SVS ("Societies").

We are also grateful to the numerous individuals who provided general public comment (i.e., not addressing evidence, project scope, or draft key questions) on the topic of angioplasty and stenting. A list of the names of those who contributed can be found after **Table 2** below.

Full texts of peer reviews and public comments may be found in the appendix immediately following the list of individuals who provided general public comment.

Table 1. Responses to Clinical and Peer Reviewers

	Comment	Response
Matthew C. Smith, MD PhD, Assistant Professor of Surgery, Section Head of Vascular Surgery, UWMC Northwest Hospital; Associate Program Director, Vascular Surgery Residency and Fellowship Division of Vascular Surgery, University of Washington		
	Specific comments	
Introduction	PAD can affect any of the arteries in the body and is termed "peripheral" when described outside the cart or brain. To state that it affects "three major arterial segments" suggests that it is localized. It would be more accurate to state that trials studying PAD are broken down into those 3 segments	We have made edits to clarify what is meant by "peripheral" and that the focus of this is review on the specific arterial segments for the legs
Introduction	Aspirin, statin and antihypertensives shouldn't state "may" be prescribed. There is level 1 evidence for the reduction of MACE with each of these therapies and they are the mainstay of all treatment of PAD	Thank you for your comments. We have made edits to the introduction
Introduction	If it is important to discuss GDMT in the intro then it's worth mentioning the smoking cessation is the #1 recommendation in applicable patients rather than throwing it in the same sentence as "stress management"	Thank you for your comments. We have made edits to the introduction.
Introduction	Reference 43 isn't designed to conclude that "few people with PAD develop critical limb ischemia or amputation." This statement introduces bias into the report and is misleading and diminishes the scope of the problem. Your prior statements about the percentage of patients developing CLTI or claudication are more accurate.	We have reviewed the reference(s) related to this and made edits for accuracy. We strive to provide an objective review and follow accepted standards of systematic review methodology as described in the methods. This reference, which is not used as primary evidence for the review, should not bias the results based on this methodology.
Report objectives and KQs	For the most part yes, the questions address the relevant issues however it is a bit difficult to assess the "effectiveness" of a treatment without clarifying what that effectiveness means. This could often be addressed by stating a timeline for how long it should work for (solves the problem short time, long term, etc.) This would also make it easier to clearly define if the questions were adequate for achieving the aims. An example in this space is the SVS guidelines for treating claudication and the study on if endovascular interventions met those guidelines. Questions on safety are not specific. are you asking if the interventions are safe to perform as procedures or if they are safe in the long run? Key questions clearly defined and adequate for achieving aims? -See above	The Key Questions and PICOTS scope were based on clinical input and the policy questions posed by the agency. They were established a priori as the basis for this review. DRAFT KQ and PICOTS were also posted for public comment. Comments were considered prior to finalization. Based on this input, patient-important outcomes are listed as the primary clinical outcomes in the PICOTS inclusion/exclusion table for effectiveness. Harms are also listed in the PICOTS table to reflect specific procedure-related harms,

	Comment	Response
		including long-term, as well as those related to the durability of the intervention (e.g., need for amputation). We report on the harms/outcomes as described in the included studies.
Section on CLTI	It is not appropriate to compare endovascular interventions to conservative therapy in CLTI because conservative therapy in this case is known to lead to amputation so there is no longer equipoise in this question. The question becomes comparing endovascular therapy to open surgical techniques.	Thank you for your comments. The comparator was included as we understand that a proportion of patients with CLI may be not candidates for revascularization and that there has been research related to conservative management in patients with CLI. (Martini R. Vasc Invest Ther 2021;4:87-94) Authors of the BASIL trial (Adams, 2005) suggest that about half of patients presenting with severe limb ischemia may be suitable for revascularization. We did not identify studies that met our inclusion criteria for a comparison with conservative care.
Methods	No, in a clinical space with such limited Level1A evidence it becomes more important to include all types of studies that contribute to the question so excluding smaller studies, NRSI or studies comparing types of interventions reduces your power for effect analysis. Obviously those studies have higher levels of bias but this can be noted rather than excluded. Additionally in this space, uncoated balloons are not considered equivalent to drug coated balloons. For demonstration I would note that if only 4 of 6256 trials analyzed meet criteria for high quality/low bias then your report becomes severely biased into what those 4 reports suggest.	Per the PICOTS/methodology, the intention is to focus on the evidence for least potential for bias. Particularly for the evaluations of subjective patient reported outcomes (e.g., pain) where there may be substantial potential for selection bias, confounding by indication and confounding by important prognostic factors and NRSI results may be misleading and contradictory. Important prognostic factors include comorbid conditions, patient overall health and lifestyle factors in addition to age and sex. It is frequently difficult to adequately control for such factors particularly in retrospective NRSI and administrative data studies. For some outcomes (e.g., amputation) consideration of competing risks may also be important (REF Vasc Med. 2024 October; 29(5): 496–506). Administrative database studies in particular may not adequately capture confounding factors.

	Comment	Response
		Patient and intervention characteristics as well as outcomes may be also misclassified depending on the data source and methods for extracting and analyzing the data. Per the PICOTS, large NRSIs that controlled for confounding were considered to help evaluate rare or long-term harms that generally are difficult to capture in RCTs. The NRSI we identified did not consistently control for important prognostic factors related to harms in particular. Studies evaluated at full text for this review either did not control for prognostic factors and/or did not provide analyses on outcomes of interest listed in the PICOTS. Most were rated at high risk of bias and thus evidence was considered insufficient. We understand that uncoated and drug-coated balloons may not be considered equivalent. Where information was available, we indicated what type of balloon (or stent) was used. There was insufficient data to stratify by type. Comparisons of types of balloons or types of stents were not within the scope of this review. Our search was intentionally broad, consistent with accepted methodological standards. Most citations returned by a broad systematic search of the bibliographic databases are not relevant. Broad searches include case reports, case series as well as citations not relevant to the topic. Few relevant randomized controlled trials may be identified, depending on the topic and key questions. Exclusion of a large proportion of studies from a broad search very common in reviews of this type (e.g., reviews for ARHQ, Cochrane, etc.). Most citations get removed

	Comment	Response
		from consideration based on review at the title/abstract level when compared with the established inclusion/exclusion criteria for the review. For this review, while a number of randomized controlled trials were identified, they did not meet the inclusion/exclusion criteria set *a priori* generally because they did not address the interventions and comparators articulated by these criteria. In particular, most RCTs were excluded as they compared types of ballons, types of stents or compared balloons to stents and thus were not in the scope of this review. Trials of endovascular treatments other than angioplasty or stenting (e.g., atherectomy) were excluded as well. These excluded trials may be relevant to answering different questions related to different intervention/comparator combinations. Dual review was done at both the title/abstract level and at evaluation of full text to help assure objectivity and that the studies met the inclusion criteria. The list of studies excluded at full text review and rationale for exclusion is documented in Appendix C
Results	Key questions are answered? • No, Though, I think this is only partly due to the report and largely reflective on the availability of high quality data in this specific medical space. However, this is also why it is so important to lean towards lower quality evidence and even expert opinion and just acknowledge this rather than exclude these things from the analysis Have gaps in the literature been dealt with adequately? • No, there is a large proportion of "no evidence" fields and not much description as to why or how to interpret that information.	Yes, for some questions, there is limited high-quality evidence. Per the PICOTS/methodology, the intention is to focus on the evidence for least potential for bias. Concerns related to inclusion of lower quality evidence are described in the comments above under methods. "No evidence" denotes that there were no studies that met the inclusion criteria. We have clarified this. The areas of "no evidence" point to gaps in the literature available to answer the KQ based on the PICOTS.

	Comment	Response
Overall Presentation & Relevancy, General Comments	Is the review well-structured and organized? • Moderately. The overall key clinical questions are valid however the data is presented to mirror the available evidence rather than to answer the precise questions. Additionally the clinical questions are close enough to each other that the same very few studies are presented over and over and over again to summarize the findings for each of the clinical questions. When the entire report is generated off of so few studies it would be more appropriate to summarize the individual studies and then make recommendations accordingly. The most useful portion of the report is actually the summary of the guidelines that are already published.	Thank you for your comments. We attempt to describe patterns seen across the studies for the primary outcomes by key questions as part of the synthesis across studies while pointing out aspects of individual studies that may introduce heterogeneity or may impact synthesis across them. Individual study information is also available in the report and the data abstraction. We can only report on the data that is available for the key questions from the included studies. To the extent that included studies report on multiple outcomes, they are cited appropriately in multiple sections of the report.
Overall Presentation & Relevancy, General Comments	Are the main points clearly presented? • Moderately for the same reason as listed above.	Please see above responses.
Overall Presentation & Relevancy, General Comments	Is it relevant to clinical medicine? Yes, overall these are very important clinical questions.	Thank you for your comments.
Overall Presentation & Relevancy, General Comments	Is it important for public policy or public health? • It is very important for both public policy and public health however the narrowing of the data selection adds significant bias to the overall results	Thank you for your perspective. We followed accepted methods for systematic review to maintain objectivity in reporting, including *a priori* specification of KQ and PICOTS criteria which were developed with clinical input to address the policy questions of the agency.
Quality Rating	**Quality of Report** Superior Good Fair **X** Poor	Thank you for your comments
Rita Redberg, MD MS, Professor of Medicine, School of Medicine, University of California, San Francisco		
	Specific comments	

	Comment	Response
Report Objectives and KQs	The report aims and objectives clearly address relevant policy and clinical issues. The key objectives are well described and the key questions address the questions we see in everyday clinical practice. The key questions included both a comparison of balloon angioplasty and stenting to conservative care as well as to surgery. They examined both safety and effectiveness, and looked at differential harms depending on patient subgroup and comorbidities. The report also looks at cost-effectiveness of these procedures compared to both conservative care, and to surgery. These key questions and scope address all reasonable clinical situations and comparisons and represent an exhaustive literature review.	Thank you for your comments
Methods	Although I understand that these statement may come from professional guidelines, they are not based on high quality studies. Statements such as below seem misleading and not in patients interest: "However, these symptoms are present in the minority of patients with PAD and symptoms may be atypical. Patient presentation and symptoms are heterogeneous. Patients may not report exertional leg symptoms but may experience functional impairment and decline.43 Some researchers suggest that only 5% to 10% of patients with PAD have identifiable symptoms of IC, while others indicate that 8.7% to 32% present with IC symptoms.18,26,68" Risk factor reduction via lifestyle counseling and medical management when appropriate of blood pressure and other risk factors, such as obesity, etc. should be offered to all patients."	Thank you for your comments. We have made edits to the introduction and background.
Methods	The HTA team did an excellent job identifying all of the relevant studies and an exhaustive analysis. The search is well described in the Methods, and meets the highest standards for literature review. They not only pulled and reviewed all of the relevant studies, and guidelines, but also and importantly analyze for risk of bias, and strength of evidence. Data abstraction and analysis/review are carefully done. The methods, population, length of follow up, any technical issues with the trial and endpoints are all described for each trial and also summarized in the Tables. The criteria for inclusion and exclusion are all appropriate. The risk of bias and study quality assessment is well done, and clearly explained.	Thank you for your comments

	Comment	Response
Results	Results are clearly laid out in the text and supplemented by the tables. All of the key questions and objectives have been addressed and answered. The major findings are clearly stated and gaps in the literature (dearth of high quality RCT) are addressed.	Thank you for your comments
Summary	The general conclusions in the ES are well supported and valid.	Thank you for your comments
Overall Presentation & Relevancy, General Comments	In terms of relevance to clinical medicine, I would like to emphasize that PAD is a disease that presents with symptoms, of intermittent claudication. I note this point as unfortunately, there have been a proliferation of screening programs for PAD, which seek to identify disease and offer revascularization to people that are not having symptoms of PAD. As well described in Marty Makary's, The Price We Pay, peripheral revascularization is a highly profitable procedure and there is widespread inappropriate use of this procedure. He describes health screening fairs aimed to generate revascularization procedures in people who will not benefit from the procedures, will suffer harms and most have no symptoms of IC. Such inappropriate use results in patient harms. If people don't have symptoms, it is not clear to me why they would be diagnosed as having PAD. There is no benefit to screening for PAD. There is no specific treatment for "asymptomatic PAD". All patients with PAD likely have other vascular disease, and certainly risk factors for ASCVD, so all should be counseled on healthy diet, physical activity and smoking cessation. There is no reason to do testing for PAD in someone with no symptoms. Testing is not even necessary on all patients with IC, as treatment in the form of exercise, and smoking cessation can and should be offered without testing first. The counseling and management is the same for PAD (and other types of vascular disease) and should be focused on healthy lifestyle and smoking cessation support. This report is extremely important to public health and clinical medicine.	Thank you for your comments

	Comment	Response
Quality Rating	**Quality of Report** Superior **X** Good Fair Poor	Thank you for your comments

ASCVD = atherosclerotic cardiovascular disease; CLTI = chronic limb-threatening ischemia; ES = executive summary; GDMT = guideline-directed medical therapy; HTA = Health Technology Assessment; IC = intermittent claudication; KQ = key question; MACE = major adverse cardiovascular event; NRSI = non-randomized study if intervention; PAD = peripheral artery disease; PICOTS = populations, intervention, comparator, outcomes, timing, setting; RCT = randomized controlled trial

This second section responds to comments received during the public comment period from the following:

- Washington State Agency Medical Directors
- Jason McKitrick, Principal of Liberty Partners Group on behalf of ACR, OEIS, SCAI, SIR, and SVS ("Societies").
- Christopher Ward, Vascular Surgery, Multicare/PULSE Heart and Vascular Institute; Regional Medical Director, Inland Northwest.

Responses to public comment on draft report

No individuals provided general public comment (i.e., not addressing evidence, project scope, or draft key questions) on the topic of/their personal experience with angioplasty or stenting

Complete comments submitted and associated data are attached following the responses below.

Table 2. Responses to public comments

Comment	Commenter	Response
The comparator groups for angioplasty and stenting are reported as optimal medical therapy OR supervised exercise therapy. Were there any studies comparing angioplasty/stenting to both OMT and SET? Ie—intervention compared to conservative. (Later in report, it seems OMT includes SET—page 59) May need more clarification (and may differ by study- which should be highlighted).	Agency Medical Directors	One trial (CLEVER) randomized a group to SET + MT, and another group to MT alone. Trials that specified SET as a comparator were evaluated separately from studies that provided advice to exercise. We have made edits to the report to clarify aspects of conservative care as they were reported. Trials provided limited detail of what was included for medical therapy and if exercise was mentioned, unless SET was specified and described, the assumption was that it was general advice to exercise. It is unclear across trials that conservative care, including medical therapy was optimized or that it was truly guideline-directed. We have edited the report to reflect this. It is likely that all patient in trials received some level of counseling and medical therapy to address comorbidities to reduce risk for cardiovascular events, given that patients with PAD P Tables 17, 19, and 20 provide details as reported by trial authors and additional detailed data abstraction is in the appendices.
Was there consideration or discussion of excluding studies beyond a certain date? For example, some studies referenced are >20 years old. (Creasy, Perkins, Whyman all from 1990s) Medical therapy has substantially evolved since 1990s as have methods for percutaneous interventions. (evident for example in percentage of groin hematomas in Creasy (1990) – 15% vs Koelemay (2022) – 4%.	Agency Medical Directors	Our search strategy searched from database inception. We did not exclude studies before a certain date. We recognize that there have been changes to medical practices and technology, in particular regarding stenting and use of drug coated or drug eluting devices. There were insufficient studies to do sensitivity analysis based on study age or technology type or age. We provide information on the devices as reported in the included trials throughout the report. The concern regarding changes in technology and practice versus what

		is reflected current practice is discussed in the Executive Summary.
For the results reported in table 20—was the SET before PTA, or after PTA? Important distinction esp in context of insurance policies which require medical and exercise therapy prior to PTA.	Agency Medical Directors	The included studies did not give detailed information on the timing of PTA and SET, but where otherwise stated, it is assumed that SET started within weeks of receiving PTA. Where information was reported, we reported the information.
Page 17. Consider reworking how the guidelines from the different organizations are presented. The table format starting on page 20 is helpful, but this narrative section is confusing.	Agency Medical Directors	We have made edits to the narrative. The guidelines themselves are very detailed and contain many nuances and should be consulted for additional detail.
Page 17. For Aortoiliac disease, is revascularization recommended first-line along with GDMT and SET? After GDMT and SET? Without GDMT and SET?	Agency Medical Directors	The guideline summary in the draft report focused on recommendations for use of revascularization methods (e.g. endovascular treatment or surgery) specifically and does not provide details regarding use of SET or GDMT. The statement in the draft report on page 17 is specific to the SVS guideline about first line therapy *when revascularization is considere*d vs. overall first-line therapy. In general, the guidelines and input from clinical experts indicate that counseling on lifestyle modifications including smoking cessation and exercise in general are the first line of treatment for PAD and to reduce risks for disease progression. This part of guideline directed medical therapy. Medical therapies are primarily intended to reduce risk of major adverse cardiovascular events and to many comorbidities (e.g., diabetes) and part of care whether or not revascularization is done. SVS guidelines state that revascularization may be appropriate in patients with IC for select patients with disabling symptoms after careful risk-benefit analysis. (Conte, J Vasc Surg 2015;61:2S-41S.), with endovascular favored for most individuals with

		aorto-iliac disease and select patients with femoropopliteal disease. The ACC/AHA guidelines recommend that revascularization (endovascular, surgical or hybrid) should be used to prevent limb loss in CLTI and can be used to improve functional status and quality of life in patients with IC who have not responded to structured exercise and medical therapy. (Gornik 2024, JACC vol 83 , no 24, pages 2497 – 2604). For CLTI, SVS states that revascularization hinges on patient risk (of procedural and all-cause mortality), limb severity and anatomic complexity. (Conte 2019 Journal of Vascular Surgery, Volume 69, Issue 6, 3S - 125S.e40)
Table 10 Page 29. Is ABI a symptom?	Agency Medical Directors	This was a mistake carried forward from an earlier version of the table. It has been removed.
Concerned that "sound clinical judgement" did not inform the review, that the AAI team lacks clinical experience, and that clinicians were not involved in the report.	Societies*	KQs and scope were refined and reviewed by clinical experts, and clinical experts were consulted throughout the review process. A clinician was on the review team.
Concerns that the change of the title from "Endovascular Intervention in Lower Extremity Peripheral Arterial Disease and Intermittent Claudication" limited the scope too much, and that the report does not address additional endovascular procedures, including atherectomy, atherectomy with stent, intravascular lithotripsy, intravascular ultrasound and transcatheter arterialization of the deep veins. Further concern that the HTCC will not make decisions for these procedures based on the report, but instead focus on the technologies addressed in the report.	Societies*	Comments pertaining to formulation of policy do not require a response by the evidence vendor. The vendor does not suggest, recommend, determine, or evaluate coverage policy.
Concerns that CLTI and IC are two very different populations.	Christopher Ward Societies*	We understand that CLTI and IC are different patient populations, and that treatment will vary. We attempted to report severity of disease and whether

		patients were classified as CLTI or IC based on how articles reported this information. Trials of BA or stenting versus conservative care were in patients with IC. Trials comparing these technologies with bypass were heterogenous as some included only patient with CLTI, some only included patients with IC and others consisted of populations having both IC an CLTI. There was insufficient data to stratify by condition or reported severity. This is discussed in the report. The demographic tables, associated text and detailed data abstraction contain additional information on this. Also of note, over the years there have been some changes in the terminology and diagnostic considerations for CLTI criteria described in trials varied.
Concerns regarding the inclusion of SET as a comparison group. Urge not to discontinue or limit coverage for any procedure on the basis of comparison to SET.	Christopher Ward Societies*	Comments pertaining to formulation of policy do not require a response by the evidence vendor. The vendor does not suggest, recommend, determine, or evaluate coverage policy. Prior to publishing the final KQ and PICOTs, all public comments from topic selection, draft key question/PICOTS posting were reviewed, and AAI sought clinical input. All of this was discussed with the HTAP.
Concern that some studies (e.g. related to conservative therapy) were not included in the report.	Societies*	The commenters do not provide a list of recommended studies, thus, we cannot determine which studies commentors feel were excluded in error, or why they were left out of the review. A complete list of excluded studies reviewed at full text can be found in Appendix C. It is not uncommon when performing a broad search to exclude a large percentage of studies that do not meet inclusion criteria. For example, in recent previous high-quality reviews on PAD, literature searches identified between 1,115 and 14,239 unique citations, with anywhere from <1% to 2% citations being relevant for inclusion.

Concerns that "device-device" studies were excluded, and that the report should have considered incremental product improvements that occur with each new generation of device.	Societies*	Comparison of different devices was not part of the review scope. Per the PICOTs, we did not compare different types of PTA or stents to each other. The scope was discussed with the HTA program during topic refinement that included clinical input. Trials evaluating newer devices were included if they met the *a priori* inclusion criteria. Comparisons with conservative care or usual practice are important to evaluation of efficacy and safety of a technology. A complete list of studies excluded at full text can be found in Appendix C.
Table A on Page ES-8, referring to reference #52 being incorrect and referring to a Gardner 1992 citation, rather than an RCT of stent vs. OMT.	Societies*	Citation #52 of the executive summary does not refer to Gardner 1992, as stated in the public comment. The executive summary and main report do not share references. Citation #52 refers to Nylaende, 2007 (Nylaende M, Kroese AJ, Morken B, et al. Beneficial effects of 1-year optimal medical treatment with and without additional PTA on inflammatory markers of atherosclerosis in patients with PAD. Results from the Oslo Balloon Angioplasty versus Conservative Treatment (OBACT) study. Vascular medicine (London, England) 2007;12:275-83.), which is included in our report.
Comments that "there are at least one factual error in the draft report".	Societies*	Commentors point out one error as noted above, commentors do not point out other specific errors.
The Draft Report takes an overly broad approach to the topic of PAD. The analysis wishes to conclude whether surgery is superior to endovascular procedures or vice versa. There are patients with different severity of disease and different treatment options that have differential benefits in different patient populations. The Technology Assessment (as Technology Assessments are known to do) does not distinguish the important differences that exist in this	Christopher Ward	Prior to publishing the final KQ and PICOTs, all public comments from topic selection, and draft key question/PICOTS posting were reviewed, and AAI sought clinical input. All of this was discussed with the HTAP program, and the scope was determined to meet the policy interests of the HTAP.

heterogeneous patient population.		

AAI = Aggregate Analytics Inc.; ABI = ankle-brachial index; AHRQ = Agency for Healthcare Research and Quality; CLTI = chronic limb-threatening ischemia; GDMIT = guideline-directed medical therapy; GRADE = Grading of Recommendations Assessment, Development and Evaluation; HCA = Health Care Authority; HTAP Health Technology Assessment Program; HTCC Health Technology Clinical Committee; IC = intermittent claudication; ION = Institute of Medicine; MT = medical therapy; NAM = National Academy of Medicine; KQ = key question; OMT = optimal medical therapy; PAD = peripheral arterial disease; PICOTS = population, intervention, comparator, outcome, timing, and setting; PTA = percutaneous transluminal angioplasty; RCT – randomized control trial; SET = supervised exercise therapy; SOE strength of evidence; SR = systematic review.
* Societies include the American College of Radiology, Society of Interventional Radiology, Outpatient Endovascular and Interventional Society, Society for Cardiovascular Angiography & Interventions, and the Society for Vascular Surgery.

Additional comments were received during the draft key question phase from the following:

- Ty Jones, MD FAAFP CPPS CPHQ, Senior Medical Director, HCA Account, Regence BlueShield, Washington

Table 3 Public Comments During Draft Key Question Phase

Comments	Commenters	Response
Consider adopting the name "Balloon angioplasty and stenting for lower extremity peripheral artery disease" to make it clear that atherectomy, lithotripsy, and endovascular venous arterialization will not be in scope.	Ty Jones (Regence)	The name will be changed to better reflect the scope.
Consider addressing the indication of restenosis to provide consistency across common patient experience due to 20% to 40% risk of requiring restenosis.	Ty Jones (Regence)	Evaluation of treatments for re-stenosis is considered a different situation/condition than de novo treatment and is not part of the scope for this HTA.

HTA = Health Technology Assessment.

APPENDIX: Clinical/peer reviews and public comments received

Peer Reviewer #1: Matthew C. Smith, MD PhD, Assistant Professor of Surgery, Section Head of Vascular Surgery, UWMC Northwest Hospital; Associate Program Director, Vascular Surgery Residency and Fellowship Division of Vascular Surgery, University of Washington

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment (HTA) Review: **Angioplasty and Stenting for Peripheral Artery Disease (PAD)**. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we can pay a **maximum** of 6 hours.

The report and appendices are available at: https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/balloon-angioplasty-and-stenting-lower-extremity-peripheral-arterial-disease

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: andrea@aggregate-analytics.com; please cc: erika@aggregate-analytics.com

We will need your review by Tuesday, July 22, 2025, at the latest.

If you have questions or concerns, please contact andrea@aggregate-analytics.com. Many thanks!

Reviewer Identification Information

Reviewer Name	**Matthew C Smith**
Address	[redacted]
Phone	[redacted]
Fax	**n/a**
E-mail	[redacted]

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate? The overview is adequate, it can be a bit confusing to add in all the incidence/prevalence numbers from different sources, especially when many of those are quoting other references and not specifically designed to look at those incidences.
- Topic of assessment is important to address? Very important
- Public policy and clinical relevance are well defined? yes

Page 10 Line 4

PAD can affect any of the arteries in the body and is termed "peripheral" when described outside the cart or brain. To state that it affects "three major arterial segments" suggests that it is localized. It would be more accurate to state that trials studying PAD are broken down into those 3 segments

Page 10 Line 35-37

Aspirin, statin and antihypertensives shouldn't state "may" be prescribed. There is level 1 evidence for the reduction of MACE with each of these therapies and they are the mainstay of all treatment of PAD

Page 10	Line towards end

If it is important to discuss GDMT in the intro then it's worth mentioning the smoking cessation is the #1 recommendation in applicable patients rather than throwing it in the same sentence as "stress management"

Page 10	Line 28

Reference 43 isn't designed to conclude that "few people with PAD develop critical limb ischemia or amputation." This statement introduces bias into the report and is misleading and diminishes the scope of the problem. Your prior statements about the percentage of patients developing CLTI or claudication are more accurate.

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient? This seems to all be included in the intro section.

Page	Line

Enter Comments Here

Page	Line

Enter Comments Here

Page	Line

Enter Comments Here

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue? -For the most part yes, the questions address the relevant issues however it is a bit difficult to assess the "effectiveness" of a treatment without clarifying what that effectiveness means. This could often be addressed by stating a timeline for how long it should work for (solves the problem short time, long term, etc.) This would also make it easier to clearly define if the questions were adequate for achieving the aims. An example in this space is the SVS guidelines for treating claudication and the study on if endovascular interventions met those guidelines. Questions on safety are not specific. are you asking if the interventions are safe to perform as procedures or if they are safe in the long run?
- Key questions clearly defined and adequate for achieving aims? -See above

Page 11	Line Section on CLTI

It is not appropriate to compare endovascular interventions to conservative therapy in CLTI because conservative therapy in this case is known to lead to amputation so there is no longer equipoise in this question. The question becomes comparing endovascular therapy to open surgical techniques.

Page	Line

Enter Comments Here

Page	Line

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METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate? yes
- Criteria for the inclusion and exclusion of studies is appropriate? No, in a clinical space with such limited Level1A evidence it becomes more important to include all types of studies that contribute to the question so excluding smaller studies, NRSI or studies comparing types of interventions reduces your power for effect analysis. Obviously those studies have higher levels of bias but this can be noted

rather than excluded. Additionally in this space, uncoated balloons are not considered equivalent to drug coated balloons. For demonstration I would note that if only 4 of 6256 trials analyzed meet criteria for high quality/low bias then your report becomes severely biased into what those 4 reports suggest.
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained? yes
- Data abstraction and analysis/review are adequate? yes

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RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate? Yes
- Key questions are answered? No, Though, I think this is only partly due to the report and largely reflective on the availability of high quality data in this specific medical space. However this is also why it is so important to lean towards lower quality evidence and even expert opinion and just acknowledge this rather than exclude these things from the analysis
- Figures, tables and appendices clear and easy to read? yes
- Are the major findings clearly stated? yes
- Have gaps in the literature been dealt with adequately? No, there is a large proportion of “no evidence” fields and not much description as to why or how to interpret that information.

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Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy) Yes

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized? Moderately. The overall key clinical questions are valid however the data is presented to mirror the available evidence rather than to answer the precise questions. Additionally the clinical questions are close enough to each other that the same very few studies are presented over and over and over again to summarize the findings for each of the clinical questions. When the entire report is generated off of so few studies it would be more appropriate to summarize the individual studies and then make recommendations accordingly. The most useful portion of the report is actually the summary of the guidelines that are already published.
- Are the main points clearly presented? Moderately for the same reason as listed above.
- Is it relevant to clinical medicine? Yes, overall these are very important clinical questions.
- Is it important for public policy or public health? It is very important for both public policy and public health however the narrowing of the data selection adds significant bias to the overall results

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QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior ☐

Good ☐

Fair x☐

Poor ☐

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We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

This form is very inefficient. The sections of the form do not in any way match the section titles of the report. There are no line numbers on any pages so the format of “page, Line” doesn’t really apply.

Peer Reviewer #2: Rita Redberg, MD MS, Professor of Medicine, School of Medicine, University of California, San Francisco

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment (HTA) Review: **Angioplasty and Stenting for Peripheral Artery Disease (PAD)**. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we can pay a **maximum** of 6 hours.

The report and appendices are available at: https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/balloon-angioplasty-and-stenting-lower-extremity-peripheral-arterial-disease

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: andrea@aggregate-analytics.com; please cc: erika@aggregate-analytics.com

We will need your review by Tuesday, July 22, 2025, at the latest.

If you have questions or concerns, please contact andrea@aggregate-analytics.com. Many thanks!

Reviewer Identification Information

Reviewer Name	**Rita Redberg**
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INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

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BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

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REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

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The report aims and objectives clearly address relevant policy and clinical issues. The key objectives are well described and the key questions address the questions we see in everyday clinical practice. The key questions included both a comparison of balloon angioplasty and stenting to conservative care as well as to surgery. They examined both safety and effectiveness, and looked at differential harms depending on patient subgroup and comorbidities. The report also looks at cost-effectiveness of these procedures compared to both conservative care, and to surgery. These key questions and scope address all reasonable clinical situations and comparisons and represent an exhaustive literature review.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

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Although I understand that these statement may come from professional guidelines, they are not based on high quality studies. Statements such as below seem misleading and not in patients interest -
"However, these symptoms are present in the minority of patients with PAD and symptoms may be atypical. Patient presentation and symptoms are heterogeneous. Patients may not report exertional leg symptoms but may experience functional impairment and decline.43 Some researchers suggest that only 5% to 10% of patients with PAD have identifiable symptoms of IC, while others indicate that 8.7% to 32% present with IC symptoms.18,26,68"

Risk factor reduction via lifestyle counseling and medical management when appropriate of blood pressure and other risk factors, such as obesity, etc. should be offered to all patients.

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The HTA team did an excellent job identifying all of the relevant studies and an exhaustive analysis. The search is well described in the Methods, and meets the highest standards for literature review. They not only pulled and reviewed all of the relevant studies, and guidelines, but also and importantly analyze for risk of bias, and strength of evidence. Data abstraction and analysis/review are carefully done. The methods, population, length of follow up, any technical issues with the trial and endpoints are all described for each trial and also summarized in the Tables. The criteria for inclusion and exclusion are all appropriate. The risk of bias and study quality assessment is well done, and clearly explained.

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Are the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?

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Results are clearly laid out in the text and supplemented by the tables. All of the key questions and objectives have been addressed and answered. The major findings are clearly stated and gaps in the literature (dearth of high quality RCT) are addressed.

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Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy)

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The general conclusions in the ES are well supported and valid.

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

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In terms of relevance to clinical medicine, I would like to emphasize that PAD is a disease that presents with symptoms, of intermittent claudication. I note this point as unfortunately, there have been a proliferation of screening programs for PAD, which seek to identify disease and offer revascularization to people that are not having symptoms of PAD. As well described in Marty Makary's, The Price We Pay, peripheral revascularization is a highly profitable procedure and there is widespread inappropriate use of this procedure. He describes health screening fairs aimed to generate revascularization procedures in people who will not benefit from the procedures, will suffer harms and most have no symptoms of IC. Such inappropriate use results in patient harms.

If people don't have symptoms, it is not clear to me why they would be diagnosed as having PAD. There is no benefit to screening for PAD. There is no specific treatment for "asymptomatic PAD". All patients with PAD likely have other vascular disease, and certainly risk factors for ASCVD, so all should be counseled on healthy diet, physical activity and smoking cessation. There is no reason to do testing for PAD in someone with no symptoms. Testing is not even necessary on all patients with IC, as treatment in the form of exercise, and smoking cessation can and should be offered without testing first. The counseling and management is the same for PAD (and other types of vascular disease) and should be focused on healthy lifestyle and smoking cessation support.

This report is extremely important to public health and clinical medicine.

QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior X☐

Good ☐

Fair ☐

Poor ☐

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