November 8, 2025

Part A Policy
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RE: Endovascular Management for Peripheral Arterial Disease of the Upper and Lower Extremities (DL40228)

To whom it may concern:

The Outpatient Endovascular and Interventional Society, the American College of Cardiology, the Association of Black Cardiologists, the Society of Interventional Radiology, the Society for Cardiovascular Angiography and Interventions, and the Society for Vascular Surgery appreciate the opportunity to offer comments to Palmetto GBA on the Proposed Local Coverage Determination (LCD): Endovascular Management for Peripheral Arterial Disease of the Upper and Lower Extremities (DL40228). The societies signing this letter 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] Every day the members of our societies strive to help patients who struggle with peripheral

[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.

artery disease to complete normal daily activities without significant leg pain and to help patients with critical limb threatening ischemia (CLTI) keep their legs. Our societies 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.

We commend Palmetto GBA's commitment to improving patient outcomes and ensuring appropriate use of endovascular therapies. However, several provisions of this proposed LCD diverge from the statutory and regulatory standards set forth under Section 1862(a)(1)(A) of the Social Security Act, which requires that services be "reasonable and necessary" for the diagnosis or treatment of illness or injury. Furthermore, multiple elements are inconsistent with current national clinical practice guidelines and evidence-based practice.

This letter offers recommendations, including specific revisions, clarifications, and suggested language changes to align the LCD with evidence-based practice, preserve physician discretion, and maintain access to high-quality, cost-effective care in outpatient settings.

I. Limitations for Endovascular Revascularization

The proposed LCD lists several exclusions under which endovascular revascularization would be deemed not reasonable and necessary, including lack of 90 days of medical therapy or supervised exercise and performance in non-accredited facilities. We respectfully disagree with these blanket exclusions.

This requirement may be reasonable for stable claudication but is unsafe and clinically inappropriate for patients with CLTI or acute limb ischemia (ALI). Mandating a 90-day waiting period risks irreversible ischemic damage or amputation. The 2024 AHA/ACC PAD guidelines emphasize individualized assessment rather than arbitrary timeframes.

We do note that supervised exercise therapy is dependent on patient accessibility to such programs. In many rural locations this may not be available, or patients may be unable to attend such activities to continue with their job. In such instances, it is appropriate to provide instructions on walking exercise that the patient can comply with at home with the indirectly monitored supervision of their care provider.

Recommendation: We recommend replacing this provision with language that exempts CLTI and ALI and allows physician judgment for severe claudication. Alternatively, we would recommend "structured," rather than "supervised" exercise therapy. Structured exercise is a recognized and approved CMS quality measure and has been utilized by registries, such as the OEIS National Registry, to report MIPS quality measures.

II. Provider Qualifications and Site of Service

We firmly support appropriate credentialing, facility oversight, and quality assurance, but do not endorse the imposition of mandatory "national accreditation standards" that would create unnecessary and duplicative regulatory and financial burdens for office-based laboratory (OBL) owners. The LCD should instead acknowledge that OBLs operating under existing CMS Conditions for Coverage, state licensure, and professional oversight mechanisms already meet high standards of safety and quality.

Numerous peer-reviewed studies demonstrate that procedures performed in office-based laboratories are

equally safe, and in some cases safer, than those performed in hospital outpatient departments (HOPDs) or ambulatory surgical centers (ASCs) when performed by appropriately trained physicians with established safety protocols.[7][8][9][10]

These findings confirm that OBLs already maintain rigorous quality and safety standards through well-established practices in use today—including credentialing, staff training, and emergency protocols—without the need for additional, duplicative, and costly national accreditation mandates.

Recommendation: We recommend that Palmetto GBA recognize and preserve the effectiveness of these existing safety systems and strike any language suggesting that national accreditation by a specific external body is required for reimbursement or coverage.

III. Acute Limb Ischemia

ALI represents a vascular emergency with a 15% thirty-day mortality rate. Limiting revascularization solely to amputation prevention fails to recognize systemic risks such as compartment syndrome, loss of function, and sepsis. Revascularization is medically necessary to preserve limb viability and reduce mortality.

Recommendation. We urge Palmetto GBA to clarify this in the final LCD.

IV. Claudication

The LCD relies on Conte et al. (2015) to require >50% two-year patency likelihood for coverage. This benchmark is outdated. The 2024 AHA/ACC and SVS/SCAI/AHA guidelines favor and explicitly endorse individualized decision-making.

Recommendation: We recommend removing rigid numeric thresholds and substituting a standard based on documented functional improvement and symptom relief.

V. Requests for Clarification and Revision

We respectfully request Palmetto GBA to: 1) remove fixed guideline-directed medical therapy (GDMT) / Supervised Exercise Therapy (SET) timelines for CLTI/ALI; 2) remove accreditation requirements; 3) eliminate surgical preference bias; 4) update citations to 2024 guidelines; and 5) reinforce patient-centered decision-making.

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[7] Aurshina et al., 2021 (J Vasc Surg Cases Innov Tech, 7(4): 673-680) reviewed 6,201 consecutive OBL procedures over four years and reported zero peri-procedural mortality, no myocardial infarctions or strokes, and only 0.5 % minor complications, with 30-day mortality (unrelated to procedure) 0.32 %.

[8] Jain et al., 2024 (J Soc Cardiovasc Angiography Interv, "Running a Quality-Focused Office-Based Laboratory") found OBL outcomes comparable to or better than hospital and ASC benchmarks when standard safety protocols are used.

[9] Kumar et al., 2021 (J Vasc Surg, 73(6): 2111-2118) reported no difference in major adverse events between OBL and HOPD settings for lower-extremity revascularization, while OBL care reduced cost and improved access.

[10] The OEIS Clinical Registry (2023) likewise documents consistently low complication rates across thousands of OBL procedures nationwide.

VI. Additional Considerations Relevant to OBLs and Policy Implementation

The LCD references intraoperative imaging modalities including digital subtraction angiography (DSA), intravascular ultrasound (IVUS), and extravascular ultrasound (EVUS) as "reasonable and necessary." We agree that these may enhance procedural success but strongly caution against interpreting them as mandatory. Mandating such technologies would disproportionately burden smaller OBLs, increasing procedural costs by 20–30% without clear evidence of improved outcomes in all lesion subsets.

Recommendation: We request language clarifying that use of these adjuncts remains at the physician's discretion.

VII. Conclusion

We appreciate the opportunity to engage constructively with Palmetto GBA on this important policy. The recommendations contained herein align the LCD with the statutory standard of "reasonable and necessary," current national clinical guidelines, and CMS's objectives of cost-effective, high-quality care.

We respectfully request that Palmetto GBA incorporate these modifications before finalizing the LCD and consider convening a joint stakeholder working group to ensure continued alignment with evidence-based practices and patient-centered outcomes.

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

Sincerely,

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David Han, MD, Chair, SVS Coding Committee

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2. Society for Vascular Surgery. 2024 Clinical Practice Guidelines for Chronic Limb-Threatening Ischemia (CLTI).
3. SVS / SCAI / AHA Joint Consensus Statement on Revascularization in PAD (2024).
4. Conte MS, et al. Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. J Vasc Surg. 2019;69(6S):S3-S125.
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7. Kumar V, et al. Outcomes of Endovascular Procedures in OBL vs HOPD. J Vasc Surg. 2021;73(6):2111-2118.
8. OEIS Clinical Registry Annual Report. OEIS Publications, 2023.
9. Medicare Program Integrity Manual, CMS Pub. 100-08, Chapter 13 (§13.5.4, §13.7.1).
10. CMS National Coverage Determination (NCD) 20.7 – Percutaneous Transluminal Angioplasty.
11. CMS National Coverage Determination (NCD) 20.35 – Supervised Exercise Therapy for PAD.
12. Palmetto GBA. Proposed Local Coverage Determination DL40228 (2025).
13. Centers for Medicare & Medicaid Services. 42 CFR §410.27 – Conditions for Coverage for Outpatient Therapeutic Services.