

Society for Vascular Surgery SVS

May 28, 2024

Sent electronically via email to tpower@aimspecialtyhealth.com

Tomas Power, MD National Medical Director, Cardiology and Sleep Programs **Carelon Health** 220 Virginia Avenue Indianapolis, IN 46204

RE: Endovascular Revascularization 2023-06-18

Dear Dr. Power,

We are writing on behalf of the Society for Cardiovascular Angiography and Interventions (SCAI), the Society of Interventional Radiology (SIR), the American College of Cardiology (ACC), the Society for Vascular Surgery (SVS), and the Outpatient Endovascular and Interventional Society (OEIS) to address the medical policy Endovascular Revascularization 2023-06-18. We believe that the policy as written is restrictive to best patient care and inconsistent with current appropriate use criteria and research.

Our concerns relate to your atherectomy policy that states "The use of atherectomy is considered not medically necessary for all indications."

Atherectomy can be utilized and should be approved as an adjunct to angioplasty or stenting in peripheral disease. The ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Interventions state that atherectomy may be appropriate for femoropopliteal and below the knee artery disease (tables 5.4 and 5.5).1

¹ Bailey SR, Beckman JA, Dao TD, Misra S, Sobieszczyk PS, White CJ, Wann LS; on behalf of the ACC Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237. doi: 10.1016/j.jacc.2018.10.002.

Revascularization for patients diagnosed with critical limb ischemia (or chronic limb threatening ischemia) is critical for the reduction of high morbidity and mortality associated with limb loss.¹ Atherectomy utilized in patients with chronic limb-threatening ischemia has shown to preserve limbs and provide positive outcomes.²

Atherectomy is often utilized for plaque modification. For example, a lesion that on IVUS shows extensive superficial calcification may be treated with atherectomy to avoid extensive dissection and the need for stent placement. Also, SCAI criteria for appropriate use clearly support the use of drug-eluting balloons for mechanical or laser peripheral atherectomy for the treatment of in-stent restenosis of peripheral arteries.³ Laser atherectomy is also backed by randomized clinical trials⁴⁵, indicated by the FDA for ISR⁶ and supported by SCAI appropriate use guidelines² for diffuse (>20cm) lesions and entire combination of ISR, CTO and undilatable lesions.

We respectfully request that Carelon revise this policy to reflect the appropriate treatment of peripheral artery disease and include coverage for atherectomy. We also would like to request a meeting to discuss this matter further.

Sincerely,



James Hermiller, MD, MSCAI President Society for Cardiovascular Angiography and Interventions

² Giannopoulos S, Secemsky EA, Mustapha JA, et al. Three-Year Outcomes of Orbital Atherectomy for the Endovascular Treatment of Infrainguinal Claudication or Chronic Limb-Threatening Ischemia. J Endovasc Ther Off J Int Soc Endovasc Spec. 2020;27(5):714-725. doi:10.1177/1526602820935611

³ Klein, A. J., Jaff, M. R., Gray, B. H., Aronow, H. D., Bersin, R. M., Diaz-Sandoval, L. J., Dieter, R. S., Drachman, D. E., Feldman, D. N., Gigliotti, O. S., Gupta, K., Parikh, S. A., Pinto, D. S., Shishehbor, M. H., & White, C. J. (2017). SCAI appropriate use criteria for peripheral arterial interventions: An update. Catheterization and Cardiovascular Interventions, 90(4). https://doi.org/10.1002/ccd.27141

⁴ Dippel EJ, Makam P, Kovach R, George JC, Patlola R, Metzger DC, Mena-Hurtado C, Beasley R, Soukas P, Colon-Hernandez PJ, Stark MA, Walker C; EXCITE ISR Investigators. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial results from the EXCITE ISR trial (EXCImer Laser Randomized Controlled Study for Treatment of Femoropopliteal In-Stent Restenosis). JACC Cardiovasc Interv. 2015 Jan;8(1 Pt A):92-101. doi: 10.1016/j.jcin.2014.09.009. Epub\2014 Dec 10. PMID: 25499305.

⁵ Gandini R, Del Giudice C, Merolla S, Morosetti D, Simonetti G. Treatment of Chronic SFA In-Stent Occlusion With Combined Laser Atherectomy and Drug-Eluting Balloon Angioplasty in Patients With Critical Limb Ischemia: A Single-Center, Prospective, Randomized Study. Journal of Endovascular Therapy. 2013;20(6):805-814. doi:10.1583/13-4308MR.1

⁶ Lookstein, R., Haruguchi, H., Ouriel, K., Weinberg, I., Lei, L., Cihlar, S., & Holden, A. (2020). Drug-coated balloons for dysfunctional dialysis arteriovenous fistulas. New England Journal of Medicine, 383, 733–742. https://doi.org/10.1056/NEJMoa1914617

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Bob Tahara, MD President Outpatient Endovascular and Interventional Society