



November 27, 2023

Christopher Jagmin, M.D.
Executive Medical Officer

Mary Moffitt, M.D.
Chief Medical Officer

Aetna - CVS Health
151 Farmington Ave
Hartford, CT 06156

RE: Policy 0295 Peripheral Atherectomy and Thrombectomy Devices

Dear Dr. Jagmin and Dr. Moffitt:

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 shared concerns regarding the medical policy revision to Policy 0295 Peripheral Atherectomy and Thrombectomy Devices scheduled for March 2024. We believe that the proposed changes to Policy 0295 are restrictive to best patient care and inconsistent with current guidelines and research.

Our primary concerns stem from the list of interventions that are considered experimental and investigational. We ask that you reconsider the following:

1. The use of drug-eluting balloons for in vein grafts and dialysis/vascular accesses, and for the treatment of primary lesion/occlusion of other peripheral arteries because its long-term effectiveness has not been established.
2. Intravascular shockwave lithotripsy of the anterior tibial, common iliac, external iliac, internal iliac, popliteal, posterior tibial, peroneal arteries, and superficial femoral artery for the treatment of atherosclerosis / calcified peripheral arterial lesions / intermittent claudication.

We do not believe categorizing these interventions as experimental or investigational is appropriate. The long-term effectiveness of drug-eluting balloons for arteriovenous fistulas has been demonstrated

in multiple randomized controlled trials and should no longer be deemed experimental.¹²³ SCAI guidelines 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.⁴ The Disrupt PAD III randomized clinical trial with long-term outcomes clearly shows the efficacy of intravascular lithotripsy.⁵

Additionally, we have concerns that the eviCore policy being used for prior authorization is more restrictive than this Aetna policy for atherectomy potentially creating authorization denials for care Aetna intends to provide to patients. According to the eviCore policy:

Atherectomy can be approved as an adjunct to angioplasty prior to stenting in lesions that are $\geq 70\%$ stenosis caused by a highly calcified eccentric plaque; AND able to pass a wire fully across the lesion into the true lumen; AND all of the following:

- Treatment of target lesion will establish inline flow to the foot, with at least 1 runoff vessel.
- Lesion is 20 cm or less in length
- Rutherford chronic ischemia classification 2 or higher, documented in clinical notes
- Debulking to $< 30\%$ diameter stenosis is attainable.

Atherectomy can be utilized and should be approved as an adjunct to angioplasty or stenting, not just prior to stenting. Also, we do not believe it should only allow for highly calcified eccentric plaque. These devices are not only intended for calcified eccentric plaque. We recommend that the language be changed to:

Atherectomy can be approved as an adjunct to angioplasty or stenting for atherosclerotic plaque, which results in greater than or equal to 70% stenosis...

¹ Lookstein, R., Haruguchi, H., Suemitsu, K., Isogai, N., Gallo, V., Madassery, S., Misra, S., Wang, H., Roffe, P. S., & Holden, A. (2023). IN.PACT AV access randomized trial of drug-coated balloons for dysfunctional arteriovenous fistulae: Clinical outcomes through 36 months. *Journal of Vascular and Interventional Radiology*. <https://doi.org/10.1016/j.jvir.2023.07.007>

² 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>

³ Trerotola, S. O., Saad, T. F., & Roy-Chaudhury, P. (2019). The lutonix av randomized trial of paclitaxel-coated balloons in arteriovenous fistula stenosis: 2-year results and subgroup analysis. *Journal of Vascular and Interventional Radiology*, 31(1). <https://doi.org/10.1016/j.jvir.2019.08.035>

⁴ 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>

⁵ Tepe, G., Brodmann, M., Bachinsky, W., Holden, A., Zeller, T., Mangalmurti, S., Nolte-Ernsting, C., Virmani, R., Parikh, S. A., & Gray, W. A. (2022). Intravascular lithotripsy for peripheral artery calcification: Mid-term outcomes from the Randomized Disrupt Pad III trial. *Journal of the Society for Cardiovascular Angiography & Interventions*, 1(4), 100341. <https://doi.org/10.1016/j.jscai.2022.100341>

Additionally, we are of the opinion that the lesion length restriction is too specific. Patients can result in clinical scenarios with critical limb ischemia where treatment of a lesion >20 cm is appropriate as the procedure is intended to salvage the limb.

Finally, the requirement “debulking to <30% diameter stenosis is attainable” suggests that debulking is the only role for atherectomy. While in clinical practice, atherectomy is utilized more for plaque modification without the primary goal of debulking. For example, a lesion shown via intravascular ultrasound displays extensive superficial calcification may be appropriately treated with atherectomy and avoid extensive dissection and the need for stent placement. Furthermore, data results support the role for better efficacy of drug-coated devices when plaque modification is performed prior to treatment.⁶

We respectfully request that Aetna make these revisions to the policy to support our members in providing best outcomes to patients. We would be happy to schedule a meeting to discuss this matter further.

Sincerely,

A handwritten signature in black ink, appearing to read "George Dangas". The signature is fluid and cursive, with a prominent loop at the end.

George Dangas, MD, PhD, MSCAI
President
Society for Cardiovascular Angiography and Interventions

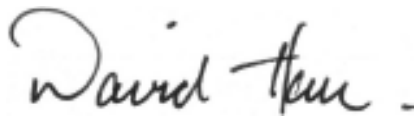
A handwritten signature in black ink, appearing to read "Hadley Wilson". The signature is cursive and somewhat stylized, with a long horizontal stroke at the end.

B. Hadley Wilson, MD, FACC
President
American College of Cardiology

⁶ Tepe, G., Brodmann, M., Bachinsky, W., Holden, A., Zeller, T., Mangalmurti, S., Nolte-Ernsting, C., Virmani, R., Parikh, S. A., & Gray, W. A. (2022). Intravascular lithotripsy for peripheral artery calcification: Mid-term outcomes from the Randomized Disrupt Pad III trial. *Journal of the Society for Cardiovascular Angiography & Interventions*, 1(4), 100341. <https://doi.org/10.1016/j.jscai.2022.100341>

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Alda L. Tam, MD, MBA, FSIR
President
Society of Interventional Radiology

A handwritten signature in cursive script that reads "David Han".

David Han, MD
Chair, SVS Coding Committee
Society for Vascular Surgery

A handwritten signature that appears to be "Bob Tahara", written in a cursive style.

Bob Tahara, MD
President
Outpatient Endovascular and Interventional Society