



November 27, 2023

Chris Jagmin, M.D.
Executive Medical Officer

Mary Moffitt, M.D.
Chief Medical Officer

Aetna - CVS Health
151 Farmington Ave
Hartford, CT 06156

RE: Policy 0382 Intravascular Ultrasound (IVUS)

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 express our shared concern around the medical policy revision to Policy 0382 Intravascular Ultrasound scheduled for February 2024. We believe that the proposed revisions to Policy 0382 are not consistent with current research and best practice for the use of IVUS.

The medical policy states that the first criterion for IVUS to be used as a clinical decision-making tool to evaluate the need for an intracoronary interventional procedure in a symptomatic member whose angiogram shows 50 to 70 % stenosis(es) is restrictive for intermediate stenosis. It is important to note that three recent studies define intermediate stenosis as 40-70% and we feel this range would be a

more reasonable requirement as it provides clinicians with decision-making tools before advancing disease leaves fewer clinical options.¹²³

We strongly disagree with the assessment and phrasing that IVUS is experimental and investigational for:

Screening for coronary artery disease, diagnosing coronary vulnerable plaques, and its use in other coronary procedures;

For any of the following (not an all-inclusive list) because its use for these indications has not been validated by clinical studies:

- Diagnosis of aortic dissection
- Diagnosis / evaluation of pulmonary hypertension
- During endovascular interventions of failing hemodialysis access grafts
- Evaluation of chronic venous obstruction/venous stenting
- Evaluation of carotid artery stenosis
- Stenting of non-coronary arteries
- Diagnosis and treatment of functional popliteal artery entrapment syndrome
- Guidance during endovascular treatment of subclavian artery disease
- Prediction of clinical improvement following ilio-femoral vein stenting
- Prediction of outcome following carotid artery stenting
- Thoracic endovascular aortic repair for blunt thoracic aortic injury
- Other non-coronary vascular (i.e., including veins) procedures (other than those listed above).

While limited evidence exists for the efficacy in screening for coronary artery disease or diagnosing coronary vulnerable plaques, the statement “and its use in other coronary procedures” is extremely broad and could encompass conditions for which IVUS is appropriate, such as coronary artery fistula or dissection. Our organizations would like to work with you to narrow the scope of the statement to avoid unintended denials of patient care for procedures when IVUS is appropriate.

Clinical studies to validate the rest of the list of indications have been performed, several of which are attached for your review. These documents include a peer-reviewed Systematic Literature Review (SLR) that shows the quality of evidence for IVUS-guided PAD procedures is in line with Deep Venous

¹Koo, B., Hu, X., Kang, J., Zhang, J., Jiang, J., Hahn, J., Nam, C., Doh, J., & Lee, B. et al. (2022). Fractional Flow Reserve or intravascular ultrasound for PCI. *New England Journal of Medicine*, 387(22), 2097–2099. <https://doi.org/10.1056/nejmc2212953>

² Tobis, J., Azarbal, B., & Slavin, L. (2007). Assessment of intermediate severity coronary lesions in the catheterization laboratory. *Journal of the American College of Cardiology*, 49(8), 839–848. <https://doi.org/10.1016/j.jacc.2006.10.055>

³ Nagic, J., Prosser, H., O’Brien, J., Thakur, U., Soon, K., Proimos, G., & Brown, A. J. (2020). The assessment of intermediate coronary lesions using intracoronary imaging. *Cardiovascular Diagnosis and Therapy*, 10(5), 1445–1460. <https://doi.org/10.21037/cdt-20-226>

interventions and is one level below a randomized study at Level of Evidence 2b⁴; a PAD Randomized Controlled Trial that shows reductions in binary restenosis with IVUS guidance in femoropopliteal interventions⁵; peer-reviewed nationwide CMS outcomes show reductions in amputation rates associated with IVUS use in real-world practice and across places of care and user taxonomies,⁶ and a peer-reviewed expert consensus document with a global, multidisciplinary panel showing the highest strength of recommendations for IVUS use in various PAD and venous indications encompassing 3 phases of the interventional procedures and with health benefits far outweighing risks⁷.

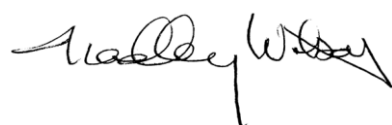
We have an additional concern that this policy is inconsistent with the eviCore prior authorization policy that was implemented in September, which clearly states that the use of IVUS is not typically medically necessary instead of experimental and investigational. This discrepancy could lead to procedures that have been approved though the prior authorization process being denied payment because Aetna's policy is more restrictive than that of its prior authorization contractor.

We respectfully request that Aetna reconsider and make these revisions to the policy to help our members practice using the most current standards for best patient care. We would be happy to schedule a meeting to discuss this matter further.

Sincerely,

Handwritten signature of George Dangas in black ink.

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

Handwritten signature of B. Hadley Wilson in black ink.

B. Hadley Wilson, MD, FACC

⁴Natesan, S., Mosaria, R., Parikh, S., Rosenfield, K., Suomi, J., Chalyan, D., Jaff, M., & Secemsky, E. (2022). Intravascular ultrasound in peripheral venous and arterial interventions: A contemporary systematic review and grading of the quality of evidence. *Vascular Medicine*, *27*(4), 392-400.

⁵Allen, R., Puckridge, P., Spark, J., & Delaney, C. (2022). The impact of intravascular ultrasound on femoropopliteal artery endovascular interventions. *Journal of the American College of Cardiology*, *15*(5), 536-546.

⁶Divakaran, S., Parikh, S., Hawkins, B., Chen, S., Song, Y., Banerjee, S. Rosenfield, & K., Secemsky, E. (2022). Temporal trends, practice variation, and associated outcomes with IVUS use during peripheral arterial intervention. *Journal of the American College of Cardiology*, *15*(20), 2080-2090.

⁷Secemsky, E., Mosarla, R., Rosenfield, K., Kohi, M., Lichtenberg, M., Meissner, M., Varcoe, R., Holden, A., Jaff, M., Chalyan, D., Clair, D., Hawkins, B., & Parikh, S. (2022). *Journal of the American College of Cardiology*, *15*(15), 1558-1568.

President
American College of Cardiology



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

A handwritten signature in cursive script that reads "David Han" followed by a dash.

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

A stylized signature logo consisting of a single continuous line that forms a loop on the left side and then extends into a long, sweeping curve on the right.

Bob Tahara, MD
President
Outpatient Endovascular and Interventional Society