

March 25, 2024

James Schuster, MD, MBA
Chief Medical Director
UPMC Health Plan
Attn: Commercial Plans
U.S. Steel Tower
600 Grant Street
Pittsburgh, PA 15219

RE: Policy MP.091 Intravascular Ultrasound (IVUS)

Dear Dr. Schuster:

We are writing on behalf of the undersigned groups to address concerns with Policy MP.091 Intravascular Ultrasound.

Specifically, we strongly disagree that IVUS is experimental and investigational. Your policy states that IVUS is experimental and investigational for:

Coronary IVUS is not medically necessary for any of the following (this is not an all-inclusive list):

- A. Screening for coronary artery disease in asymptomatic individuals*
- B. Routine assessment of coronary plaques when revascularization is not being considered*
- C. Evaluation of carotid artery stenosis/carotid stent placement*
- D. Follow-up monitoring of medical therapies for atherosclerosis*
- E. Peripheral vascular intervention*

Non-coronary IVUS evaluation of chronic venous obstruction is not medically necessary, other than for the diagnosis and post-therapeutic intervention evaluation of lower extremity extrinsic venous compression.

In opposition we cite specific clinical studies to validate the list of indications that have been published, 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 interventions and is one level below a

randomized study at Level of Evidence 2b¹; a PAD Randomized Controlled Trial that shows reductions in binary restenosis with IVUS guidance in femoropopliteal interventions²; and peer-reviewed nationwide CMS outcomes study that shows reductions in amputation rates associated with IVUS use in real-world practice and across places of care and user taxonomies.³ Broader use of IVUS in PAD is aligned to multi-disciplinary⁴ and multi-societal expert opinion⁵ and its impact on amputation rates is consistent with American Heart Association goal to reduce amputations by 20% nationally by 2030.⁶

Utilization of IVUS in chronic venous disease is high at 77.3% of all venous procedures nationally⁷ backed by the Society for Vascular Surgery (SVS) guidelines⁸ and peer-reviewed CMS outcomes data⁷ showing a reduction in both primary and secondary endpoints. Recent observational data also shows that IVUS changes patient management in up to 57% of procedures.⁹

¹Natesan, 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.

²Allen, 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.

³Divakaran, 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.

⁴Secemsky EA, Mosarla RC, Rosenfield K, Kohi M, Lichtenberg M, Meissner M, Varcoe R, Holden A, Jaff MR, Chalyan D, Clair D, Hawkins BM, Parikh SA. Appropriate Use of Intravascular Ultrasound During Arterial and Venous Lower Extremity Interventions. *JACC Cardiovasc Interv*. 2022 Aug 8;15(15):1558-1568. doi: 10.1016/j.jcin.2022.04.034. PMID: 35926922.

⁵Secemsky E, Aronow H, Knowlek C, et al. Intravascular Ultrasound Use in Peripheral Arterial and Deep Venous Interventions: Multidisciplinary Expert Opinion From SCAI/AVF/AVLS/SIR/SVM/SVS. *JSCAI*. Published online January 9, 2024. doi.org/10.1016/j.jscai.2023.101205.

⁶Creager MA, Matsushita K, Arya S, Beckman JA, Duval S, Goodney PP, Gutierrez JAT, Kaufman JA, Joynt Maddox KE, Pollak AW, Pradhan AD, Whitsel LP. Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association. *Circulation*. 2021 Apr 27;143(17):e875-e891. doi: 10.1161/CIR.0000000000000967. Epub 2021 Mar 25. PMID: 33761757.

⁷Divakaran S, Meissner MH, Kohi MP, Chen S, Song Y, Hawkins BM, Rosenfield K, Parikh SA, Secemsky EA. Utilization of and Outcomes Associated with Intravascular Ultrasound during Deep Venous Stent Placement among Medicare Beneficiaries. *J Vasc Interv Radiol*. 2022 Dec;33(12):1476-1484.e2. doi: 10.1016/j.jvir.2022.08.018. Epub 2022 Aug 23. PMID: 35998803; PMCID: PMC9758974.

⁸O'Donnell TF Jr, Passman MA, Marston WA, Ennis WJ, Dalsing M, Kistner RL, Lurie F, Henke PK, Gloviczki ML, Eklöf BG, Stoughton J, Raju S, Shortell CK, Raffetto JD, Partsch H, Pounds LC, Cummings ME, Gillespie DL, McLafferty RB, Murad MH, Wakefield TW, Gloviczki P; Society for Vascular Surgery; American Venous Forum. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery[®] and the American Venous Forum. *J Vasc Surg*. 2014 Aug;60(2 Suppl):3S-59S. doi: 10.1016/j.jvs.2014.04.049. Epub 2014 Jun 25. PMID: 24974070.

⁹Gagne PJ, Tahara RW, Fastabend CP, Dzieciuchowicz L, Marston W, Vedantham S, Ting W, Iafrafi MD. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. *J Vasc Surg Venous Lymphat Disord*. 2017 Sep;5(5):678-687. doi: 10.1016/j.jvsv.2017.04.007. Epub 2017 Jun 28. PMID: 28818221.

We respectfully request that UPMC consider removing the experimental designation from these interventions based on the evidence provided.

Sincerely,

Association of Black Cardiologists
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery