RE: PROPOSED/DRAFT Local Coverage Determination (LCD): Lower Extremity Revascularization (DL37404)

Dear Dr. Corcoran:

The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 7,000 members committed to the practice and advancement of the specialty of vascular and interventional radiology. The Society and its membership are dedicated to improving public health through pioneering advances in minimally-invasive, image-guided therapy. Our members are at the forefront of innovative and minimally invasive therapies to treat an array of diseases and conditions without surgery.

The American College of Radiology (ACR) represents over 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, and nuclear medicine physicians and medical physicists. The College has reviewed carefully the draft LCD, and is pleased to endorse this letter.

We thank First Coast Services for the opportunity to comment on the draft LCD noted above. Our organizations are at the forefront to treating these patients, and our goal is to ensure our member physicians provide the best evidence-based care to Medicare beneficiaries. The SIR and ACR are also pleased to endorse the comments of the American College of Phlebology, which has submitted to First Coast a separate letter specifically addressing treatments for patients with venous disease under this draft LCD.

We applaud CMS’s recent decision to cover Supervised Exercise Therapy for PAD patients, and look forward to working with First Coast on a policy for SET.

We do have some comments about the draft LCD, which we will go into below.

We would like to highlight the following.

1. While there are indeed reasons to do so, we feel that separating arterial and venous disease into two separate LCDs might be a more appropriate approach. The clinical treatments of these disease conditions are quite different. In this respect, it is important to understand that the venous system has significantly different hemodynamics from the arterial system. Additionally,
because gravity is a key factor in producing venous symptoms and pressure gradients are measured with the patient supine, resting pressure gradients in venous disease (unlike arterial disease) are not an accurate way to determine hemodynamic significance.

2. With respect to the draft’s citation of an Ankle Brachial Index (ABI) of 0.65, we would encourage First Coast not to use this measure as a limit to providing care. Assuming this proposed number is a “resting ABI,” many patients with aorto-iliac occlusive disease will have a near-normal or mildly abnormal resting ABI. However following exercise stress, the ABI may decompensate significantly. We would recommend stating that documentation of an abnormal ABI (pre- or post-exercise), generally <0.80, would be considered a covered indication.

3. The draft makes mention of stenting, with Food and Drug Administration (FDA) approval for the device being a prerequisite condition. As First Coast is aware, off-label use in lower-extremity interventions is common, eg, drug-eluting and covered stents. We suggest text in the LCD that makes mention of off-label device usage.

4. With regards to the language in the draft about arterial coverage, specifically about the proposed limitations to use of stents for tibio-peroneal arterial stenosis and/or claudication, we have concerns about this draft language. It is generally accepted that tibial/peroneal artery intervention for patients with intermittent claudication is not indicated, with perhaps some unique exceptions. In addition, tibial/peroneal artery angioplasty certainly plays a role in PAD patients with critical limb ischemia (CLI). While we agree that primary stenting in the tibial/peroneal arteries may have a limited role, there is concern that this proposed limitation would not allow coverage for patients with critical limb ischemia undergoing angioplasty who may develop an intraprocedural arterial dissection, not uncommon due to the nature of disease in these smaller arteries. Indeed, this situation often requires “bail-out” stenting to avoid acute occlusion and/or thrombosis. The concern with the proposed determination is that the ability to salvage an intraprocedural complication would not be considered acceptable. Further, the definition of critical limb ischemia should include patients with ischemic rest pain and not just those patients with tissue loss. We would propose that stenting in the tibial/peroneal arteries be considered reasonable and necessary in patients who undergo intervention for critical limb ischemia that have the need for a “bail-out” strategy to avoid a potentially severe intraprocedural complication.

5. Though rare, it seems the LCD should allow that bail out stenting be considered reasonable in all settings, not just CLI. As an example, a wire dissection caused during popliteal intervention for claudication might require a stent in the tibio-peroneal segment as a bail-out maneuver.

6. For clarification, in the Limitations section, number 4: While it is acknowledged that use of drug-eluting stents in the tibial arteries is considered “off-label,” there is evidence of their superiority in patency for lesions less than or equal to 3.0cm, as shown in a meta-analysis of 5 randomized controlled trials.1

7. Regarding the section on use of intravascular ultrasound (IVUS) in arterial intervention, there are important uses for this technology in this setting. As an example, if placing a stent-graft in the superficial femoral artery, appropriate
sizing of the native vessel is critically important in order to maintain long term patency. This is best done with IVUS to avoid magnification error using standard angiographic images. Similarly, use of IVUS for treating aneurysmal disease in the femoropopliteal segment is paramount. Finally, placement of drug-eluting stents in the SFA requires adequate stent position to achieve its maximum desired antiproliferative effect. This is best done with IVUS. We would recommend stating that use of IVUS is reasonable and necessary in certain situations (including these) where adjunctive imaging can play an integral role.

We thank First Coast for the opportunity to comment, and the SIR/ACR members in Florida who treat these patients are available to speak further about this topic if so desired by First Coast. If we can be of assistance, please reach out to Robert White on the SIR staff at 703-460-5599, or rwhite@sirweb.org.

With kind regards,

Suresh Vedantham, MD, FSIR
President, Society of Interventional Radiology

Robert R. Zeman, MD, FACP
Chair, ACR Carrier Advisory Committee Network

Cc: David H. Epstein, MD, FACP, FL Radiology CAC Representative (Fort Lauderdale, FL)
    Bret N. Wiechmann, MD, FSIR, FAHA  SIR PAD Service Line (Gainesville, FL)

1 Drug-eluting stents for revascularization of infrapopliteal arteries: updated meta-analysis of randomized trials.