June 20, 2020

Noridian Healthcare Solutions, LLC JF Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6781
Fargo, ND 58108-6781
policydraft@noridian.com

Re: Proposed Local Coverage Determination (LCD): Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (DL38615)

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non- profit professional association with over 4,500 members representing interventional cardiologists. SCAI promotes excellence in interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

SCAI supports expanded coverage for non-invasive fractional flow reserve (CT-FFR) in patients with stable ischemic heart disease. We do object to one sentence: "Medicare will not pay for both CT-derived Fractional Flow Reserve data, and Fractional Flow Reserve data obtained by pressure wire at catheterization." That sentence should be removed.

We are surprised to encounter a proposed policy which bans all invasive FFR procedures after a non-invasive test is performed. While this non-invasive test is an important risk stratification tool, it does not replace invasive coronary angiography nor invasive FFR. Invasive assessment is the gold standard with the largest number of published studies and known benefit in selecting patients and lesions for revascularization and/or deferral which in turn decreases major adverse cardiovascular events.

First, we would like to emphasize the strong scientific evidence for the diagnostic performance of CT-FFR as a noninvasive tool. The NXT trial showed a per-vessel accuracy of 86% for CT-FFR compared to invasive FFR in 254 patients. The PACIFIC study demonstrated 87% per-vessel accuracy for CT-FFR compared to invasive FFR, higher than SPECT, PET, and CCTA. CT-FFR is a useful alternative to stress imaging testing for clinical decision making in who to and who not to refer to coronary angiography. However, its evidence base is less comprehensive than the evidence

supporting stress testing as a predictor of myocardial ischemia and we do not think it should universally supplant stress imaging as a first line test for ischemia. More importantly, it does not supplant the need for invasive coronary angiography nor the specificity of invasive FFR in determining lesion specific assessment in decision making regarding the revascularization of moderate coronary lesions.

Patients with abnormal CT-FFR who then undergo catheterization sometimes have lesions that are abnormal by CT-FFR but do not look significant on angiography. In these patients the possibility of a false-positive CT-FFR must be considered and if invasive FFR is negative then PCI may not be needed. Thus, a policy that allows for invasive FFR to double-check dubious CT-FFR findings may save patients from having unnecessary stenting and save Medicare money. If even 1 in 7 invasive FFR studies prevented an unnecessary coronary stenting procedure, it would still be a cost-saving policy.

Another situation where invasive FFR would be appropriate after CT-FFR is the patient whose symptoms are evaluated by CT-FFR, who then has progressive symptoms warranting cardiac catheterization. In these patients, the ability to assess significance of lesions should not be restricted by a policy banning invasive FR after CT-FFR.

In summary, invasive FFR remains the gold standard for determining the physiologic significance of intermediate coronary lesions and in certain situations it is clinically indicated after CT-FFR.

We recommend coverage for CT-FFR and but also strongly recommend that it should not replace invasive FFR. It is complementary to invasive physiology, not a replacement.

We thank Dr. James Blankenship, MD, MSCAI, Joaquin Cigarroa, MD, FSCAI and Deepali Nivas Tukaye, MBBS. PhD. FSCAI for their efforts in developing this response. If we can be of any assistance as Noridian continues to consider and review this policy, please do not hesitate to contact Wayne Powell at 703.772.7910 or wpowell@scai.org.

Sincerely

Cindy L. Grines, MD, MSCAI
President

Lyndon Box, MD, FSCAI
Chair of Government Relations Committee