



June 20, 2020

Noridian Healthcare Solutions  
Part B Policy  
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RE: Proposed Local Coverage Determination (LCD): Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (DL38461).

The American College of Cardiology would like to thank you for the opportunity to comment on Noridian's proposed Local Coverage Determination (LCD) on Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (SIHD). The American College of Cardiology (ACC) envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care and offers cardiovascular accreditation to hospitals and institutions. For more, visit [acc.org](http://acc.org).

The College has several areas of concern with the LCD as proposed:

- Incomplete indications
- Indications related to coronary CT angiography (CCTA) image quality
- Restrictions on use of FFRct in severe 3-vessel disease
- Refinement to documentation requirements.

## Incomplete Indications

Several criteria for coverage of FFRct in stable symptomatic patients are listed in the draft LCD. Gaps and odd criteria exist within that list of five criteria. First, one of the major coronary arteries is not even listed. The policy should include the right coronary artery. Second, coverage criteria for the left anterior descending coronary artery and the left circumflex disease are limited to proximal portions of the arteries. This should be changed to include both proximal AND mid-portions of the arteries. Third, the indication for left circumflex disease appears to be limited to the dominant system. The word "dominant" should be removed so that coverage is simply for left circumflex disease.

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## FFRct in relation to CCTA

There are several coverage restrictions in the proposed LCD for FFRct that are related to image quality of the CCTA and its perceived effect on the accuracy and clinical utility of FFRct. These include:

1. Severe obesity (BMI >35 kg/m<sup>2</sup>)
2. Prosthetic valves
3. Extensive coronary calcification

The mentioned criteria do not apply to current generation scanners aimed at image acquisition of the heart (>64 slice scanners). Contemporary scanners contain improved hardware and software components, such as dual-source CT and wide-detector scanners, which allow quality imaging of the most difficult patient anatomies and situations. These proposed restrictions should be removed or broadly expanded in order to ensure adequate access for Medicare beneficiaries. Alternatively, simply requiring a technically adequate CCTA would achieve the spirit of these restrictions in a more flexible way.

There are multiple publications that speak to the performance of CCTA in both the obese and high heart rate populations. A recent study from Mangold et. Al examined that accuracy of CCTA in obese ( $\geq 30$  kg/m<sup>2</sup>) and non-obese ( $< 30$  kg/m<sup>2</sup>) patients. The investigators determined that there was no statistically significant difference in overall per-patient sensitivity, specificity, positive predictive value, negative predictive value, and accuracy and concluded that CCTA “provides high diagnostic accuracy in non-obese and obese patients.” Another publication from Zimmerman et al. evaluated how accuracy was affected by both obesity and heart rate control. Four heart rate groups were included in the trial ( $< 70$ , 70-79, 80-89,  $\geq 90$  bpm) and physicians graded image quality based on their ability to visualize the artery. The authors found that 99% of coronary arteries were of diagnostic quality and concluded that “diagnostic quality [CCTA] examinations can be obtained without premedication regardless of body size.”

The presence of prosthetic valves and extensive coronary calcification only preclude the performance of quality CCTA to the extent that these factors prevent adequate imaging of the lumen of the coronary arteries and prevent the reading physician from interpreting the presence of SIHD. It is the current position of the College that the decision to proceed with CCTA in the presence of high coronary calcium score should be left to the direction of the referring and attending physicians. The presence of other traditional obstacles, including the presence of prosthetic valves should be handled in a similar manner. If the performing and interpreting physicians are confident in their ability to perform and read the CCTA in the presence of these or other factors, then the decision to perform the CCTA should be left up to the attending physician.

Evidence from the recent NXT trial that examined the accuracy of FFRct in patients with a wide range of coronary calcium scores concluded that there was no statistically significant difference in per-patient or per-vessel diagnostic accuracy of FFRct across Agatston Score quartiles. It was also found that FFRct diagnostic performance was equal to or superior to diagnostic performance characteristics reported for most conventional noninvasive ischemia testing modalities.

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## FFRct in Severe 3-Vessel Disease

The proposed LCD limits FFRct utilization in patients with known severe 3-vessel disease (>50% in all 3 major vessels) referencing a forgone conclusion that coronary artery bypass grafting (CABG) is necessitated by patients whose CCTA finds such disease. There is substantial clinical evidence investigated in the three SYNTAX family of randomized controlled trials, that PCI or stenting is a viable option for patients with 3-vessel disease that is determined to be not functionally significant via FFR information. It is accepted practice that when FFR shows 1 or 2 of the vessels in a 3-vessel disease patient to be not hemodynamically significant, that patient is redefined as a 1 or 2-vessel disease patient.

In these trials, the Syntax Score (SS) and objective assessment of the severity of a patient's SIHD, aides the heart team in determining the best course for revascularization, either PCI or CABG. Patients with a low risk SS ( $\leq 22$ ) were shown to have similar outcomes with CABG or PCI while patients with an SS  $\geq 23$  had better outcomes with CABG after 5-year follow up. Use of FFRct to determine a patient's functional SS in the SYNTAX III trial reclassified 30% of patients to a low risk SS, potentially enabling a less invasive (PCI) form of treatment.

The College urges Noridian to remove restrictions on use of FFRct in severe 3-vessel disease.

### Coverage for invasive FFR:

The ACC recommends the restriction of coverage for FFR data obtained by pressure wire at catheterization, should it be performed in addition to FFRct, be removed from the LCD. Invasive and non-invasive FFRct are two different tests with different purposes. There are clinical instances in which FFRct is sufficient to provide strong data toward revascularization, but it is not the same test as invasive FFRct. FFR data, whether obtained non-invasively via FFRct or invasively via a pressure wire, is a continuous value that has an accepted cut off of 0.8. When FFR is  $> 0.8$ , the lesion is understood to be non-ischemic and literature indicates that the patient may do better with medical therapy. When FFR is  $\leq 0.80$ , literature indicates that the patient may do better with revascularization.

The ACC opposes this approach out of concern it would eliminate a tool to detect false positives. It is rare that an interventional cardiologist would have an abnormal FFRct that corresponds to a concerning lesion and then choose to perform FFR. In most circumstances an interventionalist will have an abnormal FFRct but then upon inspection of the lesion does not assume the lesion to be as severe as the test indicated. An invasive FFR would not be common but may rarely be appropriate. In those instances, the physician would be performing FFR with an eye to avoiding intervention. Rather than install an absolute prohibition, it would be more productive for Noridian to gather information through claims data before applying a solution to a problem that does not currently exist.

## Conclusion

Several of the restrictions found within the proposed LCD will limit the ordering of FFRct and place financial burden on providers who do when reimbursement for this important service is denied. Access to FFRct can lead to fewer unnecessary diagnostic catheterizations making it a cost-effective diagnostic test.

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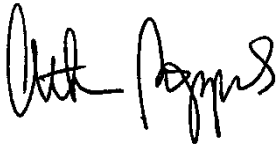
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We appreciate the opportunity to comment. If you have any questions or concerns, please contact Sarah Cartagena at [scartagena@acc.org](mailto:scartagena@acc.org) or 202-375-6232.

Sincerely,



Athena Poppas, MD, FACC  
President

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