PROPOSED Local Coverage Determination (LCD): Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (DL38461)

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Please Note: This is a Proposed policy.
Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Please Note: This is a Retired LCD.

Contractor Information

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**Proposed LCD Information**

**Document Information**
**Source LCD ID**
N/A

**Proposed LCD ID**
DL38461

**Proposed LCD Title**
Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease

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**CMS National Coverage Policy**

Title XVIII of the Social Security Act, §1862 (a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862 (a)(1)(D) Items and services related to research and experimentation.

Title XVIII of the Social Security Act, §1862 (a)(7) states Medicare will not cover any services or procedures associated with routine physical checkups.

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 CFR §410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements).


The Protecting Access to Medicare Act (PAMA) of 2014, Section 218(b), established a new program to increase the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries.

42 CFR §414.92 codifies the Appropriate use Criteria Program policies.

**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

Noninvasive fractional flow reserve derived from computed tomography relies on computer-assisted processing of coronary computed tomographic angiography (CCTA) images to estimate changes in coronary blood flow related to coronary artery stenoses. Based on physical theories of fluid dynamic modeling, FFRct is a post-processing software for the analysis of previously acquired digital imaging from CCTA.

FDA-approved FFRct technology may be considered reasonable and necessary in the management of patients with symptomatic, stable ischemic heart disease (SIHD), when the CCTA analysis is completed and demonstrates one of the following criteria:

1. Left main disease with intermediate coronary stenosis (lumen diameter reduction of 30-50%); OR
2. Proximal left anterior descending (LAD) coronary artery disease with intermediate coronary stenosis (lumen reduction 50-70%); OR
3. Proximal left dominant circumflex disease with intermediate (lumen reduction 50-70%) coronary stenosis (considered equivalent to two-vessel disease); OR
4. Proximal two- or three vessel disease with intermediate coronary stenosis in at least 2 vessels.

FFRct is not considered reasonable in the following clinical circumstances:

1. Severe obesity (BMI > 35 kg/m2)
2. Prior placement of prosthetic valves
3. Extensive coronary calcification
4. Renal insufficiency (estimated GFR < 60ml/min.)
5. Known severe aortic stenosis
6. Known severe 3-vessel disease
7. Prior placement of venous grafts in coronary bypass surgery
8. Suspicion of acute coronary syndrome

This service should be performed in patient with stable coronary symptoms. It should not be performed until after the base study (CCTA) has been completed and interpreted. If higher grade stenoses (i.e. greater than 70%) are present, this study is not medically necessary, as the patient should proceed to catheterization. Similarly, low grade stenoses (less than 30%) do not require additional confirmatory data. If more than two intermediate risk coronary lesions are identified, the clinical situation is considered to be of high risk and the patient should proceed directly to catheterization. Medicare will not pay for both CT-derived Fractional Flow Reserve data, and Fractional Flow Reserve data obtained by pressure wire at catheterization.

Summary of Evidence

The concept of invasive fractional flow reserve as a diagnostic tool was introduced in the early 1990’s. The FAME and FAME-II trials supported an FFR-wire guided revascularization strategy as opposed to purely angiographically guided revascularization.\(^1\) The National Cardiovascular Data Registry demonstrated a low diagnostic yield from traditional exercise stress testing when the patient progressed to invasive coronary angiography. The analysis of coronary artery disease by non-invasive coronary computed tomographic analysis has been limited by low specificity. The addition of computer derived flow analysis of the CTA data has added the potential for a non-invasive test that yields both anatomic and functional data.

The DeFACTO study (Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography) compared the first iteration of FFRct technology against invasive angiography and FFR in patients with suspected or known CAD, but did not achieve the pre-specified target accuracy.\(^2\) Another study, DISCOVER-FLOW demonstrated an accuracy of 84.6%.\(^3\) A second iteration of the FFRct algorithm was tested against invasive angiography with FFR in 251 patients with suspected CAD in the NXT (Analysis of Coronary Blood Flow Using CT Angiography- Next Steps) trial. This study reported a diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value of 81%, 86%, 79%, 65% and 83% respectively.\(^4\)

The PROMISE study demonstrated that patients with an FFRct less than or equal to 0.80 were significantly more likely to have coronary revascularization and to meet the composite endpoint of major adverse cardiac events or revascularization than those with FFRct greater than 0.80.\(^5\) The study also showed that reserving invasive coronary angiography for patients with FFRct less than or equal to 0.80 could reduce the rate of performing invasive coronary angiography by 28%. However, the initial trial did include a CCTA strategy which did not improve outcomes after 2 years of follow-up. The study, a retrospective, observational, cohort study, also highlighted the dependence of FFRct on the quality of the CCTA images being post-processed, with one third of the images submitted for review of

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The FFRct RIPCORD study involved 200 patients and compared the management of patients by cardiologists with and without the addition of FFRct data to the baseline CTA data. The additional FFRct data changed the management plan for 72 patients (36%) based on the assessment of lesion severity. With inclusion of changes in the PCI target vessel, patient management was altered in 44% of patients.\(^7\)

In the PLATFORM study, 584 patients were allocated to noninvasive or invasive coronary angiography cohorts. Each cohort was divided into standard of care and FFRct guided care groups. The 90-day primary end point of invasive catheterization without obstructive coronary artery disease occurred in significantly fewer patients with FFRct guided care than with usual care in both cohorts. This prospective, longitudinal comparative effectiveness study demonstrated that in an appropriately selected population for CCTA, 88% of the studies were of sufficient quality to perform FFRct on the derived images.\(^8,9\)

The ADVANCE registry (Assessing Diagnostic Value of Non-Invasive FFRct in Coronary Care) included 5,083 patients with symptoms suggestive of angina from 38 centers in Europe, North America and Japan. There was a change in management pathway in 66% of patients, after FFRct data were available compared with CCTA alone.\(^10\)

A recent Danish observational study that included 3674 patients with suspected coronary artery disease who underwent CCTA with FFRct for stenosis between 30% and 90% had supportive findings for use of this technology in care management. Patients with FFRct greater than 0.8 had similar outcomes to patients without obstructive disease on CCTA (i.e. less than 30%). By contrast, patients with FFRct less than or equal to 0.8 had significantly more Major Adverse Coronary Events (9.6% vs. 1.4%).\(^11\)

**Analysis of Evidence**
*(Rationale for Determination)*

These and other studies were discussed by the assembled subject matters experts in a formal CAC discussion convened by Noridian Healthcare Solutions on June 18, 2019. Based on a review of the literature there was a general consensus that FFRct is a useful modality in the guidance of, and assessment of, stable coronary artery disease. Various opinions were solicited with regard to the population (and characteristics of the population) that would specifically benefit from this service. The Noridian Medical Policy staff has concluded that FFRct is clinically useful in the re-interpretation of CCTA data, and in guiding the downstream management of patients with intermediate coronary stenosis (30-70% stenosis, established by CCTA). Two issues for evolving discussion were raised during the Noridian CAC. The first involves the growing assurance of technical quality of the study in obese patients. Many centers are extending the use of this technology to patients with a BMI over 35 kg/m\(^2\). Noridian Medicare will maintain its current position until guidelines are revised indicating general specialty acceptance. There was also robust discussion of use in Acute Coronary Syndrome. Until the evidence-based literature defines this population of patients more consistently, and professional medical society guidelines accept FFRct in more acute (and potentially less stable) clinical settings, Noridian will maintain its current position.

**Table of Proposed Changes**

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**Associated Information**

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Sources of Information


Noridian Healthcare Solutions- Carrier Advisory Committee- June 18, 2019

Bibliography


Open Meetings

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### Contractor Advisory Committee (CAC) Meetings

N/A

### MAC Meeting Information URL(s)

N/A

### Proposed LCD Posting Date

N/A

### Comment Period Start Date

10/31/2019

### Comment Period End Date

12/15/2019

### Released to Final LCD Date

Not yet released.

### Reason for Proposed LCD

- LCD Being Retired

### Contact for Comments on Proposed LCD

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

### Associated Documents

#### Attachments

N/A

#### Related Local Coverage Documents

Article(s)

[DA57405 - Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease](#)

#### Related National Coverage Documents

N/A

#### Public Version(s)

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- 0502T
- 0503T
- 0504T