| National Imaging Associates, Inc.* | |
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| **Clinical guidelines**<br>**FRACTIONAL FLOW RESERVE CT** | **Original Date: August 2017** |
| **CPT Code: 0501T, 0502T, 0503T, 0504T** | **Last Revised Date: March 2021** |
| **Guideline Number: NIA_CG_062-1** | **Implementation Date: January 2022** |

**GENERAL INFORMATION**

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

**INDICATIONS FOR FFR-CT**

- Intermediate degrees of stenosis (30 - 70%) on coronary computerized tomographic angiography (CCTA) to guide decision making and help identify those patients who would benefit from revascularization
- Intermediate lesions in the above range and coronary calcification have made percentage stenosis interpretation difficult, thus could support approval of FFR-CT, in conjunction with the above criteria (Norgaard, 2015)

**FFR-CT – ADDITIONAL INFORMATION**

(Douglas, 2016; Pontone, 2015)

None of the following clinical scenarios below apply, since FFR-CT either:

- Has not been adequately validated due to inapplicability of computational dynamics; **OR**
- Due to problematic artifacts, and/or clinical circumstances
  - When patients have artifacts (heavy calcium) or body habitus (BMI > 35) that could interfere with the examination, the suitability for FFR-CT is at the discretion of the vendor who provides the FFR-CT service
  - Known ischemic coronary artery disease that has not been revascularized and there has been no change in patient status or in the CCTA images
- Recent myocardial infarction within 30 days (Gaur, 2017)
- Prior coronary artery bypass graft surgery
- Complex congenital heart disease or ventricular septal defect (VSD) with pulmonary-to-systemic flow ratio > 1.4
- Metallic stents ≤ 3.0 mm in diameter in the coronary system

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- Coronary lesions with a vessel diameter < 1.8 mm
- Cardiac Implanted Electrical Devices
- Prosthetic Heart Valves
- Severe wall motion abnormality on CCTA results
- Severe myocardial hypertrophy
- High risk indicators on stress test
- Coronary angiography within the past 90 days
- Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

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**BACKGROUND**
(Hulten, 2017; Maroules, 2017)

Fractional flow reserve computed tomography (FFR-CT) is a relatively new technology that estimates the effect of coronary arterial narrowing on blood flow, based upon the images acquired in a coronary computed tomography angiography study. Its role is to provide information that can more appropriately select patients requiring invasive coronary angiography.

**OVERVIEW**
**The Development of FFR-CT as a Technology**

**History of FFR:** Fractional Flow Reserve (FFR) is the ratio of baseline coronary flow to coronary flow during maximal hyperemia. Its use in the cardiac catheterization laboratory has successfully demonstrated utility in the quantitation of intracoronary flow dynamics secondary to lesional and microvasculature conditions. This technology has proven helpful in evaluating individual patients, with respect to prognostication of coronary artery disease and decisions regarding the appropriateness of coronary revascularization (De Bruyne, 2014; Pijls, 2007; Tonino, 2009; van Nunen, 2015; Xaplanteris, 2018).

**Adaptation to CCTA:** CCTA has shown utility in the evaluation of patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation (Douglas, 2015b; Newby, 2015; Oberweis, 2017; Williams, 2016), as well as in low-risk emergency department scenarios (Hulten, 2013). Fractional flow reserve using CCTA seeks to provide an estimation of FFR by non-invasive methodology. Following assessment of quality CCTA images, in the appropriate subsets of patients with coronary stenoses, the technology makes mathematical assumptions to simulate maximal hyperemia and calculates an estimation of FFR (fractional flow reserve) for those coronary vessels with lesions, based upon the principles of fluid mechanics inherent to the Navier-Stokes Theorem (Taylor, 2013).

**FFR-CT Results:** Quantitative estimation of coronary lesional hemodynamic severity using FFR-CT might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization.

FFR-CT measurements appear reproducible (Gaur, 2014), with initial data demonstrating a strong correlation to invasive FFR, resulting in a high diagnostic performance (Driessen, 2019). Invasive FFR has excellent reproducibility (Johnson, 2015) and a demonstrated track record of favorable outcomes when used in the selection of patients and vessels requiring PCI (De Bruyne, 2014; Tonino, 2009; Van Nunen, 2015; Xaplanteris, 2018). Evidence suggests that FFR-CT might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA (Lu, 2016) and that a negative FFR-CT in the evaluation of chest pain results in lower revascularization rates and lower cardiovascular death and MI at 1 year follow-up (Patel, 2020). The FFR-CT data to date, however, provide no evidence showing that revascularization based upon FFR-CT improves clinical outcomes over invasive angiographic assessment. As a consequence of the above considerations, current revascularization guidelines do not advocate FFR-CT as a surrogate for invasive FFR, although, those guidelines refer to FFR-CT as an "emerging technology" (Patel, 2017).

**Abbreviations**

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| BMI | Body Mass Index |
| CCTA | Coronary Computerized Tomographic Angiography |
| FFR | Fractional Flow Reserve |
| FFR-CT | Fractional Flow Reserve derived noninvasively from CCTA |
| ICA | Invasive Coronary Arteriography |
| NPV | Negative Predictive Value |

**POLICY HISTORY**

| Date | Summary |
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| March 2021 | No changes |
| March 2020 | • Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review<br>• Added additional information to the FFR-CT Results section<br>• Updated and added new references |

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| August 2019 | • Added the following clarification: Intermediate degrees of stenosis (30 - 70%) on coronary computerized tomographic angiography (CCTA) to guide decision making and help identify those patients who would benefit from revascularization<br>• Clarified metallic stents in the coronary system to be ≤ 3.0 mm in diameter as potentially inapplicable<br>• Removed acute coronary syndrome and emergent scenarios<br>• Removed section on pre-test probability and selection of patients for CCTA |

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**Reviewed / Approved by NIA Clinical Guideline Committee**

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