



MEDICAL POLICY STATEMENT

Indiana Medicaid

| Policy Name & Number | Date Effective |
|---|-----------------------|
| Fraction Flow Reserve from Computer Tomography (FFRct) - IN MCD - MM-1165 | 05/01/2022-12/31/2022 |
| Policy Type | |
| MEDICAL | |

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A. Subject

Fraction Flow Reserve from computer tomography (FFRct)

B. Background

Heart disease, with coronary artery disease (CAD) being the most common, is the leading cause of death for men and women. The traditional test in management of coronary artery stenosis is a procedure where the fractional flow reserve measures the blood pressure to determine adequate blood flow or blockage during an invasive coronary angiography.

A noninvasive alternative for stable symptomatic members with CAD is Heartflow FFRct; in which a digital 3-D model of the heart arteries is created to assist in determining restricted blood flow. Heartflow FFRct is intended to be used in conjunction with clinical history, symptoms, diagnostic test, and the clinician's professional judgement.

C. Definitions

- **FFRct** - A mathematically derived quantity, computed from simulated pressure, velocity and blood flow information that was obtained from a 3D computer model derived from a coronary computer tomography (CT) image.
- **Heartflow FFRct** - Post-processing software for the clinical quantitative and qualitative analysis of previously acquired computed tomography.

D. Policy

- I. FFRct technology may be considered reasonable and necessary in the management of patients under the following conditions:

- A. Symptomatic, stable ischemic heart disease (SIHD);

1. For example, a member with stable angina pectoris would be a candidate for this procedure; whereas a member with unstable angina would not be a candidate for this procedure.

- II. Procedure limitations

- A. The safety and effectiveness has not been evaluated for the following populations:

1. Suspicion of acute coronary syndrome (where acute myocardial infarction or unstable angina have not been ruled out);
 2. Recent prior myocardial infarction within 30 days;
 3. Complex congenital heart disease;
 4. Prior coronary artery bypass graft (CABG) surgery;
 5. Patients with a Body Mass Index >35; and
 6. Patients who require emergent procedures or have any evidence of ongoing or active clinical instability, including acute chest pain (sudden onset), cardiogenic shock, unstable blood pressure with systolic blood pressure <90 mmHg, severe congestive heart failure (New York Heart Association [NYHA] III or IV) or acute pulmonary edema.

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

| DATE | | ACTION |
|----------------|------------|---|
| Date Issued | 01/06/2021 | |
| Date Revised | 12/15/2021 | No changes; Updated references. |
| Date Effective | 05/01/2022 | |
| Date Archived | 12/31/2022 | This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy. |

H. References

1. Budde R, Nous F, Roest S, et al. Non-Invasive Functional Coronary Artery Evaluation by CT-Derived Fractional Flow Reserve (FFRct) in Heart Transplant Patients. J Heart Lung Transplant. 2020;39(4S):S62
2. Centers for Disease Control. (2020, June 22). Heart Disease Facts. Retrieved August 25, 2020 from www.cdc.gov
3. Food and Drug Administration. (n.d.). DeNovo Classification Request for FFRctv. 1.4. Retrieved August 25, 2020 from www.accessdata.fda.gov
4. ECRI. (2019, March 15). FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease. Retrieved August 25, 2020 from www.ecri.org
5. Hayes Inc. (2019, September 24). Noninvasive Computed Fractional Flow Reserve from Computed Tomography for Coronary Artery Disease. Retrieved August 25, 2020 from www.hayesinc.com
6. Heartflow. (n.d.). Heartflow. Retrieved August 25, 2020 from www.heartflow.com
7. Knuuti J. 2019 ESC guidelines for the diagnosis and management of chronic coronary syndromes. European Heart Journal. 2020;41:407-477
8. Nous F, Budde RPJ, Fairbairn TA, et al. Temporal changes in FFRCT-Guided Management of Coronary Artery Disease - Lessons from the ADVANCE Registry. J Cardiovasc Comput Tomogr. 2020
9. Pontone G, Guaricci AI, Palmer SC, et al. Diagnostic performance of non-invasive imaging for stable coronary artery disease: A meta-analysis. Int J Cardiol. 2020;300:276-281

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 12/2020

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Issue Date 01/06/2021

Approved OMPP 01/26/2022

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.