



MEDICAL POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Fraction Flow Reserve from computer tomography (FFRct)-OH-MCD-MM-1046	02/01/2023-01/31/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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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 (FFR) 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 obtained from a 3D computer model derived from a 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.

II. Procedure limitations

A. Safety and efficacy have not been evaluated for the following populations:

1. Suspicion of acute coronary syndrome, where acute myocardial infarction or unstable angina has 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 10/12/2022	No changes; Updated references. No changes; Updated references.
Date Effective	02/01/2023	
Date Archived	01/31/2024	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 October 6, 2022 from www.cdc.gov.
3. Food and Drug Administration. (n.d.). DeNovo Classification Request for FFRctv. 1.4. Retrieved October 6, 2022 from www.accessdata.fda.gov.
4. ECRI. (2019, March 15). FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease. Retrieved October 6, 2022 from www.ecri.org.
5. Hayes Inc. (2019, September 24). Noninvasive Computed Fractional Flow Reserve from Computed Tomography for Coronary Artery Disease. Retrieved October 6, 2022 from www.hayesinc.com.
6. Heartflow. (n.d.). Heartflow. Retrieved October 6, 2022 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.

Independent medical review – 12/2020

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