



# MEDICAL POLICY STATEMENT

## Michigan Marketplace

Policy Name & Number	Date Effective
Fraction Flow Reserve from Computer Tomography (FFRct)-MI MP-MM-1662	01/01/2025
Policy Type	
<b>MEDICAL</b>	

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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 Fraction Flow Reserve from Computer Tomography (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 tests, 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 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 with symptomatic, stable ischemic heart disease (SIHD). For example, a member with stable angina pectoris would be a candidate for this procedure, but a member with unstable angina would not.

II. Procedure limitations

The safety and effectiveness of FFRct has not been evaluated for the following populations:

- A. suspicion of acute coronary syndrome (where acute myocardial infarction or unstable angina have not been ruled out)
- B. recent prior myocardial infarction within 30 days
- C. complex congenital heart disease
- D. prior coronary artery bypass graft (CABG) surgery
- E. patients with a body mass index >35
- F. 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
<b>Date Issued</b>	07/31/2024	New Policy. Approved at Committee.
<b>Date Revised</b>		
<b>Date Effective</b>	01/01/2025	
<b>Date Archived</b>		

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. doi:10.1016/j.healun.2020.01.1259
2. Cardiac catheterization and angiography: ACG-A-0001. MCG, 28th ed. Updated June 27, 2023. Accessed June 4, 2024. [www.careweb.careguidelines.com](http://www.careweb.careguidelines.com)
3. Centers for Disease Control. Heart Disease Facts. June 22, 2020. Accessed June 4, 2024. [www.cdc.gov](http://www.cdc.gov)
4. ECRI. FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease. March 15, 2019. Accessed June 4, 2024. [www.ecri.org](http://www.ecri.org)
5. Food and Drug Administration. DeNovo Classification Request for FFRctv. 1.4. Accessed June 4, 2024. [www.accessdata.fda.gov](http://www.accessdata.fda.gov)
6. Health Technology Assessment Noninvasive Computed Fractional Flow Reserve from Computed Tomography for Coronary Artery Disease. January 30, 2023. Accessed June 30, 2023. [www.hayesinc.com](http://www.hayesinc.com)
7. Heartflow. Heartflow. Accessed June 4, 2024. [www.heartflow.com](http://www.heartflow.com)
8. Knuuti J, Wijns W, Saraste A, et al. 2019 ESC guidelines for the diagnosis and management of chronic coronary syndromes. *Eur Heart J*. 2020;41(3):407-477. doi:10.1093/eurheartj/ehz425.
9. 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*. 2021;15(1):48-55. doi:10.1016/j.jcct.2020.04.011.
10. 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: doi:10.1016/j.ijcard.2019.10.046.

*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.