MEDICAL POLICY STATEMENT
Arkansas PASSE

Policy Name & Number	Date Effective
Fraction Flow Reserve from Computer Tomography (FFRct)-AR PASSE-MM-1164	01/01/2023-12/31/2023
Policy Type	
MEDICAL	

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Table of Contents

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 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 CT image.
- **Heartflow FFRct -** Post-processing software for the clinical quantitative and qualitative analysis of previously acquired computed tomography.

D. Policy

I. Prior authorization is required.

II. Prior authorization must include the following:
   A. A prescription; and
   B. Documentation supporting a clinically stable symptomatic member with coronary artery disease. 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.

III. 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; and
   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
Date Issued	01/06/2021	
Date Revised	09/28/2022	Updated references; No changes
Date Effective	01/01/2023	
Date Archived	12/31/2023	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 September 9, 2022 from www.cdc.gov.
3. Food and Drug Administration. (n.d.). DeNovo Classification Request for FFRctv. 1.4. Retrieved September 9, 2022 from www.accessdata.fda.gov.
4. ECRI. (2019, March 15). FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease. September 9, 2022 from www.ecri.org.
5. Hayes Inc. (2019, September 24). Noninvasive Computed Fractional Flow Reserve from Computed Tomography for Coronary Artery Disease. Retrieved September 9, 2022 from www.hayesinc.com.
6. Heartflow. (n.d.). Heartflow. Retrieved September 9, 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. MCG. 26th ed. (2022). ACG - A-0001 - Cardiac Catheterization and Angiography. Retrieved September 9, 2022 from www. careweb.careguidelines.com.
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. 2020.
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;300:276-281.

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.