CareSource

MEDICAL POLICY STATEMENT
KENTUCKY MARKETPLACE

Policy Name	Policy Number	Date Effective
Fraction Flow Reserve from computer tomography (FFRct)	MM-1161	04/01/2021-02/28/2022

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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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According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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 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 mathematicaly 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 members with coronary artery disease;
      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.

III. 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		
Date Effective	04/01/2021	
Date Archived	02/28/2022	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. Centers for Disease Control. (2020, June 22). Heart Disease Facts. Retrieved August 25, 2020 from www.cdc.gov
2. Food and Drug Administration. (n.d.). DeNovo Classification Request for FFRctv. 1.4. Retrieved August 25, 2020 from www.accessdata.fda.gov
3. ECRI. (2019, March 15). FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease. Retrieved August 25, 2020 from www.ecri.org
4. 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
5. Heartflow. (n.d.). Heartflow. Retrieved August 25, 2020 from www.heartflow.com

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