Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Fractional Flow Reserve from Computed Tomography (FFRCT)

Policy Number: PG0386
Last Review: 02/28/2022

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Fractional flow reserve (FFR) is a physiologic indicator used to identify significantly restricted coronary artery blood flow in individuals with known or suspected coronary artery disease (CAD). FFR is typically measured using invasive techniques, which is performed during invasive coronary angiography. FFR is considered the gold standard for assessing the hemodynamic significance of intermediate coronary stenosis by measuring the pressure difference across a coronary artery stenosis. Intracoronary catheter pressure measurement before and after the stenosis are compared, and FFR of 0.80 correlates with a 20% pressure drop after the stenosis. This measurement can help determine if the vessel narrowing is limiting blood flow and access the need for revascularization or stenting. Clinical studies have demonstrated that invasive FFR reduces unnecessary stenting procedures and associated risk.

Noninvasive fractional flow reserve can be modeled from computed tomography (FFRCT) using computer-assisted processing of coronary computed tomography angiography (CCTA) images to estimate changes in blood pressure inside coronary arteries that have partial blockages, with the goal of determining how severely the blockages impede blood flow to the heart. FFRCT is a post-processing software for analyzing previously acquired digital imaging from CCTA. FFRCT uses simulated pressure, velocity and blood flow information generated from static CCTA images to determine the fraction of maximal coronary blood flow that can be achieved in a restricted artery. The results of FFRCT are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment. FFRCT has been proposed as a replacement for invasive FFR. It has been determined that FFRCT helps to assess and guide management of stable coronary artery disease with the ultimate goal of reducing the need for invasive intervention (i.e. percutaneous coronary cauterizations.)

HeartFlow FFRCT Analysis is an example of a Food & Drug Administration (FDA) approved software device that obtains the FFRCT noninvasively from previously acquired CCTA image data to create three-dimensional (3D) images of the coronary arteries.

The National Institute for Health and Care Excellence published a medical technology document supporting the evidence for adopting HeartFlow FFRCT for estimating fractional flow reserve from coronary CT (CCT) angiography. This non-invasive procedure is safe and was found to have a high level of diagnostic accuracy for patients with stable, recent onset chest pain of suspected cardiac origin and a clinically determine intermediate

(10% to 90%) risk of coronary artery disease. Additionally documented was that using HeartFlow FFRCT, with access to 64-slice coronary CT angiography, may avoid the need for invasive coronary angiograph and revascularization.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Fractional flow reserve from computed tomography (FFRCT), procedures 0501T-0504T, are covered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount has determined that fractional flow reserve from computed tomography (FFRCT) for coronary artery disease is considered medically necessary:

- When coronary computed tomography angiography (CCTA) shows coronary artery disease (CAD) with 40-90% stenosis in a proximal or middle coronary artery.
  And
- Where the addition of functional information provided by FFRCT can assess CAD of uncertain physiological significance seen on the coronary CT angiogram.

Indications:

Calculation of fractional flow reserve (HeartFlow FFRCT) for persons who have a coronary CTA that has shown coronary artery disease of uncertain functional significance, or in non-diagnostic.

FDA-approved FFRCT technology may be considered reasonable and necessary in the management of patients with:

- Intermediate risk* patients with acute chest pain and no known coronary artery disease, with coronary artery stenosis of 40-90% in proximal or middle coronary artery on CCTA;

  OR

- Intermediate risk with acute chest pain and known coronary artery stenosis of 40-90% in a proximal or middle segment on CCTA;

  OR

- Stable nonobstructive coronary artery disease with persistent symptoms requiring further test, and ≥ 40-90% stenosis on CCTA;

  AND

- Not in conjunction with stress testing (unless FFRCT was not high quality and alternative study needed)

*Intermediate and high-risk is as defined in the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain

Pretest Probability of Coronary Artery Disease by Age, Gender, and Symptoms					
Very Low < 5%; Low < 10%; Intermediate 10% - 90%; High > 90%					
Age (yrs)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
30-39	Men	Intermediate	Intermediate	Low	Very Low
30-39	Women	Intermediate	Very Low	Very Low	Very Low
40-49	Men	High	Intermediate	Intermediate	Low
40-49	Women	Intermediate	Low	Very Low	Very Low
50-59	Men	High	Intermediate	Intermediate	Low

50-59	Women	Intermediate	Intermediate	Low	Very Low
60-69	Men	High	Intermediate	Intermediate	Low
60-69	Women	High	Intermediate	Intermediate	Low

FFRCT should be performed in patients with stable coronary symptoms. It should not be performed until after the base study (CCTA) has been completed and interpreted. If higher-grade stenosis (i.e. greater than 90%) are present, this study is not medically necessary, as the patient should proceed to catheterization. Similarly, low-grade stenosis (less than 40%) do not require additional confirmatory data.

FFRCT should be performed as an alternative to stress testing. If extensive plaque is present, a high quality CCTA is unlikely and stress testing is preferred.

Limitations:

- FFRCT is not covered for screening, i.e., in the absence of signs, symptoms or disease.
- New or additional information should facilitate the management decision, not merely add a new layer of testing.
- FFRCT is not warranted if it is anticipated that the patient would require invasive cardiac angiograph for further diagnosis or for therapeutic intervention. (e.g., angina decubitus, unstable angina, Prinzmental angina, etc.)
- The study must be ordered by the physician/qualified non-physician practitioner treating the patient and who will use the results of the test in the management of the patient
- FFRCT is not considered reasonable in the following clinical circumstances:
    - Prior placement of prosthetic valves
    - Known severe aortic stenosis
    - Prior placement of grafts in coronary bypass surgery
    - Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out)
    - Intracoronary metallic stent
    - Status post-heart transplantation
    - Recent MI (30 days or less)
    - Prior pacemaker or defibrillator lead placement
    - Newly diagnosed systolic heart failure, with no prior left heart catheterization
    - Coronary vessels with greater than 90% stenosis
    - Left main coronary artery disease with Intermediated Coronary Stenosis (lumen reduction less than or equal to 30%)
    - Non-obstructing stenosis (<50% of all major epicardial vessels) on CTA or catheterization in the past twelve months, in the absence of a new symptom complex.
    - If turnaround times may impact prompt clinical care decisions
    - High risk defined by left main stenosis ≥ 50%

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report (New code effective 01/01/2018)
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission (New code effective 01/01/2018)

0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model (New code effective 01/01/2018)
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report (New code effective 01/01/2018)

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 11/18/2016

Date	Explanation & Changes
11/18/16	• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
04/26/18	• Added codes 0501T-0504T as non-covered • Removed unlisted code 93799 • Policy reviewed and updated to reflect the most current clinical evidence per The Technology Assessment Working Group (TAWG).
08/04/2020	• Documentation supports CMS LCD coverage, L33559, coverage for Fractional Flow Reserve from Computed Tomography (FFRCT), on January 1st, 2018 • Medical Policy updated to allow coverage per CMS Medicare coverage criteria for Elite and Commercial product lines • ODM does not allow coverage for the Advantage product line
12/28/2020	• Medical policy placed on the new Paramount Medical policy format
02/28/2022	• Policy updated to reflect most current clinical evidence
03/01/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
04/09/2024	• Medical policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review

Medical Policy History – Prior to 04/01/2024

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Paramount Commercial Insurance Plans and Medicare Advantage Plans
Fractional flow reserve from computed tomography (FFRCT), procedures 0501T-0504T, are covered.

Paramount Advantage Medicaid
Fractional flow reserve from computed tomography (FFRCT), procedures 0501T-0504T, are non-covered.

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

Paramount Advantage Medicaid
Per the Ohio Department of Medicaid procedures 0501T-0504T are noncovered.