Fractional Flow Reserve from Computed Tomography (FFRCT)
Policy Number: PG0386
Last Review: 09/01/2020

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
Professional
Facility

DESCRIPTION
Fractional flow reserve (FFR) is typically measured using invasive techniques. 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. 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 fractional flow reserve (FFR), which is performed during invasive coronary angiography, to help cardiologists decide whether percutaneous coronary interventions (PCIs) such as angioplasty and stenting should be performed or if medical therapy is appropriate.

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.

In 2017, The American College of Cardiology CathPCI Registry documented the acceptance of the noninvasive method, FFRCT, for documenting ischemia around the time of revascularization. Indicating that the documentation of ischemia around the time of revascularization is important to the appropriate use criteria (AUC) for percutaneous coronary interventions (PCI).

POLICY
HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan
Fractional flow reserve from computed tomography (FFRCT), procedures 0501T-0504T, are covered.

Advantage
Fractional flow reserve from computed tomography (FFRCT), procedures 0501T-0504T, are non-covered.
COVERAGE CRITERIA
HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan

Paramount has determined that fractional flow reserve from computed tomography (FFRCT) for coronary artery disease is considered medically necessary when CCTA shows CAD of uncertain functional significance, or is non-diagnostic and where the addition of functional information provided by FFRCT can help the physician determine which patient may require invasive evaluation and/or treatment. 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 catherizations).

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.

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, Prinzmetal 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.

In November 2014, FFRCT simulation software (HeartFlow) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the de novo 510(k) process (class II, special controls; FDA product code: PJA). In January 2016, the FFRCT v2.0 device was cleared through a subsequent 510(k) process.

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

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.

<table>
<thead>
<tr>
<th>CPT CODES</th>
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<tbody>
<tr>
<td>0501T</td>
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in comparison with estimated FFR model to reconcile discordant data, interpretation and report (New code effective 01/01/2018)

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis</th>
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<tbody>
<tr>
<td>I20.8 Other forms of angina pectoris</td>
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<tr>
<td>I20.9 Angina pectoris, unspecified</td>
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<tr>
<td>I25.10 Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
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<tr>
<td>I25.118 Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris</td>
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<tr>
<td>I25.119 Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris</td>
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**REVISION HISTORY EXPLANATION**

**ORIGINAL EFFECTIVE DATE: 11/18/2016**

**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

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.
National Institute for Health and Care Excellence (NICE)