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Original Effective Date: 12/15/17

Reviewed: 07/24/25

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Subject: Noninvasive Fractional Flow Reserve Measurement

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Fractional flow reserve (FFR) derived by standard acquired coronary computed tomography angiography (FFR_{CT}) enables computational assessment of coronary blood flow and pressure. Noninvasive calculation of FFR from coronary computed tomographic (FFR_{CT}) applies computational fluid dynamics to determine the physiologic significance of coronary artery disease (CAD). Coronary physiology is a tool that can guide management decisions for intermediate lesions and multivessel coronary artery disease (CAD), determine whether the patient would benefit from coronary revascularization or medical therapy (Jesen et al. 2017, Min et al. 2012, Shlofmitz et al. 2017).

Fractional flow reserve (FFR) is the ratio of maximal blood flow in a stenotic artery to normal maximal flow. FFR is easily measured during coronary angiography by using a pressure guidewire to calculate the ratio of distal coronary pressure to aortic pressure. FFR in a normal coronary artery equals 1.0. An FFR value of 0.80 or less identifies ischemia-causing coronary stenosis with an accuracy of more than 90% (Tonino et al. 2009).

The HeartFlow fractional flow reserve (FFRCT); $FFR_{CT\ v}$.1.4 simulation software was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the de novo 510(k) process (Nov 2014) and the $FFR_{CT\ v}$2.0 device was cleared through a subsequent 510(k) process (Jan 2016). The HeartFlow FFR_{CT} is classified as a coronary physiologic simulation software device. HeartFlow FFR_{CT} is a coronary physiologic simulation software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography *DICOM data for clinically stable symptomatic patients with coronary artery disease. It provides FFR_{CT}, a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. FFR_{CT} analysis is intended to support the functional evaluation of coronary artery disease (FDA, 2017).

* Digital Imaging and Communications in Medicine (DICOM)

Summary and Analysis of Evidence: In an UpToDate article "Coronary artery pressure flow measurements are catheter-based intracoronary tests that can help determine the hemodynamic significance of coronary artery stenoses. In some patients, the coronary angiogram identifies lesions that are not clearly flow-limiting (e.g., in the range of 30 to 70 percent luminal diameter reduction). In such cases, coronary artery pressure or flow measurements can facilitate clinical decision making regarding the need for revascularization, particularly in individuals without noninvasive stress test documentation of myocardial ischemia. Fractional flow reserve (FFR) is a measure of the ischemic potential of a suspicious coronary artery lesion obtained by comparing pressure beyond a suspicious coronary stenosis to pressure proximal to that coronary stenosis during hyperemia (i.e., adenosine injection or infusion). FFR measures are obtained during hyperemia. To measure FFR, a pressure-sensing wire is advanced over the lesion in question, hyperemia is established with infusion of a vasoactive agent, pressure is continuously measured distal and proximal to the lesion, and the ratio of the distal and proximal pressures are calculated. In scenarios where diffuse disease is suspected, measurement is performed during a pullback of the wire across the diseased segment. The normal value for FFR is 1 for each patient, coronary artery, myocardial distribution, and microcirculatory status. An FFR value of ≤0.75 in patients with stable angina is strongly related to provocable myocardial ischemia using multiple stress testing methods. Because of variance among FFR measures and lack of agreement between stress test results, FFR values between 0.76 and 0.8 are considered a "gray zone." During pullback, diffuse flow-limiting disease is defined as an abnormal FFR value measured over the diseased segment (i.e., ≤0.75) in which there is no discrete pressure change along the length of the suspected lesion. The degree to which flow-limiting disease is diffuse versus focal can be quantified. Clinically, FFR is a measure of the ischemic potential of a coronary artery stenosis. FFR was initially validated against a three-stress-test standard of inducible ischemia, which provided a threshold value of 0.75 to define ischemia-associated lesions. The sensitivity of FFR is 88 percent, and the specificity is 100 percent. FFR values reflect a continuum of risk such that lesions with more severely abnormal FFR (i.e., <0.6) have a higher risk of clinical events and thus are more likely to benefit from revascularization. The ratio of pressure measured distal to the lesion and pressure measured in the aorta (Pd/Pa) during hyperemia is called FFR. FFR represents the fraction of normal flow through a diseased artery relative to estimated flow through the same theoretically normal artery."

Becker et al. (2023) conducted a retrospective, single-center study comparing a cohort that received coronary CT angiography (CCTA) with CT-derived fractional flow reserve (FFR-CT) to a historical cohort that received CCTA before FFR-CT was available. We assessed the clinical management decisions after FFR-CT and CCTA and the rate of major adverse cardiac events (MACEs) during the 1-year follow-up using chi-square tests for independence. Kaplan-Meier curves were used to visualize the occurrence of safety outcomes over time. A total of 360 patients at low to intermediate risk of CAD were included, 224 in the CCTA only group, and 136 in the FFR-CT group. During follow-up, 13 major adverse cardiac events (MACE) occurred in 12 patients, 9 (4.0%) in the CCTA group, and three (2.2%) in the FFR-CT group. Clinical management decisions differed significantly between both groups. After CCTA, 60 patients (26.5%) received optimal medical therapy (OMT) only, 115 (51.3%) invasive coronary angiography (ICA), and 49 (21.9%) single positron emission CT (SPECT). After FFR-CT, 106 patients (77.9%) received OMT only, 27 (19.9%) ICA, and three (2.2%) SPECT ($p < 0.001$ for all three options). The revascularization rate after ICA was similar between groups ($p = 0.15$). Patients in the CCTA group more often underwent

revascularization (p = 0.007). The authors concluded that Addition of FFR-CT to CCTA led to a reduction in (invasive) diagnostic testing and less revascularizations without observed difference in outcomes after 1 year.

POSITION STATEMENT:

The use of noninvasive fractional flow reserve following a positive coronary computed tomography angiography **meets the definition of medical necessity** to guide decisions about the use of invasive coronary angiography in members with stable chest pain at intermediate risk of coronary artery disease (i.e., suspected or presumed stable ischemic heart disease).

The use of noninvasive fractional flow reserve for all other indications when the above criteria are not met is considered **experimental or investigational**. The evidence is insufficient to determine that noninvasive fractional flow reserve results in improvement in net health outcome.

Note: * Cardiac Risk Assessment Tools for Coronary Artery Disease (CAD)

BILLING/CODING INFORMATION:

CPT Coding:

75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional

ICD-10 Diagnosis Codes That Support Medical Necessity:

I20.9	Angina pectoris, unspecified
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

*** Cardiac Risk Assessment Tools for Coronary Artery Disease for (CAD) (Note:** Not all inclusive**)**

Determination of Pretest Probability for Coronary Artery Disease (CAD)

Table 1: Determination of Pretest Probability for Coronary Artery Disease Based on Age, Gender, and Symptoms (Source: American College of Cardiology Criteria for Pretest Probability of Coronary Artery Disease (CAD)).

The following risk assessment may be used to determine pre-test probability of coronary artery disease.

Table 1:

Age (years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
30 – 39	Men	Intermediate	Intermediate	Low	Very low
	Women	Intermediate	Very low	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very low	Very low
50 – 59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very low
60 – 69	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low

High: Greater than 90% pre-test probability of CAD	**Intermediate**: Between 10% and 90% pre-test probability of CAD	**Low**: Between 5% and 10% pre-test probability of CAD	**Very low**: Less than 5% pre-test probability of CAD

Angina: As defined by the American College of Cardiology (ACC)/American Heart Association (AHA)
Typical Angina (Definite): 1.) Substernal chest pain or discomfort that is 2.) Provoked by exertion or emotional stress and 3.) Relieved by rest and/or nitroglycerine.
Atypical Angina (Probable): Chest pain or discomfort that lacks one of the characteristics of definite or typical angina.
Non-Anginal Chest Pain: Chest pain or discomfort that meets one or none of the typical angina characteristics.

Framingham Risk Assessment for Coronary Heart Disease (CHD) Risk

Table 2: Framingham Risk Assessment for Coronary Heart Disease (CHD) Risk

Framingham risk assessment is a calculation to predict the 10-year risk of heart disease. The calculation is based on the individual's age, sex, most recent lipid values, blood pressure, smoking history, and presence of diabetes.

Table 2:

CHD Risk Level	Framingham Score
CHD Risk-Low Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CHD risk.	Less than 10%
CHD Risk-Moderate Defined by the age-specific risk level that is average or above average.	Between 10% and 20%
CHD Risk-High Defined as the presence of diabetes mellitus.	Greater than 20%

Duke Treadmill Score

The equation for calculating the Duke treadmill score (DTS) is, DTS = exercise time in minutes - (5 * ST deviation in mm or 0.1 mV increments) - (4 * exercise angina score), with angina score being 0 = none, 1 = non limiting, and 2 = exercise-limiting. The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of >/= +5), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of </= -11) categories.

Online cardiac risk calculator and assessment tools:

The links for the online cardiac risk calculator and assessment tools are to an outside source and is provided for your convenience. Use of the links and related calculator and assessment tools are subject to the terms and conditions of the website and is not warranted, maintained or affiliated with Florida Blue.

Framingham Risk Score Calculator

https://www.framinghamheartstudy.org/

http://tools.acc.org/ASCVD-Risk-Estimator/

Reynolds Risk Score

http://www.reynoldsriskscore.org/

Pooled Cohort Risk Assessment Equations

http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

NOTE: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/24/25.

GUIDELINE UPDATE INFORMATION:

01/01/18	New Medical Coverage Guideline.
06/15/19	Review; no change in position statement. Updated references.
09/15/21	Review; no change in position statement. Updated references.
08/15/23	Review; no change to position statement. Updated references.
01/01/24	Annual CPT/HCPCS coding update. Added 75580. Deleted 0501T, 0502T, 0503T and 0504T.
08/15/25	Review; no change to position statement. Updated references.