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Subject: Noninvasive Fractional Flow Reserve Measurement

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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)

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.

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 07/27/23.

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.