

## Corporate Medical Policy

### Computed Tomography Angiography for Coronary Artery Evaluation

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#### Description of Procedure or Service

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Invasive coronary angiography (ICA) is clinically useful in stable ischemic heart disease (SIHD) to determine if there is coronary artery obstruction that may benefit from revascularization. However, many individuals undergoing ICA will not benefit from revascularization. Therefore, if there are noninvasive alternatives to guide decisions about the use of ICA to avoid invasive procedures, there is potential to improve health outcomes. Using noninvasive measurement of fractional flow reserve as part of a noninvasive imaging strategy prior to ICA, may be beneficial to avoid the need for ICA.

##### **Stable Ischemic Heart Disease**

Coronary artery disease (CAD) is a significant cause of morbidity and mortality. Evaluation of obstructive CAD involves quantifying arterial stenosis to determine whether significant narrowing is present. Lesions with stenosis more than 50% to 70% in diameter accompanied by symptoms are generally considered significant. It has been suggested that coronary computed tomography angiography (CCTA) or other noninvasive functional cardiac testing may help rule out CAD and avoid invasive coronary angiography in patients with a low clinical likelihood of significant CAD. Invasive coronary angiography (ICA) is frequently unnecessary in patients with suspected stable ischemic heart disease (SIHD), as evidenced by low diagnostic yields for significant obstructive CAD. For example, from a sample of over 132,000 ICAs, Patel and colleagues (2010) found 48.8% of elective ICAs performed in patients with what was thought to be stable angina did not detect obstructive CAD (left main stenosis  $\geq 50\%$  or  $\geq 70\%$  in a major epicardial or branch  $>2.0$  mm in diameter). Moreover, for the large majority of patients with SIHD, revascularization offers no survival advantage over medical therapy, and there are few who might benefit from ICA if they have not first failed optimal medical therapy. A noninvasive imaging test, performed prior to ICA, that can distinguish candidates who may benefit from early revascularization (eg, patients with unprotected left main stenosis  $\geq 50\%$  or hemodynamically significant disease) from those unlikely to benefit, could avoid unnecessary invasive procedures and their potential adverse consequences.

##### **Fractional Flow Reserve (FFR)**

Invasively measured FFR evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization may be beneficial.

Randomized controlled trials and observational studies have demonstrated that FFR-guided revascularization can improve cardiovascular outcomes, reduce revascularizations, and decrease costs. For example, the Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) trial randomized 1005 patients with multivessel disease and planned percutaneous coronary intervention (PCI). At one year, compared with PCI guided by angiography alone, FFR-guided PCI reduced the number of stents placed by approximately 30%; followed by lower rates

(13.2% vs 18.3%) of major cardiovascular adverse events (myocardial infarction, death, repeat revascularization) and at a lower cost. The clinical benefit persisted through 2 years, although by 5 years events rates were similar between groups.

The 2013 European Society of Cardiology guidelines for stable CAD recommended FFR be used “to identify hemodynamically relevant coronary lesion(s) when evidence of ischemia is not available” (class Ia), and “[r]evascularization of stenoses with FFR <0.80 is recommended in patients with angina symptoms or a positive stress test.” European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) Guidelines (2014) also recommended using “FFR to identify hemodynamically relevant coronary lesion(s) in stable patients when evidence of ischemia is not available” (class Ia recommendation). The 2012 American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons (ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS ) stated that an FFR of 0.80 or less provides level Ia evidence for revascularization for “significant stenosis amenable to revascularization and unacceptable angina despite guideline directed medical therapy. ”In addition, the importance of FFR in decision making appears prominently in the 2017 ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS guidelines for appropriate use criteria for coronary revascularization in patients with SIHD.

Measuring FFR during invasive coronary angiography (ICA) can be accomplished by passing a pressure-sensing guidewire across a stenosis. Coronary hyperemia (increased blood flow) is then induced and pressure distal and proximal to the stenosis is used to calculate flow across it. FFR is the ratio of flow in the presence of a stenosis to flow in its absence. FFR levels less than 0.75 to 0.80 represent significant ischemia while those 0.94 to 1.0 are normal. Measurement is valid in the presence of serial stenosis, is unaffected by collateral blood flow, and reproducibility is high. Potential complications include adverse events related to catheter use such as vessel wall damage (dissection); the time required to obtain FFR during a typical ICA is less than 10 minutes.

FFR using CCTA requires at least 64-slice CCTA and cannot be calculated when images lack sufficient quality (11% to 13% in recent studies), for example, in obese individuals (eg, body mass index, >35 kg/m<sup>2</sup>). The presence of dense arterial calcification or an intracoronary stent can produce significant beamhardening artifacts and may preclude satisfactory imaging. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

### **Noninvasive FFR Measurement**

FFR can be modeled noninvasively using images obtained during CCTA, also called fractional flow reserve, using coronary computed tomography angiography (FFR-CT; HeartFlow software termed FFRCT; Siemens cFFR). The process involves constructing a digital model of coronary anatomy and calculating FFR across the entire vascular tree using computational fluid dynamics. FFR-CT can also be used for “virtual stenting” to simulate how stent placement would be predicted to improve vessel flow.

### **Regulatory Status**

In November 2014, FFR-CT simulation software (HeartFlow) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the de novo 510(k) process. In January 2016, the FFR-CT v2.0 device was cleared through a subsequent 510(k) process.

HeartFlow FFR-CT post processing software is cleared “for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography (CT) DICOM [Digital Imaging and Communications in Medicine] 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. The results of this analysis [FFR-CT] are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow FFR-CT 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.”

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**The use of CT Coronary Angiography (CCTA), with or without Fractional Flow reserve assessed by CT (FFR-CT) may be considered medically necessary when the following criteria listed below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Computed Tomography Coronary Angiography is covered

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The use of CT Coronary Angiography (CCTA), with or without Fractional Flow Reserve assessed by CT (FFR-CT) may be covered when accompanied by pre-test considerations as well as supporting clinical data and prerequisite information based on the following diagnostic indications:

### **Indications where FFR-CT will not be required in conjunction with CCTA:**

Congenital coronary artery anomalies

- For evaluation of suspected congenital anomalies of the coronary arteries.

### **Indications where FFR-CT may be appropriate but is not a required capability of the performing imaging facility**

#### Congestive heart failure/cardiomyopathy/LV dysfunction

For exclusion of coronary artery disease in patients with left ventricular ejection fraction <55% and low to moderate coronary heart disease risk (using standard methods of risk assessment, such as the SCORE risk calculation) in whom coronary artery disease has not been excluded as the etiology of the cardiomyopathy.

- Patients with high coronary heart disease risk should undergo cardiac catheterization.

#### Pre-operative evaluation for patients undergoing non-coronary cardiac surgery

Evaluation of symptomatic\* or asymptomatic patients at moderate coronary heart disease risk (using standard methods of risk assessment, such as the SCORE risk calculation) to

avoid an invasive angiogram, where all the necessary pre-operative information can be obtained using cardiac CT.

- Procedures include open and percutaneous valvular procedures or ascending aortic surgery

Suspected coronary artery disease in **symptomatic\*** patients who have not had evaluation of coronary artery disease (MPI, cardiac PET, stress echo, CCTA or cardiac catheterization) within the preceding sixty (60) days

**When both of the following (1-2) apply:**

1. Patient has low or moderate coronary heart disease risk (using standard methods of risk assessment such as the SCORE risk calculation)**AND**
2. During testing the patient had exercise-induced chest pain, ST segment change, abnormal BP response or complex ventricular arrhythmias

Suspected CAD in symptomatic\* patients who have had **equivocal** MPI or SE within the past 60 days

**When both of the following (1-2) apply:**

1. Patient has low or moderate coronary heart disease risk (using standard methods of risk assessment such as the SCORE risk calculation)**AND**
2. The imaging portion of the study is neither clearly normal nor clearly abnormal

Suspected CAD in symptomatic\* patients who have had **abnormal** MPI or SE within the past 60 days

**When both of the following (1-2) apply:**

1. Abnormal MPI or stress echo is suspected to be false positive on the basis of low coronary heart disease risk (using standard methods of risk assessment such as the SCORE risk calculation)**AND**
2. The imaging portion of the study is abnormal

**Indications where FFR-CT may be appropriate and is a required capability of the imaging facility**

Suspected CAD in symptomatic\* patients who have **abnormal resting EKG**

When resting EKG abnormalities (left bundle branch block, electronically paced ventricular rhythm, left ventricular hypertrophy with repolarization abnormalities, resting ST segment depression 1 mm or more, digoxin effect or pre-excitation syndrome) would render an exercise treadmill test (without imaging) uninterpretable

Suspected CAD in symptomatic\* patients who **have not had** recent CAD evaluation

When no CAD imaging evaluation (MPI, cardiac PET, stress echo, CCTA or coronary angiography) has been performed within the preceding sixty (60) days

**\*For the purposes of this guideline, a patient is considered to be “symptomatic” when one of the following (A-D) applies:**

- A. Chest pain
  - With intermediate or high pretest probability of CAD; OR
  - With low or very low pretest probability of CAD and high risk of CAD (SCORE)

- B. Atypical symptoms: syncope, shortness of breath (dyspnea), neck, jaw, arm, epigastric or back pain, or sweating (diaphoresis)
  - With moderate or high risk of CAD (SCORE)
- C. Other symptoms; palpitation, dizziness, lightheadedness, near syncope, nausea, vomiting, anxiety, weakness, fatigue etc.
  - With high risk of CAD (SCORE)
- D. Patients with any cardiac symptom who have diseases/conditions with which coronary artery disease commonly coexists such as:
  - Diabetes mellitus; OR
  - Abdominal aortic aneurysm; OR
  - Established and symptomatic peripheral vascular disease; OR
  - Prior history of cerebrovascular accident (CVA), transient ischemic attack (TIA) or carotid endarterectomy (CEA) or high grade carotid stenosis (>70%); OR
  - Chronic renal insufficiency or renal failure

## **When Computed Tomography Angiography is not covered**

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The use of CT Coronary Angiography (CCTA), with or without Fractional Flow Reserve assessed by CT (FFR-CT) is considered investigational for all other indications.

## **Policy Guidelines**

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The available evidence provides support that use of CCTA with selective FFR-CT is likely to reduce the use of ICA in individuals with stable chest pain who are unlikely to benefit from revascularization by demonstrating the absence of functionally significant obstructive CAD. In addition, the benefits are likely to outweigh potential harms because rates of revascularization for functionally significant obstructive CAD appear to be similar and treatment-related adverse events do not appear to increase following CCTA with a selective FFR-CT strategy. While individual studies are noted to have specific methodologic limitations and some variation has been noted in the magnitude of benefit across studies, in aggregate the evidence provides reasonable support that the selective addition of FFR-CT following CCTA results in a meaningful improvement in the net health outcome. The evidence is sufficient to determine that the technology results in meaningful improvements in the net health outcome..

### **Biosafety Issues**

Ordering and imaging providers are responsible for considering safety issues prior to the CCTA exam. One of the most significant considerations is the requirement for intravascular iodinated contrast material, which may have an adverse effect on patients with a history of documented allergic contrast reactions or atopy, as well as on individuals with renal impairment, who are at greater risk for contrast-induced nephropathy. In addition, radiation safety issues including cumulative exposure to ionizing radiation should be considered

### **Ordering Issues**

- CCTA exams are not covered as a screening study, in the absence of signs, symptoms or known disease.
- Selection of the optimal diagnostic work-up for cardiac evaluation should be made within the context of other available studies (which include treadmill stress test, stress myocardial perfusion imaging, stress echocardiography, cardiac MRI, cardiac PET imaging and invasive cardiac/coronary angiography), so that the resulting information facilitates patient management decisions and does not merely add a new layer of testing.
- In general, follow-up CCTA exams should be performed only when there is a clinical change, with new signs or symptoms, or specific finding(s) requiring imaging surveillance.
- This policy does not apply to Cardiac CT for quantitation of coronary artery calcification (CPT 75571).

- This policy does not apply to Cardiac CT for evaluation of cardiac structure (CPT 75572-75573).
- Duplicative testing or repeat imaging of the same anatomic area with same or similar technology may be subject to high-level review and may not be medically necessary unless there is a persistent diagnostic problem or there has been a change in clinical status (e.g. deterioration) or there is a medical intervention which warrants interval reassessment.

**(Requests for re-imaging due to technically limited exams is the responsibility of the imaging providers.)**

Several clinical indications listed for CCTA include standard methods of risk assessment, such as the SCORE (Systematic Coronary Risk Evaluation) or the Framingham risk score calculation\*. These risk calculation systems include consideration of the following factors:  
Age, Sex, Lipid Profile, Hypertension, Diabetes Mellitus and Cigarette Smoking

\*The Framingham risk calculator is available at <http://cvdrisk.nhlbi.nih.gov/calculator.asp>

SCORE is available at <http://www.escardio.org/Guidelines-&-Education/Practice-tools/CVD-prevention-toolbox/SCORE-Risk-Charts>

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbnc.com](http://www.bcbnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes:*

*75574 Computed tomographic angiography, heart, coronary arteries and bypass grafts (where present), with contrast material, including 3-D image post-processing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)*

*93799 Unlisted cardiovascular service or procedure (Used for the FFR-CT Analysis as there is currently no unique CPT code assigned)*

*Effective 1/1/18, there are specific CPT codes for FFR-CT analysis::*

*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;*

*0502T data preparation and transmission;*

*0503T analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model;*

*0504T anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report*

- *(Report 0501T, 0502T, 0503T, 0504T one time per coronary CT angiogram)*
- *(Do not report 0501T in conjunction with 0502T, 0503T, 0504T)*

**This policy does not apply to Cardiac CT for quantitation of coronary artery calcification (CPT 75571).**

**This policy does not apply to Cardiac CT for evaluation of cardiac structure (CPT 75572-75573).**

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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## Policy Implementation/Update Information

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1/27/17 New policy developed. Use of noninvasive FFR-CT is considered investigational preceding invasive coronary angiography in patients with suspected stable ischemic heart disease. Medical Director review 12/2016. Policy noticed 1/27/17 for effective date 4/1/17. (jd)

Date Minor update to Description section. Policy statement changed from investigational to medically necessary for use of noninvasive fractional flow reserve following a positive coronary computed tomography angiography, to guide decisions about the use of invasive coronary angiography in patients with stable chest pain at intermediate risk coronary artery disease (ie, suspected or presumed stable ischemic heart disease). Policy guidelines extensively revised to align with policy statement. Medical Director review. (jd)

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